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*Original Article*

# Diagnosis of congenital heart disease in an era of universal prenatal ultrasound screening in southwest Ohio

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**Abstract** *Objectives:* Diagnostic ultrasound is widespread in obstetric practice, yet many babies with major congenital heart disease remain undiagnosed. Factors affecting prenatal diagnosis of major congenital heart disease are not well understood. This study aims to document prenatal detection rates for major congenital heart disease in the Greater Cincinnati area, and identify factors associated with lack of prenatal diagnosis. *Methods:* All living infants diagnosed with major congenital heart disease by 4 months of age at our centre were prospectively identified. Prenatal care data were obtained by parent interview. Neonatal records were reviewed for postnatal data. Obstetricians were contacted for diagnostic ultrasound data. *Results:* A total of 100 infants met the inclusion criteria. In all, 95 infants were analysed, of whom 94 were offered diagnostic ultrasound. In all, 41 had a prenatal diagnosis of major congenital heart disease. The rate of prenatal detection varied by cardiac lesion, with aortic arch abnormalities, semilunar valve abnormalities, and venous anomalies going undetected in this sample. Among subjects without prenatal detection, the highest proportion consisted of those having Level 1 diagnostic ultrasound only (66%). Prenatal detection was not significantly influenced by maternal race, education level, income, or insurance type. *Conclusions:* Despite nearly universal diagnostic ultrasound, detection rates of major congenital heart disease remain low in southwest Ohio. An educational outreach programme including outflow tract sweeps for community-level obstetrical personnel may improve detection rates.

Keywords: Screening; ultrasound; congenital heart disease

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THE ULTRASOUND MACHINE HAS BEEN DESCRIBED AS "the stethoscope of the 21st century".[1] Prenatal ultrasound screening is routinely used in most countries to detect a broad spectrum of congenital malformations; however, despite its broad use, the overall detection rate for many of these defects remains discouragingly less than expected.[2] The RADIUS study and other investigations suggest that the failure to prove the effectiveness of prenatal screening has been largely due to the low detection rate of foetal anomalies in many screening programmes.[2–6] However, the RADIUS study has been criticised as not being powered to support these conclusions.

The critical need for improvement – and perhaps, for regulation of standards – in prenatal ultrasound screening is best demonstrated in infants with congenital heart disease. Congenital heart disease is the most common birth defect, found in nearly 1% of live births and significantly more among conceptions.[7–10] Congenital heart disease also accounts for a significant proportion of observed neonatal mortality.

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Although nearly all forms of major congenital heart disease can be accurately identified before birth with foetal echocardiography, the majority of affected infants are not identified prenatally.[11–13] Overall detection rates of major congenital heart disease of 20% or less have been reported in areas without dedicated initiatives to prenatally screen for congenital heart defects.[14,15] Obtaining regional data pertaining to prenatal detection of congenital heart disease, and defining barriers to prenatal detection in each region would be important in more strongly justifying system changes to improve prenatal detection of congenital heart disease in the United States of America.

It was the primary objective of this study to document the overall prenatal detection rate of major congenital heart disease in the greater Cincinnati area, to define detection rates for different categories of major congenital heart disease, and to evaluate factors affecting prenatal diagnosis of congenital heart disease in order to define the barriers to prenatal detection of these lesions. The secondary objective of this study was to ascertain whether postnatal pre-intervention clinical outcomes were different based on the presence or absence of prenatal diagnosis.

## Methods

From October, 2007 to May, 2009, 100 consecutive infants diagnosed with major congenital heart disease who received prenatal care in the Cincinnati eight-county area were prospectively identified. Infants diagnosed with major congenital heart disease at $\leq 3$ months of age in this region during the study period were included. Major congenital heart disease was defined as any congenital heart defect diagnosable before birth that required intervention, defined as requiring surgery, cardiac catheterisation, or cardiac medications within the first 2 months of life. Data for all major foetal structural heart disease diagnosed at Cincinnati Children's Hospital and affiliated centres in the time period of the study were included.

The primary outcome was the presence or absence of prenatal diagnosis of major congenital heart disease. Prenatal history and maternal/paternal demographic data were obtained through a parent questionnaire that was administered by one of the investigators in person near the time of the newborn's initial presentation. This questionnaire was previously developed and used in an earlier investigation by Friedberg et al[13] that documented prenatal detection rates in Northern California (Supplementary Appendix). The questionnaire captured data regarding the highest level of ultrasound imaging in pregnancy. This includes level 1 ultrasounds, which are focused assessment of foetal size/growth, position, and amniotic fluid; level 2 ultrasounds, which are more detailed than level 1 and include evaluation of the foetal anatomy including measurements of the head, body, extremities, and all internal organs that can be visualised by ultrasound after 18 weeks, or foetal echocardiograms. Additional data captured included maternal ethnicity, maternal education, maternal employment outside the home, maternal insurance type during pregnancy, and family income bracket. Prenatal diagnostic ultrasound was defined as any obstetrical ultrasound performed in pregnancy. Postnatal records were reviewed to extract newborn clinical data, including serum pH, lactate, and $paO_2$ at presentation when available, whether the baby was ventilated at presentation, whether prostaglandin was initiated at presentation, and whether extracardiac pathology was present.

The percentage of mothers of newborns with major congenital heart disease who received prenatal ultrasound and the level of ultrasound screening they received were documented. Prenatal detection rates were calculated and analysed by type of lesion, type of obstetrical practice, and parental demographic factors. Maternal, foetal and prenatal-care provider characteristics were analysed for infants with and without prenatal diagnosis of congenital heart disease. Student's t-test was used to compare continuous variables; $\chi^2$ or Fisher's exact tests were used as appropriate to compare categorical variables.

## Results

Between October, 2007 and May, 2009, 100 infants met inclusion criteria, and 95 families consented to participate. Of 95 mothers, 94 (99%) were offered diagnostic ultrasound. One woman initiated prenatal care at over 36 weeks of gestation and was not offered diagnostic ultrasound. Of the 95 mothers, 41 (43%) had a prenatal diagnosis of major congenital heart disease. Conotruncal defects were the most common diagnosis in the study population (22%), followed by isolated aortic arch anomalies, single-ventricle lesions, and ventricular septal defects (Fig 1). Prenatal detection varied by cardiac lesion, with no prenatal detection of either isolated semilunar valve abnormalities or total anomalous pulmonary venous return in the study population (Table 1). Cardiac lesions associated with the highest prenatal detection rates included single-ventricle anomalies (77%), heterotaxy syndrome (66%), complete atrioventricular canal (56%), and conotruncal defects (52%). Despite a relatively "high" detection rate of conotruncal defects, the large total number of conotruncal defects in the overall cohort resulted in a large number of conotruncal defects without prenatal

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diagnosis, making this category of defect both the most commonly diagnosed and undiagnosed lesions.

The majority of pregnancies without prenatal diagnosis had level 1 diagnostic ultrasound only (66%), compared with level 2 diagnostic ultrasound (28%), foetal echocardiography by maternal–foetal specialist (5%), or foetal echocardiography by cardiologist (0%). Prenatal diagnosis was not significantly influenced by maternal race, parental education, maternal employment status, family income, or insurance type (Table 2). The two perinatal clinical variables that met statistical significance between groups (Table 3) was level of ultrasound imaging ($p < 0.0001$) and delivery hospital type ($p < 0.0001$).

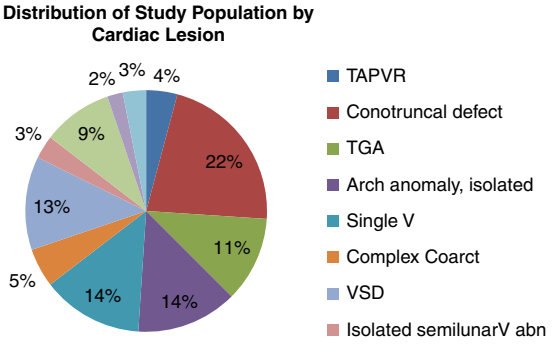


**Figure 1.**
*Pie chart showing distribution of cardiac defects among all newborns with major congenital heart disease diagnosed in the study period (both with and without prenatal diagnosis). TAPVR = total anomalous pulmonary venous return; TGA = d-transposition of the great arteries; Single V = single ventricle; VSD = ventricular septal defect; isolated semilunarV abn = isolated semilunar valve abnormality.*

Postnatal newborn clinical data were compared between patients with and without prenatal diagnosis, and are summarised in Table 3. Initiation of prostaglandin E1 was the only newborn clinical variable associated with prenatal diagnosis ($p < 0.001$). There was a trend towards lower serum lactate on presentation (in neonates with available data) in the prenatal diagnosis group ($p = 0.052$).

## Discussion

Birth defects constitute a major health burden, and congenital heart defects constitute the largest portion of birth defects.[16] Prenatal detection of congenital heart disease allows for careful planning and decision making regarding the pregnancy and delivery, and in some cases may improve postnatal clinical outcome and avoid morbidity and mortality.[11,15,17–19] Although all of this has been recognised for over 20 years, documentation of detection rates in the United States of America is sparse, in part because of the lack of centralised screening programmes for pregnant women.

The most recent US natality statistics from the American College of Obstetrics and Gynecology suggest that the percentage of pregnant women in the United States of America undergoing screening obstetrical ultrasound has increased from 1994 to 2004, with approximately two-thirds of women receiving at least one obstetrical ultrasound in pregnancy.[20] In certain areas of the United States of America, this proportion approaches 100%.[13] Despite this increase in routine pregnancy ultrasound, prenatal detection rates of congenital heart disease have not shown a corresponding increase on either a national or local level in regions where it has been studied.

Table 1. Prenatal detection rate by cardiac lesion.

| Infant Cardiac Diagnosis | No. without prenatal diagnosis (n = 54) | No. with prenatal diagnosis (n = 41) | Detection rate by lesion (%) |
|---|---|---|---|
| AVSD, complete | 4 | 5 | 56 |
| Arch anomaly | 9 | 3 | 25 |
| Complex coarctation | 3 | 2 | 40 |
| Conotruncal defect | 10 | 11 | 52 |
| Heterotaxy | 1 | 2 | 66 |
| Other* | 0 | 2 | 100 |
| Semilunar valve abn | 3 | 0 | 0 |
| Single ventricle | 3 | 10 | 77 |
| TAPVR | 4 | 0 | 0 |
| TGA | 7 | 4 | 36 |
| VSD | 9 | 2 | 18 |

AVSD = atrioventricular septal defect; TAPVR = total anomalous pulmonary venous return; TGA = d-transposition of the great arteries; VSD = ventricular septal defect
*Includes branch pulmonary artery stenosis, systemic venous anomaly

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Table 2. Comparison of parental socio-demographic data by presence of prenatal diagnosis of congenital heart disease.

| | Prenatal diagnosis | No prenatal diagnosis | p-value |
|---|---|---|---|
| GA at first prenatal visit | Mean 8.7 + 10 weeks | Mean 8.1 + 5.7 weeks | ns |
| Maternal ethnicity | | | |
| Caucasian (%) | 49 | 80 | ns |
| African American (%) | 15 | 17 | |
| Hispanic (%) | 2 | 2 | |
| Asian (%) | 5 | 0 | |
| Native American (%) | 0 | 2 | |
| Other | 0 | 0 | |
| Highest level of education (maternal) | | | |
| Middle school (%) | 3 | 0 | ns |
| High school (%) | 38 | 28 | |
| Technical (%) | 13 | 7 | |
| College (%) | 26 | 46 | |
| Graduate (%) | 21 | 19 | |
| Highest level of education (paternal) | | | |
| Middle school (%) | 0 | 0 | ns |
| High school (%) | 35 | 39 | |
| Technical (%) | 14 | 2 | |
| College (%) | 41 | 2 | |
| Graduate (%) | 11 | 20 | |
| Maternal work outside home | | | |
| None (%) | 38 | 39 | ns |
| Part-time (%) | 10 | 20 | |
| Full-time (%) | 21 | 41 | |
| Family income bracket ($) | | | |
| <25k (%) | 35 | 23 | ns |
| 25–50k (%) | 20 | 25 | |
| 50–100k (%) | 33 | 25 | |
| >100k (%) | 13 | 28 | |
| Insurance type | | | |
| Medicaid (%) | 41 | 36 | ns |
| HMO (%) | 23 | 25 | |
| PPO (%) | 36 | 34 | |
| FFS (%) | 0 | 2 | |
| Not sure (%) | 0 | 4 | |

Table 3. Comparison of perinatal clinical data by presence or absence of prenatal diagnosis of congenital heart disease.

| | Presence of prenatal diagnosis × congenital heart disease | Absence of prenatal diagnosis × congenital heart disease | p-value |
|---|---|---|---|
| Age at diagnosis | Mean: 26 weeks gestation<br>Median: 24 weeks | Mean: 24.1 days (SD 49.7)<br>Median: 4 (0–120 days) | $p = 0.001$ |
| Serum pH at presentation | Mean: 7.29 ± 0.09<br>Median: 7.31 (7.08–7.41) | Mean: 7.25 ± 0.17<br>Median: 7.31 (6.9-7.43) | $p = 0.36$ |
| Serum lactate at presentation | Mean: 3.14 ± 1.7<br>Median: 2.8 (range 0.81–9.2) | Mean: 5.4 ± 4.9<br>Median: 3.07 (1.76–16) | $p = 0.052$ |
| $paO_2$ at presentation | Mean: 38.6 ± 16.9 | Mean: 32.9 ± 11 | $p = 0.35$ |
| Ventilated at presentation | 10/41 (24%) | 12/53 (23%) | $p = 0.983$ |
| Prostaglandin E1 at presentation | 25/41 (61%) | 14/53 (26%) | $p = 0.001$ |
| Extracardiac pathology present | 17/41 (41%) | 8/53 (15%) | $p = 0.137$ |
| Highest level of ultrasound imaging | Level 1: 1/41 (2%)<br>Foetal echocardiogram: 40/41 (98%) | None: 1/53 (2%)<br>Level 1: 35/53 (66%)<br>Level 2: 14/53 (26%)<br>Foetal echocardiogram*: 3/53 (6%) | $p < 0.0001$ |
| Delivery hospital type | Local: 1/41 (2%)<br>Regional: 40/41 (98%) | Local: 18/53 (34%)<br>Regional: 35/53 (66%) | $p < 0.0001$ |

*Two of three were designated maternal foetal medicine foetal echocardiogram

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Although there are many pregnancies[13,21] considered to be at risk for foetal congenital heart disease, several studies have demonstrated that the greatest numbers of affected pregnancies are found among the masses of uncomplicated pregnancies identified at routine prenatal ultrasound screen.[8,22–24] Therefore, improving cardiac assessment at routine foetal ultrasounds is critical if the prenatal detection rates for congenital heart disease are to improve. Without improved prenatal detection rates of congenital heart disease, the impact of prenatal diagnosis on perinatal outcome of affected infants cannot be truly known.[11,25]

The data presented in this study indicate that despite nearly universal prenatal care and diagnostic ultrasound in pregnancy, detection rates of major congenital heart disease remain low in southwest Ohio. The overall prenatal detection rate of 43% for major congenital heart disease found in the greater Cincinnati region is similar to those reported in northern California in 2009 (36%), southern Nevada (36%), and one centre in Los Angeles (33%).[13,21,26] These relatively recent studies suggest that despite an increase to nearly ubiquitous ultrasound in pregnancy, prenatal detection of congenital heart disease in the United States of America has not significantly changed, particularly when compared with detection rates reported from the late 1990s in a series from Yale (33%), or in a multi-centre study from Italy (46%).[13,27,28]

Many congenital heart lesions, particularly conotruncal defects, which comprised the largest proportion of neonates with major congenital heart disease in this study, would potentially be detected prenatally if ventricular outlet views were incorporated in the screening ultrasound, increasing detection to as much as 91%.[26] Prenatal ultrasound is noted to be the most common type of ultrasound performed in the community, and a national survey of family practitioners in 1994 indicated that over 68% use prenatal ultrasound in their practice, and over half of those surveyed indicated a desire for more training.[29,30] These surveys would suggest that community physicians performing "front-line" pregnancy screening with ultrasound are receptive to educational programmes. In the past, it has been demonstrated that compliance with American Institute of Ultrasound in Medicine standards has been relatively low.[31] Although current practice statements have encouraged extension beyond the basic cardiac examination, it is unclear whether community compliance with these standards has improved.[20]

Very few of the clinical variables for newborns in this study were significantly different between prenatally and non-prenatally diagnosed patients, although there was a trend towards a higher serum lactate level at presentation in the non-prenatally diagnosed major congenital heart disease. The case for clinical benefit of prenatal diagnosis has been made by a few authors, but has not been reproduced in any large, population-based study.[19,32,33] Initiation of prostaglandin at presentation was found to be statistically significant towards the prenatally diagnosed group, as expected, owing to the prior knowledge of major congenital heart disease.

Socio-economic factors do not appear to account for lack of prenatal diagnosis in this region, which is also consistent with other regions in the United States of America.[13] This is a pertinent negative finding in the current era in US health care, where barriers to care are not always evident. In this study, the majority of cases without prenatal diagnosis were seen in subjects undergoing level 1 and/or 2 diagnostic ultrasound only, and the most logical reason for the lack of prenatal diagnosis in the southwest Ohio region is because of a lack of sensitivity at the level of the primary scan, as observed in the initial experience in parts of Europe, where universal pregnancy ultrasound is supported by the government.[34] This suggests a role for educational outreach programmes targeting general obstetrical ultrasonographers. Assessment of prenatal detection rates of major congenital heart disease after implementation of continuing professional education courses involving visualisation of abnormal outflow tract views by general obstetrical ultrasound technologists, facilitated by experienced foetal cardiac sonographers and foetal cardiologists, would be an important future direction. The efficacy of such programmes has yet to be proven, and would be encouraging for this region specifically, and for the global effort of improvement in prenatal detection of congenital heart disease in general.

In summary, overall prenatal detection rates of major congenital heart disease are $<50\%$ for most lesions, and vary by lesion, which are similar to findings reported in other geographical regions of the United States of America. The majority of pregnancies in the study population received at least one ultrasound, and thus the relatively low rate of prenatal diagnosis was not due to the lack of screening ultrasound. Parent socio-demographic variables, including insurance type, did not significantly predict the lack of prenatal diagnosis. Collaboration and educational programmes targeting health-care professionals offering screening pregnancy ultrasound is warranted.

## Limitations

One of the limitations of this study is the lack of data regarding foetal cases and pregnancy terminations in this sample. We acknowledge that the rate

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of prenatal diagnosis would be underestimated in a population where pregnancy termination after prenatal diagnosis of congenital heart disease is a commonly chosen option. Although these data are unavailable for this study sample, it is important to note that rates of pregnancy termination are generally low in this particular geographic region.

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## Conflicts of Interest

None.

## Ethical Standards

This study has been approved by the Institutional Review Board at Cincinnati Children's Hospital Medical Center.

## Supplementary materials

To view supplementary material for this article, please visit http://dx.doi.org/10.1017/S1047951113001467

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