

Original Research Article

Prevalence and pattern of congenital heart defects in infants of diabetic mothers, an experience from central India: a cross-sectional observational study

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ABSTRACT

Background: Genetic factors account for 10% cases of congenital heart defects (CHD), while maternal pre-gestational diabetes mellitus (PGDM) and gestational diabetes mellitus (GDM) are notable risk factors. Objective was to estimate the prevalence and pattern of CHD among infants of diabetic mothers (IDMs).

Methods: This one-year cross-sectional observational study was conducted at a tertiary care teaching institute in Central India. Maternal diabetic status was defined using American Diabetes Association guidelines. One hundred neonates born to mothers with PGDM or GDM were selected via simple random sampling. Exclusion criteria comprised a family history of CHD, exposure to cardiac teratogens, and neonates with known genetic syndromes. Demographic, maternal, and neonatal data were collected. Two-dimensional echocardiography was performed by a cardiologist following American Society of Echocardiography guidelines. Categorical and continuous variables were analyzed using Chi-square, Fisher's exact, and unpaired t tests, with significance set at $p < 0.05$.

Results: Of the 100 neonates, 78% were born to mothers with GDM and 22% to mothers with PGDM. The overall prevalence of CHD was 30%. Acyanotic CHD constituted 96.67% of cases, while cyanotic CHD accounted for 3.33%. Patent ductus arteriosus (PDA) was the most common defect (44.33%), followed by ventricular septal defect (23.3%), atrial septal defect (20%), and a concurrent PDA-ASD combination (10%). A single case of transposition of the great arteries was observed. The CHD prevalence difference between the PGDM (36.36%) and GDM (28.21%) groups was not statistically significant.

Conclusions: The prevalence of CHD among IDMs was 30%, with acyanotic defects, particularly PDA, being the most frequent presentation. Universal fetal and neonatal echocardiography should be routinely performed in these vulnerable infants to mitigate morbidity and mortality.

Keywords: Congenital heart defects, Infants of diabetic mothers, Pregestational diabetes, Gestational diabetes, Heart diseases

INTRODUCTION

Diabetes mellitus (DM) is a systemic, chronic metabolic disorder characterized by inappropriately elevated blood glucose levels due to impaired insulin secretion, action, or both.¹ DM is mainly classified into type 1 DM, type 2 DM, gestational diabetes mellitus (GDM), hybrid forms of diabetes, and other specific types of DM.² In 2022, an

estimated 828 million adults globally had diabetes, with a higher prevalence in low- and middle-income countries.³ In India, 19.8% (50.4 million) of adults aged 45 years and older suffer from diabetes; furthermore, the estimated pooled prevalence of GDM is 13% (range: 9-16%), which is more prevalent in urban than rural populations.^{4,5} The impairment of glucose tolerance in pregnancy varies from 3% to 10% due to an increase in

basal endogenous glucose production, decreased peripheral insulin sensitivity, and β -cell dysfunction in GDM.⁶

CHD are structural or functional heart abnormalities that occur in utero and are detectable during pregnancy or at birth. CHDs are the most common form of birth defects in humans, occurring in 9 out of 1,000 live births. It is multifactorial in origin; while genetic risk factors are noted in 10% of all CHDs, non-inherited factors-such as drugs, viral infections, maternal smoking, alcohol consumption, maternal PGDM, and GDM-are notable risk factors for the occurrence of CHD.⁷ Maternal hyperglycemia and hyperketonemia during the critical embryonic period (the first six to eight weeks of gestation) are teratogenic, altering biochemical and signal transduction pathways and leading to the excessive production of free oxidative radicals. However, the specific type of DM, the level of HbA1c in early pregnancy, and the degree and duration of hyperglycemia and hyperketonemia ultimately determine the severity of cardiac damage.^{6,7} Compared to the general population, both GDM and PGDM significantly increase the risk of CHD; notably, PGDM appears to carry a 3.5- to 4-fold increased risk of malformations.⁸ Existing literature suggests a varied prevalence of CHD in IDM. The incidence is lower in developed nations (6 in 10,000 live births in the USA and 1.7% in Finland) and higher in developing countries.⁹⁻¹¹ In India, the reported incidence of CHD in IDM ranges from 16.33% to 28%.^{12,13} Hypertrophic cardiomyopathy is the most common cardiac abnormality in IDM; however, abnormalities of laterality, looping, and conotruncal septation are also commonly encountered.^{6,7,14,15} Conotruncal and atrioventricular defects are usually associated with type 1 DM, whereas heterotaxy and left ventricular outflow tract obstructive abnormalities are more common in type 2 DM.⁷ Data on CHD in IDM are scarce in our region. Therefore, this study was designed to evaluate the prevalence and pattern of CHD in infants born to mothers with PGDM and GDM.

METHODS

Study design, duration, and setting

This cross-sectional observational study was carried out in the Neonatal Intensive Care Unit (NICU) of a tertiary care teaching institute in Central India over a period of one year (March 2025 to February 2026).

Sampling size and sampling method

Neonates born to mothers with pre-gestational and gestational diabetes were enrolled using a simple random sampling method. The sample size was calculated using the Cochrane formula, assuming an estimated CHD prevalence of 25% in IDMs, a 95% confidence level, and a 10% margin of error. Although the minimum expected

sample size was 72, a total of 100 IDMs were ultimately recruited.

Inclusion criteria

Neonates born to mothers with pre-gestational and gestational diabetes. The diabetic status of the mothers was defined according to the American Diabetes Association guidelines.¹⁶ Pre-gestational diabetes was defined as a fasting plasma glucose level ≥ 126 mg/dL, a 2-hour postprandial plasma glucose level ≥ 200 mg/dL, or an HbA1c $\geq 6.5\%$. Gestational diabetes was defined as a plasma glucose level ≥ 140 mg/dL included in study.

Exclusion criteria

Neonates with a family history of CHD or phenylketonuria; maternal exposure to cardiac teratogens such as smoking, alcohol, radiation, or medications (e.g., warfarin, anticonvulsants, and retinoids); maternal cytomegalovirus or rubella infections; and neonates presenting with genetic syndromes or chromosomal aberrations were excluded from study.

Data collection

Data were collected as early as possible by the primary investigator through parent interviews, with oversight provided by postgraduate-qualified senior residents. In addition to demographic data, maternal variables-including diabetic status, age, parity, mode of delivery, duration of diabetes, and treatment regimens-were recorded. Neonatal clinical variables, such as vital signs, blood glucose levels, oxygen saturation, presence of cyanosis, and capillary refill time (CRT), were measured in a thermoneutral environment with adequate illumination. Blood glucose was measured using a commercially available glucometer, and hypoglycemia was defined as a blood glucose level less than 40 mg/dL. The gestational age of the neonates was assessed using the New Ballard Scoring method.¹⁷ Neonatal weight was recorded at admission using a digital electronic weighing scale with a minimum margin of error of 10 g. Chest radiography was performed to evaluate cardiac size, with a cardiothoracic ratio greater than 0.5 considered indicative of cardiomegaly. Two-dimensional (2-D) echocardiography was performed using a Sonosite Edge II ultrasonography machine (Manufacturer: FUJIFILM Sonosite, United States) by a trained cardiologist who was blinded to the clinical status of the participants. Structural and functional cardiac abnormalities were identified in accordance with the guidelines of the American Society of Echocardiography.¹⁸

Ethical consideration

The study adhered to the principles of the Declaration of Helsinki and was approved by the institutional ethics committee. Written informed consent was obtained from

the parents in their vernacular language prior to participant enrollment.

Statistical analysis

Data were coded, cleaned, and entered into a Microsoft excel spreadsheet for analysis using STATA version 14.0. Categorical variables are presented as frequencies, percentages, and rates. Continuous variables are expressed as means and standard deviations. The Chi-square test, Fisher's exact test, unpaired t-test, and Mann-Whitney U test were utilized to compare variables between neonates with and without CHD. A p value less than 0.05 was considered statistically significant.

RESULTS

Female neonates predominated in the study cohort, with a male-to-female ratio of 0.79:1. Premature delivery occurred in 55% of the neonates, and 82% were delivered via caesarean section. The mean birth weight of the cohort was 2720.2 ± 598.6 gm with more than three-quarters classified as appropriate for gestational age. Regarding maternal status, 78% of the neonates were born to mothers with GDM, whereas 22% were born to mothers with PGDM. The majority of the mothers (77%) had a known duration of diabetes of less than 1 year, and most were managed with oral medications (Table 1). Apgar scores at 1, 5, and 10 minutes were statistically significantly lower in neonates diagnosed with CHD compared to those without CHD (Table 2).

The overall prevalence of CHD was 30% among the IDMs. Out of the 30 neonates diagnosed with cardiac defects, acyanotic CHD was noted in 29 (96.67%) cases,

while cyanotic CHD was present in only 1 (3.33%) neonate. Among CHD, PDA was the most common, occurring in 13 (44.33%) neonates, followed by ventricular septal defect (VSD) in 7 (23.33%), atrial septal defect (ASD) in 6 (20%), and a concurrent combination of PDA and ASD in 3 (10%) neonates. The single case of cyanotic CHD (3.33%) was identified as transposition of the great arteries (TGA) (Figure 1).

The prevalence of CHD was 36.36% among infants born to pre-gestational diabetic mothers and 28.21% among infants born to GDM mothers. Broken down by maternal diagnosis, the 8 CHD cases within the PGDM subgroup included 3 neonates with PDA, 1 with TGA, 2 with ASD, and 2 with VSD. Conversely, among the 22 CHD cases within the GDM subgroup, 10 neonates presented with PDA, 5 with VSD, 4 with ASD, and 3 with a combination of both PDA and ASD.

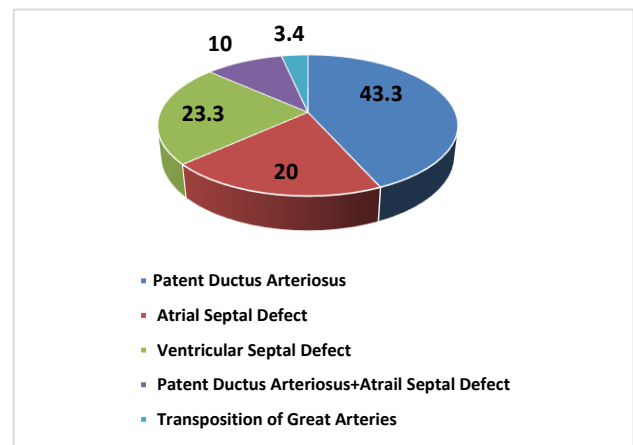


Figure 1: Patterns of CHDs in IDMs.

Table 1: Demographic, clinical and maternal characteristics, (n=100).

Characteristics	All participants, (%)
Gender (Male/Female)	44/56
Gestational age (in weeks) (Mean±SD)	36.6±1.6
Pre-term	55 (55)
Term	45 (45)
Birth weight (gm) (Mean±SD)	2720.2±598.6
1000-1499	03 (03)
1500-2499	30 (30)
2500-2499	37 (37)
≥3000	30 (30)
AGA	89 (89)
LGA	6 (6)
SGA	5 (5)
Mode of delivery	
Vaginal	18 (18)
Cesarean	82 (82)
Maternal age (in years) Mean±SD)	26.9±4
≤20	6 (6)
21-25	25 (25)
26-30	48 (48)
>30	21 (21)

Continued.

Characteristics	All participants, (%)
Gravida	
Primigravida	48 (48)
Multigravida	52 (52)
Previous abortion (yes)	23 (23)
Body-mass-index (Mean±SD)	23.9±1.8
Diabetic status	
Pre-gestational	22 (22)
Gestational	78 (78)
Duration of diabetes	
<1 year	77 (77)
1-3 years	12 (12)
>3 years	11 (11)
Treatment regimen	
Oral medication	72 (72)
Insulin	28 (28)
Apgar score (Mean±SD)	
At 1 minute	7.45±0.9
At 5 minutes	9.48±0.8
At 10 minutes	9.91±0.3
Outcome	
Survival	95 (95)
Death	5(5)

*gm-gms, AGA-Average for gestational age, LGA-Large for gestational age, SGA-Small for the gestational age, SD-Standard Deviation.

Table 2: Factors associated with occurrence of congenital heart defect.

Characteristics	Congenital heart defect		P value
	Yes (n=30, %)	No (n=70, %)	
Gender			
Male	15 (50)	29 (41.43)	0.43
Female	15 (50)	41 (58.57)	
Gestational age (in weeks)			
Pre-term	18 (60)	37 (52.86)	0.51
Term	12 (40)	33 (47.14)	
Mean±SD	36.6±1.6	36.5±1.7	0.78
Birth weight (gm)			
1000-1499	1 (3.33)	2 (2.86)	0.53
1500-2499	8 (26.67)	22 (31.43)	
2500-2499	9 (30)	28 (40)	
≥3000	12 (40)	18 (25.71)	
Mean±SD	2831±660.6	2672.7±568.5	0.22
AGA	24 (80)	65 (92.86)	0.15
LGA	3 (10)	3 (4.29)	
SGA	3 (10)	2 (2.85)	
Mode of delivery			
Vaginal	6 (20)	12 (17.14)	0.73
Cesarean	24 (80)	58 (82.86)	
Apgar score (Mean±SD)			
At 1 min	7.13±0.89	7.6±0.9	0.01
At 5 min	9.1±0.92	9.6±0.8	0.007
At 10 min	9.8±0.4	9.9±0.2	0.09
Maternal age (in years Mean±SD)	26.83±4.53	26.9±3.8	0.93
≤20	4 (13.33)	2 (2.85)	0.19
21-25	6 (20)	19 (27.14)	
26-30	15 (50)	33 (47.14)	
>30	5 (16.67)	16 (22.87)	

Continued.

Characteristics	Congenital heart defect		P value
	Yes (n=30, %)	No (n=70, %)	
Gravida			
Primigravida	14 (46.67)	34 (48.57)	0.8
Multigravida	16 (53.33)	36 (51.43)	
Previous abortion (yes)	9 (30)	14 (20)	0.41
Body-mass-index (Mean±SD)	23.9±1.7	23.9±1.8	1.00
Diabetic status			
Pre-gestational	8 (26.67)	14 (20)	0.46
Gestational	22 (73.33)	56 (80)	
Duration of diabetes			
<1 year	22 (73.33)	55 (78.57)	0.64
1-3 years	5 (16.67)	7 (10)	
>3 years	3 (10)	8 (11.43)	
Treatment regimen			
Oral medication	8 (26.67)	20 (28.57)	0.84
Insulin	22 (73.33)	50 (71.43)	

DISCUSSION

CHDs are the leading cause of mortality among infants and young children. Worldwide, around 1% of live births are affected by CHD; however, this prevalence is notably higher in IDMs. This cohort study was designed to estimate the prevalence of CHD and analyze its patterns in IDMs.¹⁹

India has a high burden of CHD, with approximately 200,000 children born with these defects annually.^{19,20} In the present study, the prevalence of CHD among IDMs was 30%, which is significantly higher than rates reported in developed countries. For instance, a population-based birth cohort study from Finland reported that only 1.7% of neonates had an isolated CHD, while a larger cohort studied by Gonuguntla et al observed an incidence of 6 per 10,000 live births.^{10,11}

Our findings are comparable with the reports of Randad et al and Arul et al who reported CHD rates of 26.7% and 28% among IDMs, respectively.^{13,21} Conversely, a lower incidence (16.3%) has been reported by other Indian researchers.¹² Higher prevalences of 45.57% and 47.5% were reported by Afridi et al and Shamaoon et al from Pakistan.^{11,22} Although a lower prevalence has been observed in Iranian studies, Armandina et al revealed that 49% of neonates born to diabetic mothers had abnormal echocardiographic findings.^{14,15,23} Recently, Al Ghadeer et al from Saudi Arabia noted that 68.3% of infants born to diabetic mothers presented with various CHDs.²⁴ This wide variation in prevalence may be attributed to differences in glycemic control during critical phase of embryogenesis, variations in the genetic susceptibility of studied populations, and differing diagnostic approaches.

Literature suggests that the degree and duration of maternal hyperglycemia and hyperketonemia, alongside early pregnancy HbA1c levels, are directly related to cardiac abnormalities.⁶ PGDM is associated with a 4.33-

fold higher risk of CHD compared to a 1.47-fold risk in GDM.⁹ Furthermore, various reports reveal that infants of PGDM mothers have a statistically significant higher chance of developing CHD than infants of GDM mothers.^{8,25-27} In our study, 22% of the mothers had pre-gestational diabetes and 78% had gestational diabetes. While the incidence of CHD in infants of PGDM mothers (36.36%) was higher than in those of GDM mothers (28.21%), the difference was not statistically significant. This lack of significance is likely due to the small sample size of PGDM mothers.

The structural patterns of CHD vary between countries and regions due to phenotypic variations that depend on the timing and type of embryonic dysregulation. Hypertrophic cardiomyopathy (HCM) is the most common cardiac abnormality associated with diabetic mothers due to the hyperplasia and hypertrophy of cardiomyocytes. Roodpeyma et al and Tabib et al noted HCM in 46.9% and 40% of IDMs, respectively.^{14,15} However, some authors have revealed that type 1 DM carries a higher risk of conotruncal and atrioventricular defects, while type 2 DM is more commonly associated with heterotaxy and left ventricular outflow tract defects.⁷

In this study, acyanotic heart diseases constituted 96.67% of the CHD cases, while only one infant presented with a cyanotic defect (transposition of the great arteries [TGA]). Among the identified CHDs, PDA, ventricular septal defect (VSD), atrial septal defect (ASD), and combined PDA+ASD were noted in 43.33%, 23.33%, 20%, and 10% of cases, respectively. Dominic et al from South India reported that among 8 neonates with CHD, 50% each had ASD and VSD.¹² Arul et al found that 28% of infants had cardiac disease (5 cyanotic and 23 acyanotic), with ASD and asymmetrical septal hypertrophy being the most common, while TGA and VSD were noted in 2 neonates each.¹³ Randad et al from Mumbai observed CHD in 26.7% of infants; their most frequent lesions were VSD (12.5%), HCM (3.6%), ASD

(3.6%), and PDA (2.6%), while tetralogy of Fallot (TOF) and TGA noted in 1.8% each among cyanotic defects.²¹

Similar to our findings, Saudi Arabian authors observed that PDA is the most common CHD associated with IDMs, followed by HCM and VSD.^{25,29,30} Afridi et al from Pakistan noted that patent foramen ovale (PFO) was the most frequent cardiac lesion (23%), followed by PDA (14.9%), VSD (5.4%), and ASD (2.7%).¹¹ They also found significant differences in the occurrence of ASD, VSD, TGA, HCM, and TOF between infants of PGDM and GDM mothers. However, Shamaoon et al reported PDA as the most common CHD, followed by VSD and ASD.²² This common triad of ASD, PDA, and VSD was also reported by Begum et al from Bangladesh.³⁰ Conversely, Iranian authors reported PFO as the most common lesion (69.5%), followed by PDA (41%).²³

Limitations

The main limitations of this study include the lack of long-term evaluation of the cardiac lesions, the absence of correlation between maternal glycemic control and CHD occurrence, and its nature as a single-center study. Therefore, these findings may not be generalizable to other clinical settings. However, this research provides valuable regional data regarding CHD among IDMs.

CONCLUSION

The prevalence of CHD among IDMs was 30%, with acyanotic defects-particularly PDA-being the most frequent presentation. Universal fetal and neonatal echocardiography should be routinely performed in these vulnerable infants to mitigate morbidity and mortality.

Recommendations

We recommend pre-conceptional counselling regarding the importance of maternal diabetes screening, alongside universal fetal and neonatal echocardiography for IDMs to reduce morbidity and mortality in this vulnerable infant population.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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