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Author manuscript

J Ultrasound Med. Author manuscript; available in PMC 2015 June 17.

Published in final edited form as:

J Ultrasound Med. 2011 July ; 30(7): 989–995.

Observed Prevalence of Congenital Heart Defects From a Surveillance Study in China

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Abstract

Objectives—The purpose of this study was to estimate the prevalence of major and minor congenital heart defects among fetuses and neonates using sonography in a general population of 4 areas surrounding Shanghai, China.

Methods—Pregnant women were recruited between April 2004 and December 2005 in Jiaxing City, Suzhou City, Changshu County, and Haining County. All participants could have 3 sonographic examinations performed by specially trained physicians regardless of medical indication: a fetal sonographic screen and fetal echocardiography between 20 and 28 weeks' gestation and neonatal echocardiography. Diagnoses of congenital heart defects were made on the basis of review of all available scans by an international group of experts in pediatric cardiology. Prevalence rates were calculated per 1000 births.

Results—Among 4006 scanned fetuses and neonates, there were 75 congenital heart defects, including 12 major defects. The observed prevalence for all congenital heart defects was 18.7 (95% confidence interval, 14.8–23.5) per 1000 births, and the prevalence for major defects was 3.0 (95% confidence interval, 1.6–5.2) per 1000 births. The most common defects were ventricular septal defects ($n = 47$ [62.7%]), atrial septal defects ($n = 14$ [18.7%]), tetralogy of Fallot ($n = 4$ [5.3%]), and hypoplastic left heart syndrome ($n = 3$ [4.0%]).

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Conclusions—The prevalence of all congenital heart defects in the 4 areas of China studied was higher than that reported in other countries, with ventricular septal defects being the most frequent defects. Our data likely reflect a better estimate of the total prevalence of congenital heart defects in China than reported previously.

Keywords

congenital heart defects; fetal echocardiography; neonatal echocardiography; prevalence

Congenital heart defects are the leading cause of infant mortality due to birth defects. In countries with low infant mortality rates, almost half of infant deaths are attributable to congenital heart defects directly or indirectly.^{1,2} Early studies in developed western countries have reported overall congenital heart defect prevalence estimates of 4 to 10 per 1000 live births^{3–5} and 2.6 to 4.4 per 1000 births for major defects,^{6–8} defined as defects requiring catheter or surgical intervention during the first year of life. The prevalence of congenital heart defects among fetuses is estimated to be even higher, at 14.6 per 1000 fetuses.⁹ Because complex congenital heart defects are common among fetuses¹⁰ and may result in spontaneous abortion or stillbirth, the total prevalence of congenital heart defects among stillbirths and live births may be higher than that reported among live births alone. The prevalence of congenital heart defects may also be underestimated because minor defects may be asymptomatic and undetected among neonates. More comprehensive surveillance among fetuses and neonates would improve prevalence estimates for congenital heart defects and help assess prevention efforts.

With the wider use of prenatal and postnatal sonography to diagnose congenital heart defects, observed prevalence estimates have risen. Although sonographic investigations to detect congenital malformations are routinely performed between 13 and 22 weeks' gestation in most European countries,^{11–13} routine sonography may still miss some defects, especially outflow tract defects and small septal defects.¹⁴ Specialized fetal or neonatal echocardiography is usually performed only when there is a risk of a congenital heart defect or it is suspected. Thus, the total prevalence of congenital heart defects in a general population is unclear regardless of medical indication.

In most parts of China, sonographic screening for malformations was seldom used during routine prenatal health care until the 1990s. Thus, early congenital heart defect prevalence estimates of 2.7 to 6.6 per 1000 live births in China based on postnatal case ascertainment alone might be lower than those reported in some developed countries.^{15,16} Recently, hospital-based studies of prenatal congenital heart defect detection have been conducted in China,^{17–19} and 1 large population-based study, which performed echocardiography on fetuses and neonates suspected of having congenital heart defects, reported a prevalence rate of 8.2 per 1000 births.²⁰

Given the recent increased use of fetal sonography in China, a surveillance program was initiated in 4 areas surrounding Shanghai to investigate the prevalence of congenital heart defects among all fetuses and neonates in a Chinese general population regardless of medical indication.

Materials and Methods

Study Initiation

This prospective cohort study was conducted through a cooperative agreement between the US Centers for Disease Control and Prevention and the Peking University Health Science Center to develop a surveillance program for congenital heart defects from April 2004 to December 2005 at 18 hospitals in 4 areas surrounding Shanghai: Jiaying City and Haining County in Zhejiang Province and Suzhou City and Changshu County in Jiangsu Province. An already-established centralized perinatal health care surveillance system monitors all pregnancies, recording outcomes, prenatal and postnatal visits, demographics, and medical histories. All women receive prenatal care at local township hospitals, which are part of the city or county health care systems.

Before the study began, a team of pediatric cardiology experts from several cities in the United States and Canada developed a 1-week training program in cardiac imaging for local Chinese sonographers. One course trained township sonographers to include the 4 chambers, outflow tracts, and views of the great arteries in their routine fetal sonographic screens. Another course trained county sonographers to obtain satisfactory fetal echocardiographic images. Ultrasound equipment used in township hospitals included Hi Vision (Hitachi Medical Systems, Tokyo, Japan), LOGIQ 3 (GE Healthcare, Milwaukee, WI), and SSA-320A (Toshiba Medical Systems, Tokyo, Japan). Echocardiographic equipment included Sonos 5500 (Philips Healthcare, Eindhoven, the Netherlands), LOGIQ 7 and Voluson 730 (GE Healthcare), and Sequoia 512 (Siemens Medical Solutions, Mountain View, CA).

Study Methods

All pregnant women presenting to a township hospital for the first prenatal visit at less than 25 weeks' gestation were eligible for the study. Assuming a baseline congenital heart defect prevalence of 15 per 1000 at $P < .05$ (2-sided test) and a total width of the estimate precision of 4 per 1000, we calculated that 3548 patients needed to be screened. We used systematic convenience sampling to invite the first 4 eligible women who visited any of the study hospitals each day to participate.

Ideally, 3 sonographic examinations were to be performed on each participant: (1) a fetal sonographic screen at a township hospital, (2) fetal echocardiography at a city or county hospital between 20 and 28 weeks' gestation, and (3) neonatal echocardiography within 7 days of birth. All images were video recorded on compact disks for subsequent review and diagnosis by pediatric cardiologists. In the event of a stillbirth or perinatal death, a pathologist was to examine the fetus or neonate for congenital malformations. If the fetus or neonate had normal findings from only a single fetal examination (fetal sonographic screen or fetal echocardiography) and no neonatal echocardiography, the fetus's or neonate's health records were checked for evidence of a previously undiagnosed congenital heart defect (ie, false-negative prenatal examination findings).

A multistage process determined the presence of a congenital heart defect. First, all examinations were reviewed by a city cardiologist, who made the primary diagnosis. Then,

Peking University Health Science Center cardiologists and the international team of experts reviewed the abnormal findings and a 10% sample of all normal findings to corroborate the findings. The final diagnosis was based on the neonatal echocardiographic findings; if there were none, the findings from fetal echocardiography or autopsy were used. The experts reached consensus on cases with discrepant findings during a workshop at the study's conclusion. An isolated patent foramen ovale and patent ductus arteriosus among neonates (ie, <28 days of life) were excluded because they are normal neonatal findings.

The study was approved by the Institutional Review Boards at the Centers for Disease Control and Prevention and the Peking University Health Science Center. All invited participants provided informed consent before any study activities.

Statistical Analysis

Prevalence estimates were reported per 1000 births (defined as pregnancies 20 weeks' gestation). Binomial 95% confidence intervals were computed for the observed prevalence rates. All *P* values were 2 sided at a level of *P* < .05. The significance of categorical variables was assessed by a χ^2 test or Fisher exact test. The data were analyzed with SPSS version 11.5 statistical software 11.5 (SPSS Inc, Beijing, China).

Results

Sociodemographic Characteristics

Among the 4477 pregnant women invited to participate in the study, 495 declined and 3982 enrolled. Sociodemographic characteristics of participants and nonparticipants (women who were pregnant during the same interval and from the same geographic locations) are presented in Table 1. Although study participants and nonparticipants were statistically different in all sociodemographic characteristics, the distributions of the two groups by these characteristics were generally similar.

Examination Completeness

A total of 4006 fetuses were examined (3958 singletons and 48 twins). As shown in Table 2, 3965 (99.0%) had a fetal sonographic screen; 3737 (93.3%) had fetal echocardiography; 3404 (85.0%) had neonatal echocardiography; and 3331 (83.2%) completed all 3 sonographic examinations. More than 60% of the neonatal echocardiographic studies were completed within 7 days after birth, and 90% were completed within 28 days. Among 216 fetuses (5%) who had only a fetal sonographic screen (no fetal echocardiography or neonatal echocardiography), 208 were live born without signs or symptoms of a congenital heart defect in infancy or childhood and thus were presumed not to have a defect. For the remaining 8 fetuses (0.2%), the congenital heart defect status could not be confirmed. These fetuses included 4 singleton pregnancies that were terminated after having diagnoses of other major birth defects during the fetal sonographic screen and 2 stillbirths (all without autopsy). Two additional pregnancies were lost to follow-up.

Diagnosis of Congenital Heart Defects

Among the 4006 fetuses and neonates who were scanned prenatally or neonatally, we identified 75 congenital heart defects, for an overall observed prevalence of 18.7 (95% confidence interval, 14.8–23.5) per 1000 births. The most common congenital heart defects were ventricular septal defects (VSDs; $n = 47$ [62.7%]) and atrial septal defects (ASDs; $n = 14$ [18.7%]; Table 3).

Of the 75 congenital heart defects, 16.0% ($n = 12$) were major, for an observed prevalence of 3.0 (95% confidence interval, 1.6–5.2) per 1000 births. There were 10 cases of major defects (83.3%), which were detected in utero; 8 of the associated pregnancies were terminated. For cultural reasons, autopsies are seldom conducted in China; therefore, autopsies to confirm the diagnoses were performed for only 3 of the terminations. Four of the 12 neonates with major defects were live born. One neonate died before neonatal echocardiography could confirm a diagnosis of transposition of the great arteries made in utero. Two neonates had normal fetal examination findings, but on neonatal echocardiography, 1 was found to have mild (pink) tetralogy of Fallot, and the other was found to have total anomalous pulmonary venous return. The fourth live-born neonate had a diagnosis of only a VSD (a minor defect) on fetal echocardiography but postnatally was discovered to have mild (pink) tetralogy of Fallot on neonatal echocardiography (a major defect; Table 4).

Only 2 minor defects (VSDs) were diagnosed in utero; the remaining 61 minor defects were identified by neonatal echocardiography in the face of previous normal prenatal examination findings. Thus, the prenatal detection rate for all congenital heart defects based on fetal echocardiography was 16% (12 of 75). The prenatal detection rate of 3% (2 of 63) for minor defects was significantly lower than the rate of 83% (10 of 12) for major defects ($P < .0001$).

Discussion

This population-based study in China used sonography to determine the observed prevalence of congenital heart defects among fetuses and neonates in 4 areas around Shanghai. We found a relatively high overall prevalence of congenital heart defects (18.7 per 1000), most of which were minor (84%), diagnosed or confirmed postnatally. Conversely, the prevalence of major defects was 3.0 per 1000, 75% of which were diagnosed prenatally by fetal echocardiography. The prenatal detection rate for minor defects was significantly lower than the rate for major defects.

The total observed prevalence of congenital heart defects was higher than that found in other studies,^{15,20–24} primarily because of the large number of minor defects that were diagnosed postnatally on neonatal echocardiography. Ventricular septal defects were the most common defects, accounting for 62.7% of all cases. In recent years, as the use of echocardiography has increased, the detection rate of small VSDs has also increased considerably. Many surveillance studies found that 30% to 40% of congenital heart defects were VSDs,^{25–27} and some suggested that the overall prevalence of congenital heart defects depends mainly on the prevalence of VSDs.²⁸ The findings from this study support the previously reported findings that VSDs are the most frequent defects and suggest that the percentage of VSDs in

a systematically screened population may be even higher than previously reported. Our prevalence estimates for other congenital heart defect types were similar to those noted previously.^{29–31} In most clinical settings, neonates have neonatal echocardiography only if medically indicated. However, in this screening study, all neonates were to undergo neonatal echocardiography; thus, more minor congenital heart defects (eg, small VSDs) were diagnosed than might have otherwise been detected in a medically indicated population.

Our observed prevalence rate for major congenital heart defects was similar to those in recent reports.^{6–8} Similar to another Chinese study, most prenatally diagnosed defects were major, whereas minor defects were predominantly diagnosed postnatally.²⁰ In our study population, as in that of the previous Chinese study, most pregnancies with major defects were terminated and did not receive a confirmatory diagnosis (ie, neonatal echocardiography or autopsy). Although 1 neonate did have a diagnostic change from VSD to tetralogy of Fallot after neonatal echocardiography, it is unlikely that misdiagnosis would have substantially altered the prevalence of major defects because studies have shown good concordance between prenatal and postnatal studies for many of the congenital heart defect types we studied.³²

Prevalence estimates for congenital heart defects are highly dependent on surveillance methods. Some studies based on results of fetal echocardiography done only on neonates with suspected defects^{11,33} might have missed some cases of small VSDs, ASDs, and coarctation of the aorta, which are not reliably diagnosed prenatally. A recent study in fetuses and neonates in Beijing reported a prevalence rate of 8.2 per 1000 births, which was lower than our estimates, perhaps because only those at risk for congenital heart defects were examined. In contrast, higher prevalence rates were reported by some studies that examined all or almost all neonates in a region and detected large numbers of small VSDs and other minor defects.^{9,30}

One strength of this study was that it was a population-based surveillance study in which most fetuses had 2 fetal examinations after 20 weeks' gestation, and neonates had neonatal echocardiography to detect congenital heart defects. Sonographic examinations were performed regardless of risk factors or clinical symptoms. Furthermore, multiple examination reviews by experts minimized the potential for misdiagnosis. Thus, our data likely reflect an improved estimation of the prevalence of congenital heart defects in southeastern China.

Another study strength was that systematic sampling avoided a selection bias. Although there were statistical differences in sociodemographic characteristics between participants and nonparticipants, these differences were of a small magnitude and likely not meaningful, reflecting a comparison of two groups with a greater than 3-fold difference in sample size. Because the nonparticipant sample was relatively small, the participants' sociodemographic characteristics likely represented all local pregnant women.

One limitation of this study was the difficulty in distinguishing between an ASD and a patent foramen ovale in the neonatal period. The exclusion of a patent ductus arteriosus and patent foramen ovale in neonates (<28 days of life) eliminated neonatal conditions (ie, false-

positive findings) from consideration, thereby improving the prevalence estimates of congenital heart defects. However, among our 14 cases of ASDs (18.7%), several were difficult to distinguish from a patent foramen ovale. Thus, our prevalence data might represent an overestimation of ASDs among this population.

Our study had other limitations. There was no long-term follow-up to determine whether cases of small VSDs and ASDs spontaneously closed. Furthermore, because some pregnancies with prenatally diagnosed congenital heart defects were terminated before having confirmatory neonatal echocardiography, the accuracy of the fetal echocardiographic diagnoses in this population was uncertain. There might also have been unknown early miscarriages before the examinations were done. Furthermore, our project was geographically limited and might not represent the prevalence of congenital heart defects throughout China. Finally, the performance and interpretation of prenatal cardiac sonographic examinations are highly dependent on operator and interpreter expertise. Our study sonographers and Chinese reviewers had little experience in fetal cardiac sonography before the training program in this study, which might have affected the quality of the results. Despite these limitations, this study, using prenatal and neonatal diagnoses, found a higher prevalence rate for congenital heart defects than other reports. Thus, these results potentially represent minimal estimates of congenital heart defect prevalence in southeastern China.

In conclusion, in 4 areas surrounding Shanghai, the observed population-based prevalence of all congenital heart defects was 18.7 per 1000 births, and the prevalence of major defects was 3.0 per 1000 births. This overall prevalence was higher than rates reported in other countries, partially reflecting the inclusion of a large proportion of minor defects detected by echocardiographic examination of all neonates. Nevertheless, our data probably reflect an improved minimal estimate of the total prevalence of congenital heart defects in China.

Acknowledgments

We thank Shixin Hong, MD (Peking University Health Science Center), Ann Chao, PhD (Centers for Disease Control and Prevention), Taimei Wang, MD, Xiujing Kou, MD, Zhaoping Li, MD, and Weihong Li, MD (Peking University Third Hospital), Chunyan Shi, MD (Peking University First Hospital), Yongqing Li, MD (Chinese Academy of Medical Science Fuwai Hospital), Guizhen Zhang, MD, and Bin Geng, MD (Beijing Anzhen Hospital, Capital University of Medical Science), and government, public health, and maternal and child health workers from the Zhejiang and Jiangsu provincial, city, county, and township levels in China. This work was supported in part by cooperative agreement U11/CCU015586 from the Centers for Disease Control and Prevention.

Abbreviations

ASD	atrial septal defect
VSD	ventricular septal defect

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Table 1

Sociodemographic Characteristics of Participants and Nonparticipants in Study Areas Near Shanghai, China, 2004–2005

Characteristic	Participant		Nonparticipant	
	n	%	n	%
Maternal age, y	3,982	24.3 ± 3.1 ^a	13,516	24.6 ± 3.6 ^a
Location				
Suzhou	817	20.5	6,001	44.4
Changshu	894	22.5	3,432	25.4
Jiaxing	1,139	28.6	2,040	15.1
Haining	1,132	28.4	2,043	15.1
Occupation				
Farmer	1,943	48.8	4,873	36.1
Other	1,242	31.2	4,849	35.9
Unemployed	730	18.3	3,697	27.4
Unknown	67	1.7	97	0.7
Education				
College	858	21.6	3,376	25.0
Middle school	2,962	74.4	9,628	71.2
Primary school	100	2.5	438	3.2
None	2	0.1	31	0.2
Unknown	60	1.5	43	0.3
Ethnicity				
Han	3,911	98.2	13,436	99.4
Other	12	0.3	73	0.5
Unknown	59	1.5	7	0.1
Gravidity				
1	1,834	46.1	6,606	48.9
2	1,382	34.7	4,378	32.4
3+	688	17.3	2,307	17.1
Unknown	78	2.0	225	1.7

^aMean ± SD.

Table 2
Frequencies and Types of Sonographic Studies Completed in Study Areas Near Shanghai, China, 2004–2005

	Study Type			n	%
	Fetal Screen	Fetal Echocardiography	Neonatal Echocardiography		
+	+	+	+	3,331	83.2
+	+	+		365	9.1
+	+		+	53	1.3
+	+			216	5.4
		+	+	19	0.5
		+		22	0.5
Total	3,965	3,737	3,404	4,006	100.0

Table 3

Congenital Heart Defects Among 4006 Fetuses and Neonates in Study Areas Near Shanghai, China, 2004–2005

Phenotype	n	%	Prevalence per 1000 Births (95% CI)
Major	12	16.0	3.0 (1.6–5.2)
Hypoplastic left heart syndrome	3	4.0	0.8 (0.2–2.2)
Tetralogy of Fallot	4	5.3	1.0 (0.3–2.5)
Transposition of the great arteries	1	1.3	0.3 (0.01–1.3)
Atrioventricular septal defect	1	1.3	0.3 (0.01–1.3)
Pulmonary atresia	1	1.3	0.3 (0.01–1.3)
Critical pulmonary valve stenosis	1	1.3	0.3 (0.01–1.3)
Anomalous pulmonary venous return	1	1.3	0.3 (0.01–1.3)
Minor	63	84.0	15.7 (12.2–20.0)
Ventricular septal defect	47	62.7	11.7 (8.7–15.4)
Atrial septal defect	14	18.7	3.5 (2.0–5.8)
Mild pulmonary valve stenosis	1	1.3	0.3 (0.01–1.3)
Coarctation of the aorta	1	1.3	0.3 (0.01–1.3)
Total	75	100.0	18.7 (14.8–23.5)

CI indicates confidence interval.

Table 4

Major Congenital Heart Defects: Diagnoses and Pregnancy Outcomes in Study Areas Near Shanghai, China, 2004–2005

Case	n	Diagnostic Procedure	Age ^a	Outcome
Hypoplastic left heart syndrome	3	Fetal echocardiography	22, 24, 25	Termination
Tetralogy of Fallot ^b	2	Fetal echocardiography/autopsy	25, 28	Termination
Pink tetralogy of Fallot ^c	2	Neonatal echocardiography	1.9 d	Living
Transposition of the great arteries	1	Fetal echocardiography	27	Neonatal death
Atrioventricular septal defect	1	Fetal echocardiography	27	Termination
Pulmonary atresia	1	Fetal echocardiography/autopsy	23	Termination
Critical pulmonary valve stenosis	1	Fetal echocardiography/autopsy	25	Termination
Anomalous pulmonary venous return	1	Neonatal echocardiography	36 d	Living

^aWeeks' gestation unless otherwise specified as days postnatally.

^bOnly 1 fetus had an autopsy.

^cOne fetus had a diagnosis of a ventricular septal defect on fetal echocardiography.