Congenital Heart Disease

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ARTICLE

Increased Incidence of Congenital Heart Disease during the COVID-19 Pandemic in 492,662 Newborns: Multicenter Observational Study

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ABSTRACT: Background: Congenital heart disease (CHD) is the most common congenital anomaly, but whether the COVID-19 pandemic affects its prevalence is unknown. We aimed to compare the incidence of CHD during the COVID-19 pandemic with that before the pandemic in China. **Methods:** This multicenter retrospective observational study involved all newborns in seven representative cities of China between 01 September 2019, and 31 December 2021. All the newborns underwent pulse oximetry monitoring combined with cardiac murmur auscultation in the first 6 h to 72 h after birth for CHD screening. We defined fetuses born in and beyond September 2020 as the exposed group, and before as the non-exposed group. The incidence of CHD and specific heart abnormalities, including atrial septal defect (ASD) and ventricular septal defect (VSD), before and during the COVID-19 pandemic were compared. **Results:** The study included 492,662 newborns; 217,003 newborns born before September 2020 and 275,659 newborns born in and beyond September 2020. There were 3115 patients with CHD in total during the whole study period. Of those, 1055 (September 2019 to August 2020) and 2060 (September 2020 to December 2021) were less and more affected by the pandemic, respectively. There was a significant increase in the incidence of CHD in the early stage of the COVID-19 pandemic (7.78 per 1000 births) compared to that before the pandemic (4.86 per 1000 births) ($p < 0.001$). The birth prevalence of ASD and VSD significantly increased during the pandemic from 3.991 per 1000 births to 4.717 per 1000 births ($p = 0.008$) and from 1.650 per 1000 births to 3.508 per 1000 births ($p < 0.001$), respectively. **Conclusions:** The incidence of CHD increased during the COVID-19 pandemic, which was possibly related to the reallocation of medical resources, increased psychological pressure, and increased socioeconomic deprivation, though underlying mechanisms remain unclear.

KEYWORDS: Congenital heart disease; COVID-19; birth prevalence; pregnancy

1 Introduction

Congenital heart disease (CHD) is a gross structural and functional abnormality of the heart or intrathoracic great vessels caused by various factors during embryonic development [1]. CHD accounts for nearly one-third of all major birth defects, with a birth prevalence of 9 cases per 1000 live births in China [2,3]. Although advances in diagnosis and treatment in recent decades have yielded favorable results, the CHD mortality rate per 1000 children younger than 1 year is estimated to be 1.20 in countries with a moderate sociodemographic index (SDI) [4].

The COVID-19 pandemic has changed the way we live, work and socialize. In the face of crises, the negative impact on women is exacerbated by social and gender inequalities [5,6]. Cross-country data from UN Women's Rapid Assessment Surveys reveal that the burden of unpaid labor and economic pressure have increased for women as a result of the pandemic [7]. Combined with the effects of segregation policies and the redistribution of social security funds, women experience great difficulty seeking family planning services and routine medical care [7,8]. These disruptions have worsened reproductive health outcomes in several countries [9,10].

There is growing evidence that the COVID-19 pandemic's indirect consequences adversely affect global maternal health and perinatal outcomes, which is possibly related to the reallocation of resources and priorities, elevated psychological pressure, and increased socioeconomic deprivation [11–15]. Between 2019 and 2021, a cohort study (n = 1,654,868) conducted in the US revealed small but significant increases in maternal death during delivery hospitalization (odds ratio [OR], 1.75; 95% CI, 1.19–2.58), gestational hypertension (OR, 1.08; 95% CI, 1.06–1.11), and obstetric hemorrhage (OR, 1.07; 95% CI, 1.04–1.10) during the COVID-19 pandemic [16].

However, studies on the effect of the COVID-19 pandemic on CHD and other birth defects in newborns are limited. Although COVID-19 no longer constitutes a public health emergency of international concern, it is now an established and ongoing health problem. We should pay close attention to the short- and long-term effects of the COVID-19 epidemic. Therefore, the present study aimed to evaluate the variations in the incidence of CHD before and during the COVID-19 pandemic in a large, population-based retrospective observational study.

2 Methods

2.1 Study Design and Participants

We performed a population-based observational study using Network Platform for Congenital Heart Diseases (NPCHD) data. Supported by the National 12th 5-Year Science and Technology Major Project of China, the National Comprehensive Hospital of Health (NPCHD) is a neonatal CHD screening, diagnosis and treatment surveillance system that includes 517 hospitals in eastern Chinese cities. All the newborns underwent pulse oximetry monitoring combined with cardiac murmur auscultation performed by trained medical staff in the first 6 h to 72 h after birth, and all the newborns' parents provided informed consent before participating in the screening campaigns for CHD. Newborns with positive screening results were offered further examination. The final diagnosis was based on echocardiography and confirmed by an experienced pediatrician. All the patients with CHD were reported to have NPCHD. The platform commits to reducing mortality and improving the prognosis in children with CHD and is responsible for the quality control of screening and skills training of primary care physicians.

The study consisted of all children born alive in seven representative cities between 01 September 2019, and 31 December 2021. The Ethics Committee of Children's Hospital, Zhejiang University School of Medicine approved this retrospective study (2023-IRB-0139-P-01) and waived the requirement for informed consent.

2.2 Procedures

Before and after childbirth, all pregnant women and their families were provided with health education about CHD by trained and qualified clinicians, including the basic concepts and risks of CHD and the necessity, benefits, process, interpretation of results and limitations of CHD screening. All parents signed informed consent forms for their children. The results of screening, diagnosis and demographic characteristic information (e.g., infant sex, birth date, birthweight, gestational age, birthplace and maternal age) were collected and analyzed through the NPCHD.

In the neonate cohort, experienced pediatricians performed universal pulse oximetry plus cardiac murmur auscultation (namely, the dual-index method) for CHD screening. The test was administered to infants between 6 h and 72 h without oxygen or oxygenation ≥12 h. Cardiac murmur auscultation was performed by a trained pediatrician with a stethoscope suitable for infants in a quiet room before pulse oximetry measurement to ensure that the result of cardiac murmur auscultation was not affected by environmental noise or the result of pulse oximetry measurement. Cardiac murmur auscultation was performed using Levine's grading system for systolic cardiac murmurs. Then, a trained nurse or pediatrician performed pulse oximetry screening with a pulse oximeter and a multisite reusable sensor to measure oxygen saturation (SpO_2) from the infants' right hand and food. Pulse oximetry was repeated 4 h later by the pediatrician if the first pulse oximeter oxygen saturation measurement was between 90% and 95%.

A screening result was considered positive if the murmur was equal to or greater than grade II (a faint murmur heard immediately); an SpO_2 of less than 95% was obtained both on the right hand and on either foot on two measurements separated by 4 h; a difference between the two extremities was more than 3% on two measures separated by 4 h; or any measure was less than 90% [17,18].

Newborns screened as positive were recommended to be referred for echocardiography. Patient clinical information was uploaded to the NPCHD. An experienced cardiologist diagnosed the patients secondarily based on echocardiography. We used the International Statistical Classification of Diseases and Related Health Problems 10th Edition (ICD-10) for CHD diagnosis.

We excluded cardiac physiological changes: (1) patent foramen ovale (PFO); (2) patent ductus arteriosus (PDA) less than 3 mm in diameter or PDA in preterm infants; (3) atrial septal defect (ASD) less than 5 mm in diameter; (4) echocardiographic maximum instantaneous gradient <20 mmHg in pulmonary stenosis (PS) or aortic stenosis (AoS) that does not expand with age; (5) physiological stenosis of the left and right pulmonary arteries; or (6) simple bicuspid aortic valve (BAV) without stenosis or regurgitation [19].

2.3 Quality Control

The NPCHD is responsible for the organization and coordination of neonatal CHD screening, diagnosis, treatment, follow-up and referral, as well as information management. Training and on-site supervision are implemented at least twice a year for relevant pediatricians and nurses. The NPCHD regularly examines the reports and data from all partner hospitals. Questionable reports or data were returned for supplementation or correction.

2.4 Statistical Analysis

In total, this study included 492,662 newborns. Considering the COVID-19 infection prevention and control program in China, we hypothesized that children born in and beyond September 2020 will be more affected by the pandemic, with gestational age week 3 occurring after 31 December 2019; of those, children es born between September 2020 and December 2020 will be most severely affected, with gestational age 3 occurring during the most severe phase of the pandemic. The newborns were divided into three groups: newborns born before September 2020 were in the non-exposed group, newborns born between September

2020 and December 2020 were in the early-epidemic group, and newborns born after December 2020 were in the late-epidemic group.

The Statistical Package for the Social Sciences (International Business Machines Corporation, New York, NY, USA) version 20.0 was used for descriptive analysis. Descriptive statistics were used to display the birth prevalence of CHD and its subtypes. The chi-square test was used to detect associations in categorical data and to identify differences in birth incidence. A 2-sided p value < 0.05 was considered to indicate statistical significance.

3 Results

3.1 Study Sample

We included 492,662 newborns who underwent CHD screening and were born between January 2019 and December 2021 in seven representative cities. Of the 492,662 newborns, 3115 (6.32‰) were diagnosed with CHD after positive screening results (Table 1). The primary clinical data of these patients were uploaded to the NPCHD. There were 1055 patients in the non-exposure group, 572 in the early pandemic group and 1488 in the late pandemic group. The maternal age did not significantly differ among the three groups or in the male/female ratio of children with CHD. The period from 2019 to 2021 witnessed a slight decrease in the gestation period from 38.37 ± 2.00 weeks to 38.04 ± 2.26 weeks. Moreover, the birthweight decreased from 3271.36 ± 612.21 g to 3211.77 ± 655.21 g. The proportion of confirmed CHD diagnoses as a percentage of the overall number of confirmed cases fluctuated in various municipalities before and after the pandemic.

Table 1: Baseline characteristics.

		No Exposure (n = 1055)	Early in the Pandemic (n = 572)	Late in the Pandemic (n = 1488)
Maternal age, y		29.69 ± 5.04	29.74 ± 4.66	29.81 ± 4.96
Gestation period, w		38.37 ± 2.00	38.10 ± 2.06	38.04 ± 2.26**
Birthweight, g		3271.36 ± 612.21	3232.35 ± 645.34	3211.77 ± 655.21*
Sex				
	Male	493	283	681
	Female	562	289	807
District				
	Ningbo	256 (24.3)	155 (27.1)	425 (28.6)*
	Huzhou	113 (10.7)	43 (7.5)	119 (8.0)
	Jiaxing	167 (15.8)	85 (14.9)	171 (11.5)*
	Shaoxing	182 (17.3)	152 (26.6)*	454 (30.5)*
	Zhoushan	41 (3.9)	26 (4.5)	55 (3.7)
	Taizhou	235 (22.3)	89 (15.6)*	163 (11.0)#
	Lishui	61 (5.8)	22 (3.8)	101 (6.8)#

Note: (1) Values are n (%) or mean ± SD; (2) Comparison with no exposure to the COVID-19 epidemic in the first trimester, *p < 0.05, **p < 0.01; (3) Comparison with the first trimester occurring early in the pandemic, #p < 0.05.

3.2 Incidence of CHD

As shown in Fig. 1, there is a significant upward trend in the incidence of CHD during 2020, with the incidence in December 2020 (0.858%) being 1.78 times the incidence in January 2020 (0.483%), a difference of 37.5 per 1000 newborns in absolute terms. In 2021, the second year after the outbreak of COVID-19, the incidence of CHD declines in fluctuation, but remains at a high level (Fig. 1).

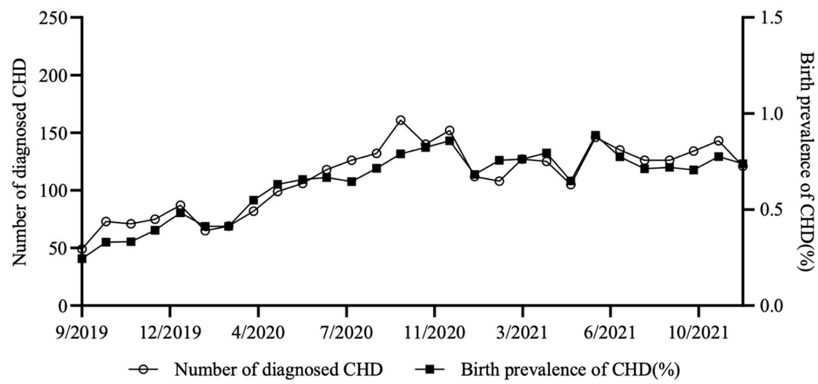

Figure 1: Temporal trends of CHD in seven representative cities of China from 2019.9 to 2021.12.

There was a significant increase in the total proportion of newborns with CHD born to pregnant women whose first trimester occurred in the early stage of the pandemic (7.78 per 1000 births) compared to that of newborns born before the pandemic (4.86 per 1000 births) (χ^2 = 83.815, p < 0.001) (Table 2). The total proportion of newborns with CHD has declined slightly as the pandemic has gone from major outbreak to normalized management (7.36 per 1000 births) (χ^2 = 1.245, p = 0.265). Significant differences were found in 7 cities. The increase in the incidence of CHD in the early pandemic group compared with that in the pre-pandemic group was the lowest in Huzhou (5.84 per 1000 births vs 5.58 per 1000 births) (χ^2 = 1.359, p = 0.244). Based on the number of people diagnosed with COVID-19 by the Zhejiang Provincial Health Commission and the residential population of each city published in the Announcement of the Seventh National Population Census of Zhejiang Province, Huzhou city had the lowest COVID-19 incidence rate (2.97 per 10,000 population) during the major outbreak of COVID-19 [20].

Table 2: The CHD birth prevalence among 7 administrative districts of China.

		Ningbo	Huzhou	Jiaxing	Shaoxing	Zhoushan	Taizhou	Lishui	Total
No Exposure (n = 1055)	Number of diagnosed CHD	256	113	167	182	41	235	61	1055
	Number of live births	53,506	23,833	39,975	28,995	3561	49,113	18,020	217,003
	Birth prevalence of CHD (/1000)	4.78	4.74	4.18	6.28	11.51	4.78	3.39	4.86
Early in the Pandemic (n = 572)	Number of diagnosed CHD	155	43	85	152	26	89	22	572
	Number of live births	21,745	7366	12,570	10,518	1771	14,449	5137	73,556
	Birth prevalence of CHD (/1000)	7.13*	5.84	6.76*	14.45*	14.68	6.16*	4.28	7.78*
Late in the Pandemic (n = 1488)	Number of diagnosed CHD	425	119	171	454	55	163	101	1488
	Number of live births	59,390	21,376	33,818	29,363	4426	40,838	12,892	202,103
	Birth prevalence of CHD (/1000)	7.16*	5.57	5.06	15.46*	12.43	3.99#	7.83#*	7.36*

Note: (1) CHD indicates congenital heart defect; (2) Comparison with no exposure to the COVID-19 pandemic in the first trimester, *p < 0.05; (3) Comparison with the first trimester occurring early in the pandemic, #p < 0.05.

3.3 Incidence of Specific CHD Subtypes

The birth prevalence of specific CHD subtypes before and during the pandemic in eastern Chinese cities is shown in Table 3. The incidence of common CHD was significantly greater during the pandemic, with the incidence of ASD increasing from 3.991 per 1000 births in the prepandemic period to 4.717 per 1000 births in the early stage of the pandemic (χ^2 = 6.980, p = 0.008); the incidence of VSD increased from 1.650 per 1000 births to 3.508 per 1000 births (χ^2 = 89.622, p < 0.001); and the prevalence of PDA increased from 1.889 per 1000 births to 4.486 per 1000 births (χ^2 = 145.849, p < 0.001) (Table 3). In regard to complex types of CHD, there was a statistically significant difference in the incidence of PS birth between the pre-pandemic group (0.014 per 1000 births) and the early pandemic group (0.095 per 1000 births) ($\chi^2 = 10.561$, $p = 0.001$). The incidence of PDA decreased significantly in the later stages of the pandemic (3.518 per 1000 births) ($\chi^2 = 13.442$, $p < 0.001$), and the incidence of other CHD subtypes decreased slightly.

Table 3: The birth prevalence of specific CHD subtypes in eastern China.

	No Exposure (n = 1055)		Early in the Pandemic (n = 572)		Late in the Pandemic (n = 1488)	
	Cases	Birth Prevalence (/1000)	Cases	Birth Prevalence (/1000)	Cases	Birth Prevalence (/1000)
ASD	866	3.991	347	4.717*	936	4.631*
VSD	358	1.650	258	3.508*	633	3.132*
PDA	410	1.889	330	4.486*	711	3.518*#
AVSD	3	0.014	2	0.027	3	0.015
TGA	1	0.005	1	0.014	0	0.000
TOF	10	0.046	6	0.082	7	0.035
PS	3	0.014	7	0.095*	16	0.079*

Note: (1) Comparison with no exposure to the COVID-19 pandemic in the first trimester, $^*p < 0.05$; Comparison with the first trimester occurring early in the pandemic, $^\#p < 0.05$;(2) CHD indicates congenital heart defect; ASD, atrial septal defect; VSD, ventricular septal defect; PDA, patent ductus arteriosus; AVSD, atrioventricular septal defect; transposition of great arteries; TOF, tetralogy of fallot; PS, pulmonary stenosis.

4 Discussion

In the present study, we selected seven geographically representative municipalities for retrospective analysis. The birth prevalence of CHD and its specific subtypes before and after the COVID-19 pandemic were quantified by analyzing clinical data from the NPCHD, 492,662 newborns and 3115 CHD individuals. We defined the start of the exposure window as the first day of the third week of pregnancy, based on evidence that cardiac development is initiated at gastrulation at the beginning of the third week of human development [21]. Previous literatures have associated increased maternal heat exposure and air pollution during early pregnancy with a higher risk of CHD [22,23].

According to the descriptive statistics of the general data, we found that the mean gestational age, based on the last menstrual period, decreased by less than half a week between 2019 (38.37 weeks) and 2021 (38.04 weeks). Additionally, the mean birth weight decreased sparingly between the three years. According to the data of the U.S. National Center for Health Statistics, birth weight decreased 16 g among term births, and the mean gestational length decreased by more than 2 days from 1990 to 2005 in the U.S [24]. Moreover, preterm birth rates have increased significantly worldwide over the past decade [25]. An observational study between 01 January 2012, and 31 December 2018, in China noted an increase in preterm births for both singleton and multiple pregnancies (8.8% increase; annual rate of increase [ARI] 1.3 [95% CI 0.6 to 2.1]), related to advanced maternal age at delivery, maternal complications, and multiple pregnancies [26]. Our study revealed a downward trend in birth weight and gestational age in the population of newborns with CHD, which is consistent with the findings of previous studies.

Before the COVID-19 pandemic, the CHD birth incidence (4.86 per 1000 births) in 2019 in eastern China was relatively higher than the national average (4.09 per 1000 births) in 2011. The incidence of CHD during the perinatal period in 2000 was 1.14 per 1000 births, and an upward trend was maintained over the next decade [27]. A meta-analysis (n = 130,758,851) reported that the incidence of CHD in Asia [9.342/1000 (95% CI 8.072–10.704)] was the highest among geographical regions in 2010–2017, which was greater than that in our study [28]. However, between 2017 and 2021, an observational study (n = 801,831) conducted in Shanghai found that the birth incidence of CHD was 4.54 per 1000 births in the coastal city of eastern China [29]. As a result, the birth incidence of CHD in eastern China is slightly lower than the Asian average and is on the rise.

We found a significant increase in the incidence of CHD at birth in the early stage of the COVID-19 pandemic compared to before the pandemic (χ^2 = 83.815, p < 0.001). This phenomenon is consistent with previous findings of increased adverse pregnancy outcomes during the COVID-19 pandemic, which are possibly related to the reallocation of resources, increased psychological pressure, and increased socioeconomic deprivation during the pandemic [30,31]. The interaction of multiple environmental and genetic factors has been shown to be involved in the development of CHD [32]. Between 2007 and 2012, a population-based cohort study (n = 2,419,651) conducted in California revealed that an increased social deprivation index was associated with a greater incidence of CHD [33]. Another meta-analysis reported that maternal psychological stress and stressful life events during pregnancy may slightly increase the risk of CHD in offspring [34]. Furthermore, maternal obesity, diabetes, alcohol consumption, tobacco use and medication exposure in the first trimester have been repeatedly recognized as potential risk factors for CHD [35]. The COVID-19 pandemic has caused a large and sudden shock to the world economy [36]. According to data released by China's National Bureau of Statistics, gross domestic product (GDP) growth for 2020 as a whole fell by 3.8 percent compared with that of the previous year, and GDP fell by 6.8 percent year-on-year in the first quarter [37]. Additionally, social distancing was one of the signature strategies used to contain the spread of the disease during the COVID-19 pandemic [38]. To achieve 'zero' transmission, China implemented stringent social distancing measures, including stay-at-home orders and strict access controls across apartment complexes and subdistricts, which may have amplified indirect adverse effects. A cross-sectional study assessed COVID-19-related health worries and current mental health symptoms in 1123 perinatal women and reported 36.4% of participants had clinically significant levels of depression, 22.7% had generalized anxiety, and 10.3% had post-traumatic stress disorder; these percentages are higher than pre-pandemic levels [39]. In light of the COVID-19 pandemic, women have poorer socioeconomic status, greater psychological stress and less access to medical care due to their assumed roles at home and gender discrimination in society [40–43]. Moreover, we found that the incidence of morbidities decreased as the impact of the pandemic waned and socioeconomic conditions improved. Therefore, we considered the COVID-19 pandemic to be an indirect risk factor for an increased incidence of CHD.

In our study, the distribution of most CHD subtypes in eastern China differed from that in the world, as reported in previous studies. The worldwide reported birth prevalence of the three most common CHD subtypes was as follows: VSD, 2.62 per 1000 live births; ASD, 1.64 per 1000 live births; and PDA, 0.87 per 1000 live births, which are all less common than those in China. ASD is the most common subtype of CHD in eastern China. Additionally, relatively rare complex CHD subtypes, such as TAGs, have a higher incidence of births worldwide than in eastern China, which may be associated with ethnic, socioeconomic, and environmental differences and with prenatal screening and medical interventions [28].

Our study has several limitations. First, observational database studies based on true-world clinical practice could be limited by the lack of direct control, heterogeneity of the populations and unmeasured confounders such as maternal health, air pollution, and healthcare access. Second, we artificially set grouping standards between the early and late stages of the pandemic, which may have resulted in bias in the research data and results. Third, we do not have standardized scales to assess the extent of the impact of the pandemic on people, which has led us to estimate only the correlation between the COVID-19 pandemic and the incidence rate of CHD. We will conduct prospective studies to explore this further in the future.

5 Conclusion

Due to the comprehensive coverage of the newborn screening programme for CHD, the birth prevalence of CHD in 7 cities of China was found to be relatively accurate. There was a significant increase in the incidence of CHD at birth in the early stage of the COVID-19 pandemic compared to before the pandemic, and the incidence of CHD decreased as the impact of the pandemic waned and socioeconomic conditions improved. Additionally, the distribution of most CHD subtypes in China differs from that in the world. In summary, birth defects during major public health emergencies should be given attention and prioritized. Our study provides positive evidence for controlling birth defects by guaranteeing women's basic labor remuneration and medical care in the event of a major public health emergency.

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Availability of Data and Materials: Not applicable.

Ethics Approval: The Ethics Committee of Children's Hospital, Zhejiang University School of Medicine approved this retrospective study (2023-IRB-0139-P-01) and waived the requirement for informed consent.

Conflicts of Interest: The authors declare no conflicts of interest to report regarding the present study.

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