



Efficacy of Antenatal Ultrasound Examination in Diagnosis of Congenital Cardiac Anomalies in an Unselected Population: Retrospective Study from a Tertiary Centre

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Abstract

Background In Low- and Middle-Income Countries like India, where the services and surgical care for Congenital Heart Disease (CHD) are available only in selected centres with geographical variations, it is important to detect Heart defects early and give the parents an opportunity to plan ahead for seeking appropriate care at the earliest. Several developments in recent years such as improvement of quality of ultrasound machines, sonographer's experience, skills and better description of cardiac views have contributed to improve detection rate.

Methods A retrospective study was done between March 2016 and December 2019, and showed ultrasound evidence of CHD was included.

Results The total number of morphology scans done during study period was 50,435. The number of congenital anomalies detected was 1482, out of which CHD was detected in 334 (22.5%). Outcome of 50 pregnancies were not available while the rest (284) were available for follow up in post-natal period. There were 51 cases of CHD, missed on routine antenatal morphological screening, which were diagnosed in the post-natal period. There were 18 cases of over-diagnosed CHD on antenatal scan, but were found to have normal echo findings after birth.

Conclusion A systematic approach is crucial for practitioner to determine the patterns of associated defects. Use of step wise strategy helps in determining the correct diagnosis of isolated cardiac defect, associated with other system or a part of syndrome. Systematic audit of morphological scans could play an important role in improving the diagnostic accuracy, which in turn will lead to early detection.

Keywords Cardiac defects · Morphology scan · Missed diagnosis · Perinatal outcome

Introduction

Congenital heart disease (CHD) is one of the most common congenital abnormalities [1]. Unfortunately, it is one of the most frequently missed anomalies. The prevalence ranges from 8 to 11 cases per 1000 live births with a lot of geographical variation [2, 3]. Prenatal diagnosis is affected by experience of operator, choice of transducer, maternal body habitus, foetal position, gestational age and amount of amniotic fluid [4].

Detection of a major CHD through Targeted Imaging for Foetal Anomalies (TIFFA) scan by 18–20 weeks followed by foetal echocardiography at 22–24 weeks and effective prenatal counselling from a multidisciplinary team approach can allow the parents to make a well-informed decision regarding termination of pregnancy or a planned obstetric

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and neonatal management to optimize the outcome in an ongoing pregnancy. Some major cardiac anomalies can be detected as early as 12 weeks of gestation. This can help to reduce mortality and morbidity secondary to CHD [5]. In a LMIC (Low- and Middle-Income Country) like India, challenges to early and effective detection of CHDs are many. Main reasons among them are a lack of equipment and expertise which vary to a great extent based on geographic, economic and sociocultural factors [6]. The time of referral to a tertiary centre where expertise is available varies greatly making an effective early prenatal diagnosis challenging.

By doing a retrospective study we tried to analyse the efficacy of antenatal ultrasound in diagnosing a CHD and the associated pregnancy outcomes. Evaluation of the utility of morphological screening ultrasound scans has been studied by large studies and a Cochrane Review [7]. Though the benefit of a TIFFA scan to parents is early diagnosis, false positive findings can result in increased patient anxiety. Hence that needs to be minimized as well. The purpose of our study was to analyse and audit the detection of congenital cardiac anomalies in a tertiary teaching hospital that provides antenatal care to a large number of low-risk and high-risk women.

Methodology

Setting Department of Obstetrics and Gynaecology, Christian Medical College Vellore is a tertiary care centre in South India.

Objectives

1. To detect sensitivity, specificity and diagnostic accuracy of antenatal morphology scan for detection of CHD in a non-selected population at a tertiary care hospital.
2. Study perinatal outcomes in pregnancies diagnosed with CHD in a non-selected population.

A retrospective study was done from a prospectively maintained database of the antenatal morphology scans done in the Department of Obstetrics and Gynaecology, after obtaining approval from the institutional review board and ethics committee (IRB Min No. 10495 retro dated 18/01/2017). Pregnant women who underwent scans between March 2016 to December 2019 and showed ultrasound evidence of CHD were included in the study. These included the ones booked in our hospital and few referred from other centres with a CHD detected outside on a scan for confirmation of diagnosis and management. Maternal demographics, gestational age at which the screening ultrasound was done, the prenatal diagnosis and the perinatal outcome for each patient were recorded. All neonates undergo a

cardiac examination with pulse oximetry screening by neonatologists and if warranted are referred for an early echocardiography. Details of echocardiography of such neonates were also noted. A prospectively maintained audit register in which the details of cardiac anomalies detected in postnatal period (pulse oximetry, cardiac examination and echocardiography), which were missed on antenatal scans, was referred to obtain the total number of missed cases. Medical autopsies of still born are done in our institution with the consent of parents when indicated to confirm the cause. The results of such autopsies were prospectively documented and were audited monthly for congenital anomalies missed on antenatal morphological scans. During the period of study, no autopsy report of still born foetus showed a missed cardiac anomaly.

Morphological screening scans All scans were done by trained staff with more than 5 years experience in doing morphology scans. The foetal cardiac images by ultrasound were obtained from the standard views: the four-chamber view, the left ventricular outflow tract view, the right ventricular outflow tract view, the aortic arch view, the three-vessel view, foetal echocardiography and colour doppler. These ultrasounds were done using either Voluson GE S8/ Voluson GE E8 machines. Detected anomalies were counter-checked by a multidisciplinary team when necessary. The anomalies were entered on a daily basis in a register maintained in the ultrasound room. Out Patient records of women with detected cardiac anomalies were marked with a coloured sticker. A proforma was filled for each woman with detected anomaly and the data were entered prospectively into an excel sheet every day. The expected date of delivery was documented after the morphology scans. All children with CHDs detected prenatally, underwent an echocardiography and detailed cardiac evaluation. The Echo findings were updated in the proforma and entered into the excel sheet prospectively. Cases with CHD detected antenatally but not seen postnatally on echocardiography were obtained from the database. Anomalies that were not detected antenatally on morphological scanning but diagnosed postnatally by clinical examination and subsequent echocardiography were maintained in a register.

Statistical analysis All the categorical variables were summarized in counts and percentages. Data were organized as per the STARD checklist (Standards for Reporting Diagnostic Accuracy Studies). Sensitivity, specificity and accuracy of the antenatal USG screening for CHD were calculated after plotting a 2X2 table. Statistical analysis was done using SPSS Version 20.0.

Results The Total number of antenatal morphology scans done in Christian Medical College, Vellore between March 2016 and December 2019 was 50,435. The total number of congenital anomalies detected during the period was 1482, out of which CHD was detected in 334 (22.5%). Outcome of

50 pregnancies were not available, while the rest (284) were available for follow up in post-natal period. There were 51 cases of CHD, missed on routine antenatal morphological screening, which were diagnosed in the post-natal period between March 2016 and December 2019 (Table 1 for details). There were 18 cases of over-diagnosed CHD on antenatal scan, but were found to have normal echo findings after birth (Fig. 1).

Sonological screening for CHD at our centre had a sensitivity of 83.91% (Confidence Interval/CI: 79.40–87.78%), specificity of 99.96% (CI: 99.94–99.98%) and a diagnostic accuracy of 99.82% (CI: 99.78–99.85%). For calculating the diagnostic accuracy, the community prevalence of CHD at birth in Indian population was considered as 0.9%. (refer Tables 2, 3).

CHD diagnosed antenatally was divided as simple isolated ($n = 49$), complex isolated ($n = 136$), CHD with extracardiac involvement ($n = 85$) and extracardiac conditions affecting the heart but not primarily heart diseases ($n = 64$).

Axis deviation of the heart on ultrasonography was seen in 76 cases. Axis deviation secondary to non-cardiac anomalies was seen in 41 cases where the cause was secondary to congenital diaphragmatic hernia (CDH) and CPAM (congenital pulmonary adenoid malformation). Axis deviation due to cardiac anomalies was found secondary to outflow tract abnormalities in 35 cases (Transposition of great arteries $n = 17$, Tetralogy of Fallot $n = 12$, Double Outlet Right Ventricle (DORV) $n = 3$, Coarctation of aorta $n = 2$, pulmonary stenosis $n = 1$).

Valvular anomalies found were Tricuspid atresia ($n = 6$) and Pulmonary stenosis ($n = 1$). Aortic arch abnormalities were seen in 6 cases.

Septal defects were seen in 76 cases (Different subtypes and their outcomes have been explained in Table 2). Other cardiac anomalies found were Hypoplastic Left Heart Syndrome (HLHS) in 22 cases and Hypoplastic Right Heart Syndrome (HRHS) in 9 cases.

Foetal Heart rate and rhythm abnormalities were seen in 7 cases of which 4 cases had foetal supraventricular tachycardia (foetal heart rate more than 180 beats per minute) and 3 cases had complete heart block.

Totally 12 cases of foetal cardiac tumours which were confirmed postnatally as Rhabdomyoma.

Conditions listed as other anomalies ($n = 48$) include cardiomegaly, dextrocardia, ectopia cordis, ventricular wall thickening, Persistent Left Superior Vena Cava (Table 4). Soft markers such as pericardial effusion, single umbilical artery, echogenic foci in heart and increased nuchal translucency were found in 39 cases. Detailed foetal echocardiography was done antenatally and all were followed up with screening echocardiography postnatally.

Out of 334 cardiac defects detected, 311 were singleton and 23 were multiple pregnancies with at least one foetus having a cardiac anomaly.

Of the 334 cardiac defects which were detected, live births were seen in 175 cases, still births were 10, six neonatal death, while there were 50 cases which were lost to follow up. Termination of pregnancy (TOP) after appropriate genetic counselling was done in 93 cases. TOP was suggested and performed only in cases of complex CHD which were not compatible with life and when CHD was associated with extracardiac anomalies that necessitated termination. No isolated and treatable CHD underwent TOP in our study (Table 4).

Table 1 Details of missed cardiac heart defect

Number of CHD missed	<i>n</i>
Ventricular septal defect (VSD)	14
Atrial septal defect (ASD)	10
ASD+VSD	3
Atrio-ventricular septal defect (AVSD)	1
Aortic arch defect	5
Coarctation of aorta	2
TAPVC	3
Tetralogy of fallot	2
Transposition of great arteries	1
Aortic stenosis	2
Pulmonary stenosis	2
Pulmonary atresia	1
Dextrocardia	2
Rhabdomyoma	1
Aortopulmonary window	2
Total	51

Discussion

Sensitivity of antenatal ultrasound screening for CHD is reported as low as 60–70% in studies published globally in last decade, mainly because the cardiac imaging was based only on the 4-chamber view. The sensitivity of our antenatal screening is 83.91% in a non-selected population. This can be attributed to our screening not being limited to just the high-risk population and seamless utility of other views along with 4C view including outflow tracts, 3 vessel view, utility of colour-doppler and foetal echocardiography whenever needed. In a disease with low prevalence such as CHD, the sensitivity of a diagnostic test tends to be low [6]. Lack of technological advances and expertise have been reported as reasons for low pick up rate of cardiac anomalies on antenatal scans when compared to anomalies of central nervous system in studies from India [8, 9]. The specificity in our study was 99.96% which is in agreement with many of the existing literature from other studies [10].

Fig. 1 Flow diagram showing recruitment of participants after exclusion at different levels

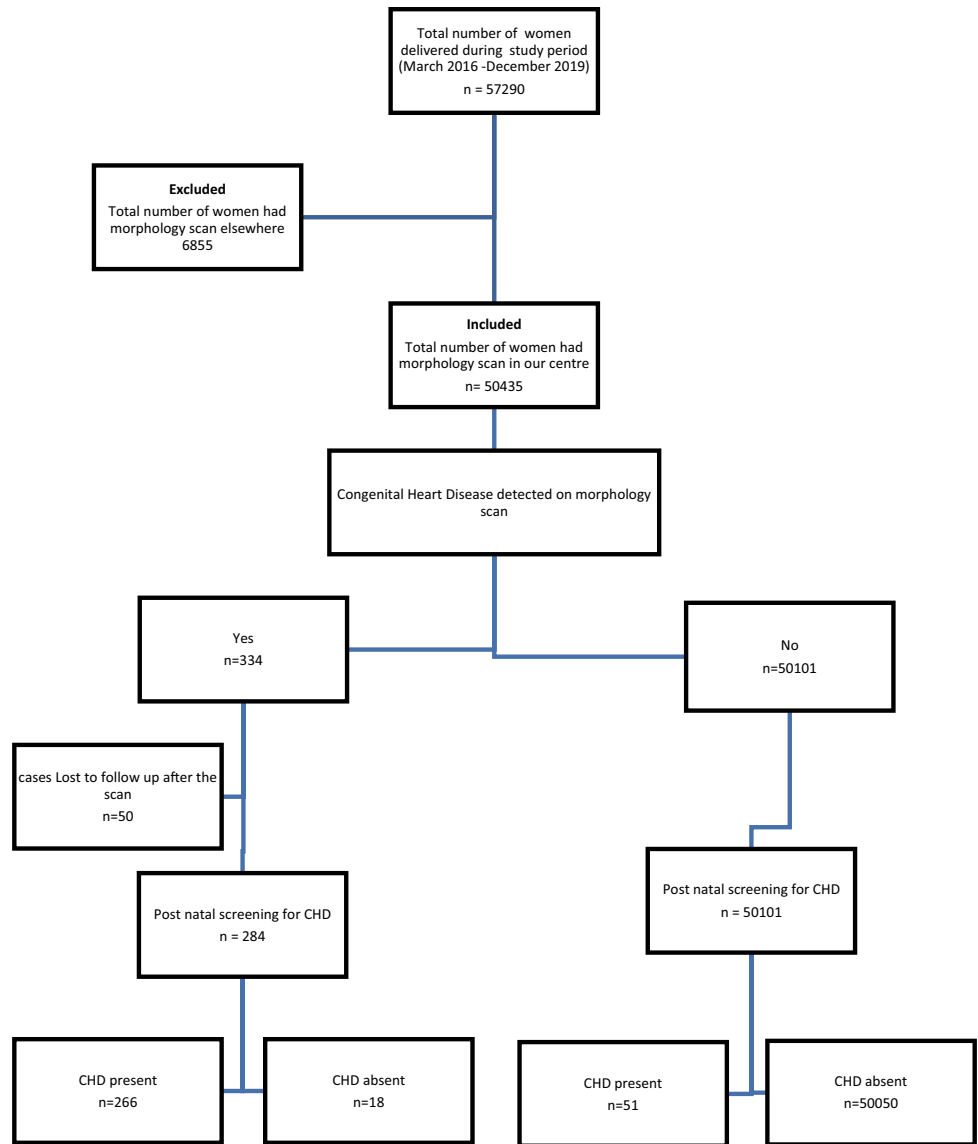


Table 2: 2X2 table for testing diagnostic accuracy of CHD

	CHD present	CHD absent	Total
CHD detected on morphology scan	266 (a)	18 (b)	284 (a + b)
CHD not detected on morphology scan	51 (c)	50,050 (d)	50,101 (c + d)
Total	317 (a + c)	50,068 (b + d)	a + b + c + d = 50,389

Table 3 Table showing statistical test values with 95% confidence interval values

Statistics	Value	95% confidence interval
Sensitivity	83.91%	79.40 to 87.78%
Specificity	99.96%	99.94 to 99.98%
Positive likelihood ratio	2334.05	1466.98 to 3713.62
Negative likelihood ratio	0.16	0.13 to 0.21
Disease prevalence	0.90%*	–
Positive predictive value	95.49%	93.02 to 97.12%
Negative predictive value	99.85%	99.81 to 99.89%
Accuracy	99.82%*	99.78 to 99.85%

*These values are dependent on disease prevalence

Table 4 Details of important CHD detected on antenatal screening and their outcomes

CHD	Number (n)	Percentage (%)	Alive at 1 month	TOP	Still birth	Early neonatal death	Lost to follow up
VSD*	51	15.17%	35	8	0	2	6
ASD*	9	2.6%	5	1	0	1	2
AVSD	16	4.7%	5	7	1	0	3
Hypoplastic heart	31	9.2%	3	21	2	1	4
Rate-rhythm abnormalities	7	2.0%	5	1	0	0	1
Truncus arteriosus	3	0.89%	1	1	0	0	1
DORV	3	0.89%	0	3	0	0	0
COA	2	0.5%	1	0	0	0	1
TGA	17	5.05%	6	7	0	1	3
TOF	12	3.5%	5	5	0	1	1
Pulmonary stenosis	1	0.2%	0	1	0	0	0
Tricuspid atresia	6	1.7%	0	5	0	1	0
Ebstein's anomaly	3	0.89%	1	0	1	1	0
Aortic arch abnormality	6	1.7%	4	1	0	0	1
Cardiac tumours	12	3.5%	11	1	0	0	0
Other anomalies	48	14.2%	20	10	6	3	9

*Includes isolated septal defects and septal defects associated with multiple cardiac and extracardiac anomalies

The community prevalence of CHD at birth in Indian population was calculated from studies on Indian population in tertiary centres and it was taken as 9 per 1000 population or 0.9% [2, 11, 12]. Diagnostic accuracy of antenatal scans in our study was found to be 99.86% which is comparable to other studies. The diagnostic accuracy of USG for CHD according to an Australian study has shown improvement over recent years due to improvement in skills, training and confidence specially with diagnosis of non-complex cardiac disorders [13].

Higher maternal age is associated with more foetal anomalies. However there's mixed evidence regarding advancing maternal age and foetal cardiac anomalies [14, 15]. In our study population, the mean maternal age was 29 years.

The cardiac apex points to the left by $45 \pm 15^\circ$ in relation to antero-posterior axis of chest. Although axis deviation is not diagnostic of a CHD, significant left axis deviation is frequently associated with it. Studies suggest that abnormal cardiac axis is present in two-thirds of fetuses with congenital heart defect in early gestation. Adding cardiac axis assessment to the nuchal translucency measurement in first trimester scan is helpful in defining a population at risk for CHD [16]. Axis deviation was found in a total of 76 cases. In our study, population axis deviation due to non-cardiac causes was 41 (54.7%) and due to cardiac causes was 35 (45.3%).

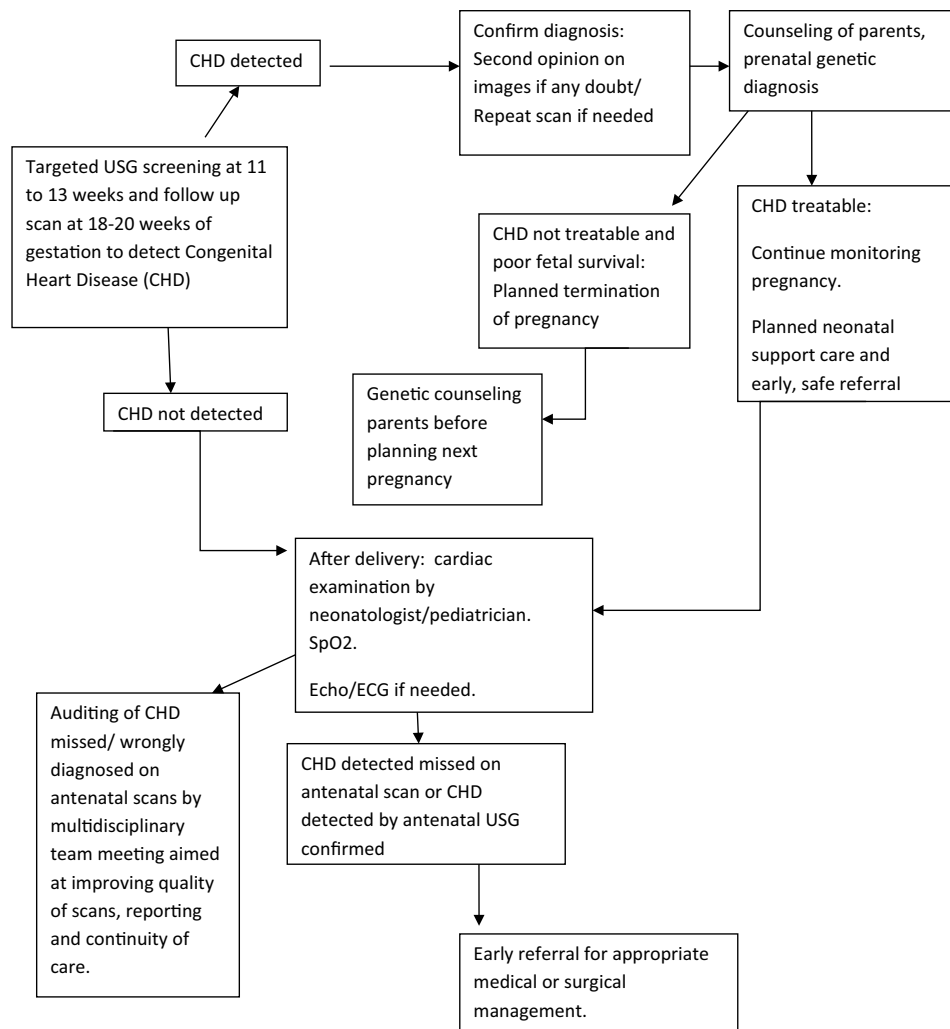
Most common CHD found in our study was VSD which is in agreement with most of the previously published studies [17]. Hypoplastic heart syndromes were the most common cause for termination of pregnancy (TOP). Out of 31 cases,

21 underwent TOP, 4 mothers were lost to follow up and 6 mothers who presented in third trimester of whom 2 were stillborn and 3 delivered at term. They were explained about the poor prognosis for the neonate and all 3 cases were lost to follow up after discharge.

Eighteen cases were over-diagnosed with a CHD, which was found to be normal on echocardiography in the post-natal period. Overdiagnosis leads to unnecessary anxiety and stress to parents. The over diagnosed cases were those of small peri-membranous VSD which tend to close by term. The antenatal findings of cardiomegaly, thickened ventricular or septal walls had a normal echocardiography finding after birth. These facts should be kept in mind while counselling the anxious parents after a morphological scan in which a CHD has been diagnosed.

The challenges in antenatal detection of CHD in a developing country are unique. The patient population whom we cater to come from a low-middle income group who lack the awareness about importance of early screening and are unwilling to come for follow up visits. This led to a major limitation of our study with more loss to follow up. In LMIC like India, where the services and surgical care for CHDs are available only in selected centres with a lot of geographical variations, it is important to detect CHD early and give the parents an opportunity to plan ahead for seeking appropriate care at the earliest. Studies in Indian settings have shown that children with prenatally diagnosed CHD, who got the benefit of early referral to tertiary centre equipped with specialized cardiac post-natal care have had satisfactory outcomes [18].

Fig. 2 Flow chart summarizing management plan for CHD after antenatal ultrasonography



Non-availability of trained sonologists and equipment at all primary and secondary level antenatal care providing centres cause delay in referral for antenatal screening. Newer health programs must focus on training personnel to detect CHD early. Various approaches for sonological assessment at primary and secondary level, like Keep It Simple and Safe (KISS) approach can enable detection of majority of clinically significant CHDs and early referral to centres equipped for detection and management of CHD [19, 20]. The use of telemedicine in adult echocardiography to assist remote diagnosis of cardiac conditions has been found to be effective in LMICs including India [21]. Tele-sonography for diagnosing foetal anomalies can also be practised to improve detection of foetal anomalies in pregnancy. Education and improving skill of care providers in primary care centres can be done through telemedicine. A systematic review suggests that though most of the studies published on tele-ultrasound

are related to fields of obstetrics and cardiology, they are not of good quality and lack of randomized controlled trials is a major limitation [22].

Our study design was retrospective, and that is one of the limitations of the study. The data were collected from a prospectively maintained database and the authenticity of our study findings depend more on the accuracy of recorded data. Despite best care, errors in data entry into the prospective database, non-availability of some of the details in many cases were seen.

Conclusion

Our antenatal ultrasound screening for CHD has a sensitivity (83.91%) with a good specificity (99.96%) and diagnostic accuracy (99.82%) which is comparable with the existing literature.

A systematic approach is crucial for a practitioner to determine the patterns of associated defects. Use of step wise strategy helps in determining the correct diagnosis of isolated cardiac defect, associated with other system or a part of syndrome. Systematic audit of morphological screening scans could play an important role in improving the diagnostic accuracy, which in turn will lead to early detection and well-planned management of CHD (Fig. 2).

Funding Did not require funding as it is a retrospective study.

Compliance with Ethical Standards

Conflict of interest Nil, Varunashree ND (VND), Ravi Shankar (RS), Manish Kumar (MK), Preethi Navaneethan, (PN), Santosh Benjamin (SB), Smitha Elizabeth Jacob (SMJ), Bijesh Yadav (BY) and Swati Rathore (SR) declare that they have no conflict of interest.

Ethical approval A retrospective study was done from a prospectively maintained database of the antenatal morphology scans done in the Department of Obstetrics and Gynaecology, after obtaining approval from the institutional review board and ethics committee (IRB Min No. 10495 retro dated 18/01/2017).

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