A prospective study of first trimester fetal cardiac examination using spatiotemporal image correlation, tomographic ultrasound and color Doppler imaging for the diagnosis of complex congenital heart disease in high-risk patients

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ABSTRACT

Objective: A 4 dimensional fetal echocardiography technique utilizing spatiotemporal image correlation, tomographic image display and color Doppler (STIC-TUI echo) was previously shown to be effective in displaying the examination planes constituting the extended cardiac examination. The aim of this study was to evaluate performance of this first trimester STIC-TUI echo in identifying complex congenital heart disease (CHD) in high-risk pregnancies.

Study Design: A prospective study of patients at high risk for CHD presenting at first trimester screening (pregestational diabetes, in-vitro (IVF) conception, increased nuchal translucency thickness (NT), first trimester tricuspid regurgitation (TR) or reversed ductus venosus (DV) a-wave, prior child with CHD, medications). First trimester STIC-TUI echo was performed. The findings were correlated with second trimester echocardiography and post-delivery echo findings in survivors.

Results: 164 fetuses from 152 patients were enrolled (75 diabetics, 30 IVF, 19 increased NT, 23 tricuspid regurgitation or DV reversed a wave, 21 with prior CHD and 2 on anti-convulsants). STIC-TUI echo was abnormal in 20 (12.2%), showing atrio-ventricular canal defect (n=9), hypoplastic left heart (n=2), pulmonary stenosis (n=2), right aortic arch (n=1), interrupted aortic arch (n=1), tricuspid atresia (n=1), heterotaxy (n=1), truncus arterioris (n=1), double outlet right ventricle and VSD (n=1), double inlet ventricle with transposition of great arteries (n=1). 85% of these anomalies were evident in the 4CV plane of the TUI display and the outflow tract planes with CDI diagnosed the remainder. In 13 CHD was isolated while 7 had extracardiac anomalies. 13 fetuses had aneuploidy and 13 women underwent first trimester termination. In the remaining 7, second trimester echo and neonatal echo/postmortem examination confirmed anomalies (2 stillborn, 1 neonatal death, 4 live births). Two CHD missed by first trimester STIC-TUI echo were diagnosed at second trimester echo. Accordingly, first trimester STIC-TUI echo had 91% sensitivity, 100% specificity for detection of CHD.

Conclusions: First trimester 4 D echocardiography using a standardized application of STIC, TUI and CDI is effective in displaying the imaging planes that are necessary to achieve the diagnosis of complex cardiac anomalies in high-risk patients. Optimal imaging of the 4CV with 2D ultrasound is the major determinant of volume acquisition.

INTRODUCTION

Congenital heart disease (CHD), which occurs with an incidence of about 4-13 per 1000 live births, is among the commonest forms of congenital anomalies[1]. The prenatal diagnosis of CHD requires a systematic approach that is based on the identification of orthogonal cardiac planes, the definition of situs and the verification of normal structure and connections using this approach[2, 3]. The factors that have consistently been shown to have an impact on the diagnostic performance of fetal echocardiography are the risk profile of the study population, the training of examiners, the cardiac planes that are incorporated into the assessment, the addition of color Doppler imaging and the gestational age when the examination is performed[4, 5]. Concerns of image resolution and the impact on identifying landmarks and discerning anatomic details is an important limitation of first trimester echocardiography and accordingly, the second trimester echocardiogram is the overall preferred screening approach4. However, in recognition of the potential advantages of earlier diagnosis the application of first trimester echocardiography has been advocated for women identified to be at high risk for CHD in the first trimester[6, 7].

We have previously described a first trimester echocardiography technique of standardized spatiotemporal image correlation (STIC) acquisition utilizing tomographic image display (TUI) and color Doppler imaging (CDI)[8]. In this study, we validated that this technique identifies the orthogonal and upper thoracic transverse view fulfilling standards for a basic extended fetal echocardiogram4. Accordingly, it could be expected that the first trimester application of STIC-TUI echocardiography should be capable of identifying the majority of complex cardiac anomalies particularly if applied to a high-risk population. It was the aim of

this study to evaluate the performance of STIC-TUI echocardiography under these circumstances.

METHODS

This study is a prospective intervention study that was performed University of Maryland Center for Advanced Fetal Care Ultrasound Center between 2007-2012 and was approved by the Institutional Review Board of the University of Maryland School of Medicine. The patient population consisted of women who presented for first trimester screening (between 11 0/7 and 13 6/7 weeks gestation) with selected risk factors that placed them at high risk for CHD. Inclusion criteria required the aforementioned gestational age range as well as any of the following maternal co-morbidities: pregestational diabetes, anticonvulsant use, conception through assisted reproductive technology (ART), personal or family history of cardiac defects. Ultrasound criteria for inclusion were: a nuchal translucency (NT) thickness > 2.5 mm, reversed DV a-wave, tricuspid regurgitation (TR) or abnormal anatomy. After informed written consent, the STIC-TUI fetal echocardiogram acquisition was performed. The first trimester screening ultrasound was performed in accordance with the guidelines of the Fetal Medicine Foundation (www.fetalmedicine.com), by sonographers that were certified for the assessment of the NT thickness, the DV Doppler and TR assessment. The standardized STIC-TUI acquisition was performed after identification of the four chamber view as previously described[8]. Briefly, using acquisition time of 10 seconds at an angle set at 20 degrees, Volume datasets with the following characteristics were considered to be of high quality: (1) fetal spine clearly seen minimizing shadowing from ribs or spine; and (2) minimal or no motion artifact observed in the sagittal plane. Volume dataset acquisition was repeated as necessary to achieve three high-quality images. A median of 4 (3-9) 4D blocks per patient were acquired. Acquisition of blocks did not increased the NT scanning time since obtaining 2D 4CV is part of the first trimester imaging protocol in our unit. Intra- and inter-observer variability for the number of obtained high quality blocks was insignificant ($p>0.05$ for both). In 111 (68%) cases, all landmarks were seen in first reviewed block.

Multiple blocks (2-4) were examined in remaining patients. Once all pertinent information was gathered, the remaining blocks were eliminated. The most common reason (90%) for inadequate quality was the motion artifact. The median time taken to analyze volumes 9 minutes (2-20) per volume.

All sonograms were performed using the Voluson E8 (GE Healthcare, Wauwatosa, WI, USA) with a 4-8 MHz transabdominal probe or a 5-9 MHz transvaginal probe. The ultrasound examination was performed using the ALARA (as low as reasonably achievable) principle, with ultrasound output settings set to yield thermal and mechanical index values below 0.8 in the region of interest.

TUI was applied off-line using Voluson 4DView software$^{\hat{E}}$ in the previously validated way to obtain standard slicing to show key cardiac planes. In these planes, twelve anatomic landmarks were identified using gray-scale and CDI: (1) four-chamber view, (2) descending aorta, (3) heart size, (4) cardiac axis at 45 degrees, (5) two equally sized atria, (6) two equally sized ventricles, (7) two opening atrioventricular valves, (8) visualization of the two great arteries, (9) visualization of crossing of great arteries, (10) great arteries with equal diameter, (11) arch and duct similar in size in a transverse view and (12) forward flow in the ductal and aortic arches. The operator performing the reconstruction was only aware of study inclusion criteria. Once a diagnosis was reached it was entered in the dedicated study database. The diagnosis was compared when a final diagnosis was issued by the attending physician following the first, second or neonatal 2D echocardiograms. The reconstructing operator and clinical management team were different in all cases.

Patients who were found to have suspected structural cardiac anomalies in the first trimester were informed of the findings and counseled on their diagnostic and therapeutic options. For patients electing continuation of pregnancy, the findings of the second trimester fetal echocardiography, neonatal examination, neonatal echocardiogram or cardiac catheterization were ascertained as applicable. For patients requesting termination of pregnancy or following fetal demise autopsy, results were recorded. All neonates received a

clinical examination by the attending neonatologist prior to discharge from the hospital. The results of this assessment were ascertained by study personnel.

The predictive accuracy of the first trimester STIC-TUI echocardiography for major CHD was evaluated by descriptive statistics, chi-square and Fisher's exact tests using SPSS 13.0 (SPSS Co, Chicago, IL, USA). A $P < 0.05$ was accepted as statistically significant.

RESULTS

During the study period, 142 (93%) women with singleton and 12 women with multiple gestation were enrolled resulting in inclusion of 164 fetuses in the study. The median crown-rump-length and NT measurements were 64.6mm (45-85mm) and 1.8mm (1.0-18mm). The median BMI was 29.2 and maternal history contributed to the majority of inclusion criteria (78%). The ultrasound examinations were performed predominantly via the trans-abdominal route (92%). The characteristics of the patient population are presented in table 1.

There were 22 (13%) CHD diagnosed/detected in this study population. The STIC-TUI echocardiogram was abnormal in 20 (12.2%) fetuses. Suspected anomalies were atrio-ventricular canal defect (n=9 (45%)) (figure 1), hypoplastic left heart (n=2 (10%)) (figure 2), pulmonary stenosis (n=2 (10%)), right aortic arch (n=1 (5%)), interrupted aortic arch (n=1 (5%)), tricuspid atresia (n=1 (5%)), heterotaxy (n=1 (5%)), truncus arterioris (n=1 (5%)), double outlet right ventricle and VSD (n=1 (5%)), double inlet ventricle with transposition of great arteries (n=1 (5%)). The majority of abnormalities presented in the 4 chamber view (85%). Outflow tract abnormalities represent the remaining cases (5%). The details of abnormal TUI findings were listed in table 2.

In 13 fetuses, only cardiac and screening factors were abnormal. In the remaining 7 fetuses, extracardiac anomalies were also present (Brain / head abnormalities (n= 4), abdominal wall abnormalities (n=3) and polydactyly (n=1)). Of the 18 women undergoing karyotyping, 12 (67%) had fetal aneuploidy (Trisomy 21 n=7, Trisomy 18 n=3, Trisomy 13 and Turner syndrome 1 respectively). Thirteen patients elected to have a first trimester termination

(65%) (atrio-ventricular canal defect (n=9), hypoplastic left heart (n=2), Double inlet ventricle with transposition of great arteries (n=1) and tricuspid atresia (n=1)). In the remaining 7, second trimester echocardiography was confirmed the diagnosis. Two anomalies, aortic stenosis and an interrupted inferior vena cava were missed at the first trimester STIC-TUI echocardiogram. These were subsequently diagnosed at the second trimester echocardiogram. Fetal death was diagnosed in 3 fetuses (interrupted aortic arc (n=1), heterotaxy (n=1) and truncus arteriosus (n=1)). Neonatal echocardiography confirmed remaining cardiac abnormalities (Right aortic arch (n=1), pulmonary stenosis (n=2), double outlet right ventricle with ventricular septal defect (n=1), aortic stenosis (n=1) and interrupted inferior vena cava (n=1)) (Figure 3). The clinical examination of all other neonates was normal indicating that no major cardiac anomaly was missed. The performance of the first trimester echo showed a 91% sensitivity (95% CI: 71-99), 100% specificity (95% CI: 97-100), 100% positive predictive value (95% CI: 83-100) and 99% (95% CI: 95-100) negative predictive value.

DISCUSSION

Two-dimensional trans-vaginal or transabdominal first trimester fetal echocardiography allows detection of the majority of CHD [9,10,11]. Concerns regarding the small cardiac size at this gestational age, lack of available expertise and uncertainty about appropriate risk groups have prevented the wider application of this technique. For several reasons, these limitations have become less significant. Ultrasound image resolution has improved, integrated first trimester screening is effective in identifying high risk populations for CHD5 and advanced 4 D ultrasound technology has become widely accessible, opening the door for high-resolution fetal cardiac imaging with optional offline expert analysis.[12] This is a prospective intervention trial of first trimester STIC-TUI echocardiography in high-risk patients at a referral center. We demonstrate that post-processing evaluation of 4D-STIC images of standard cardiac views and measurements commonly used in fetal echocardiography is reproducible between 11-14

weeks and is able to diagnose complex cardiac anomalies in a significant proportion of cases.

First-trimester NT screening for chromosomal and other congenital abnormalities has been widely implemented. Since an increased NT with normal karyotype yields a detection rates of 30ï 50% for CHD[13] , it is increasingly becoming an indication for fetal echocardiography. There is a shortage of echocardiographers trained in first trimester cardiac assessment and the additional workload created by the widespread introduction of STIC technology for early fetal cardiac assessment could be overwhelming,. However, the introduction of this technique may be worthwhile, as Vinal ***et al*** [14]reported high interobserver agreement (kappa index 0.6) in the evaluation of most cardiac structures at 11ï 14 weeksô gestation. Our results are consistent with these findings and other groups. [15, 16] However, even a systematic echocardiographic examination by experts during the first half of pregnancy may miss a proportion of CHD. One reason may be that some CHD causes undetectable anatomic distortion at this time, . Abnormalities may become more evident at later gestation, or after birth, and therefore may only be detected then. Limited resolution and erroneous diagnosis can also be a reason for unsuccessful diagnosis[17]. A normal first trimester echocardiogram does not exclude later alteration in chamber size or morphology. Discrepancies in great artery proportion or small ventricular septal defects become apparent later. In this study, coarctation of the aorta, left heart hypoplasia following aortic stenosis, pulmonary and aortic stenosis, and Tetralogy of Fallot may serve as examples for this theory. Because of the evolving nature of some CHD, second-trimester echocardiography is still considered the gold standard for their prenatal diagnosis. Yet, earlier diagnosis and counseling provides parents with the opportunity to continue or terminate the pregnancy. Our observations are also is in agreement with the subjective impression that highly optimized 2D image resolution, which is required to obtain proper 4D volume reconstruction, improves with sonographer experience. Following our feasibility study in low risk patients 8 the current study in a high-risk setting demonstrates that this technique remains accurate even with offline expert view. Although the four-chamber view is considered the standard

approach for CHD screening, most societies recommend an óextended basicôcardiac examination, including the outflow tracts and the upper thoracic transverse view.4 STIC-TUI displays of all of these planes in one image.

Our findings support the idea that the outflow tracts can be properly evaluated in most cases with STIC, accordingly prenatal detection of conotruncal anomalies could be improved with this technology. Evaluation of the great vessels is considered the most difficult part of the cardiac examination as, conotruncal anomalies are still frequently missed. Previous studies with 4D-STIC have shown that the left and right outflow tracts can be identified in 95 and 97% of fetuses beyond 17 weeksô gestation.[18] Also, other groups have standardized the off-line examination of both outflow tracts with clinically acceptable reliability (ICC of 0.69).[19] It has been suggested that the 3VT view with color Doppler should be incorporated into cardiac screening, since the finding of reversed flow in either the aortic or the pulmonary branch of this plane is strongly associated with ductal-dependent CHD. The detection of this anomaly will improve neonatal and infant outcomes. All cardiac planes were visible in one plane with the added utility of color Doppler imaging. As others have also shown color Doppler has a great value of identifying basic and extended cardiac views at 11-14 weeksy.[20]

While our findings are encouraging, their general applicability requires further study. Although 4D volumes were acquired by staff members that are not necessarily experts in fetal cardiology, their skill set acquired in a large fetal medicine center is likely to differ from a general office setting. Single operator off-line analysis has not been validated by a blinded comparison to other cardiac experts. The learning curve of acquisition and interpretation also requires further evaluation. While we separated clinical and research teams ascertainment bias cannot be excluded as for all screening studies performed at a single center, since the STIC operator can not be completely blinded to clinical data. In the majority of cases the final diagnosis was made after the STIC-diagnosis had been entered in the study database. For the cases undergoing termination for suspected CHD the clinical decision was made based on the presence of aneuploidy. While a full postmortem could not always be obtained it is

likely that the 2D diagnosis of AV-canal based on the four chamber view was accurate[21] to a degree of certainty that is unlikely to affect the statistics significantly. In conclusion, standardized fetal echocardiography using STIC, TUI and CDI is especially effective for screening and diagnosis of cardiac anomalies in the first trimester in high-risk population. This method performs well in patients at high risk for aneuploidy and lethal prognosis. Optimal imaging of the four chamber view, either at acquisition or through 3D volume manipulation thereafter is the cornerstone to identify CHD in the first trimester. Combined with second trimester echo to exclude later-appearing lesions, first trimester echo excludes CHD in the majority of patients. Future directions for research may include an evaluation of the effectiveness of offline analysis by non-expert examiners for cardiac screening.

Legends:

Figure 1: This figure is an example of grey scale STIC TUI. Panel (a) shows a normal heart and panel (b) shows an atrio-ventricular (a-v) canal defect. Separate a-v valves were not seen in panel b. White arrows indicate each valve in a normal heart (a). Yellow arrows show the absence of a-v valves in a-v canal defect.

Figure 1

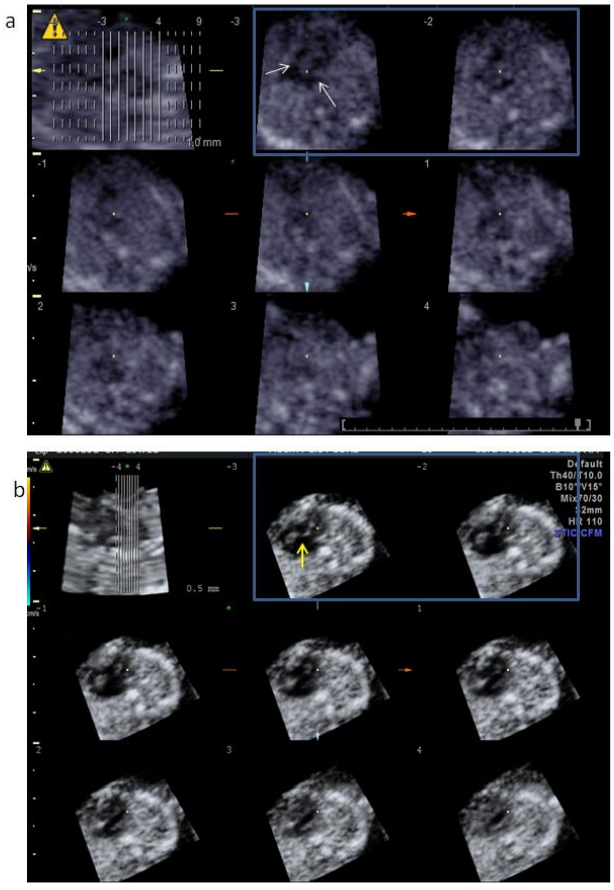

Figure 2: This figure is an example of color STIC TUI. Panel (a) shows a normal heart and panel (b) a hypoplastic left heart. Only the right ventricle (RV), atrium (RA) and pulmonary artery (P) were visible in panel b. There was reversed flow in transverse arch (TA) in hypoplastic heart. LV: left ventricle, LA: left atrium, Ao: aorta, DA: ductal arch

Figure 2

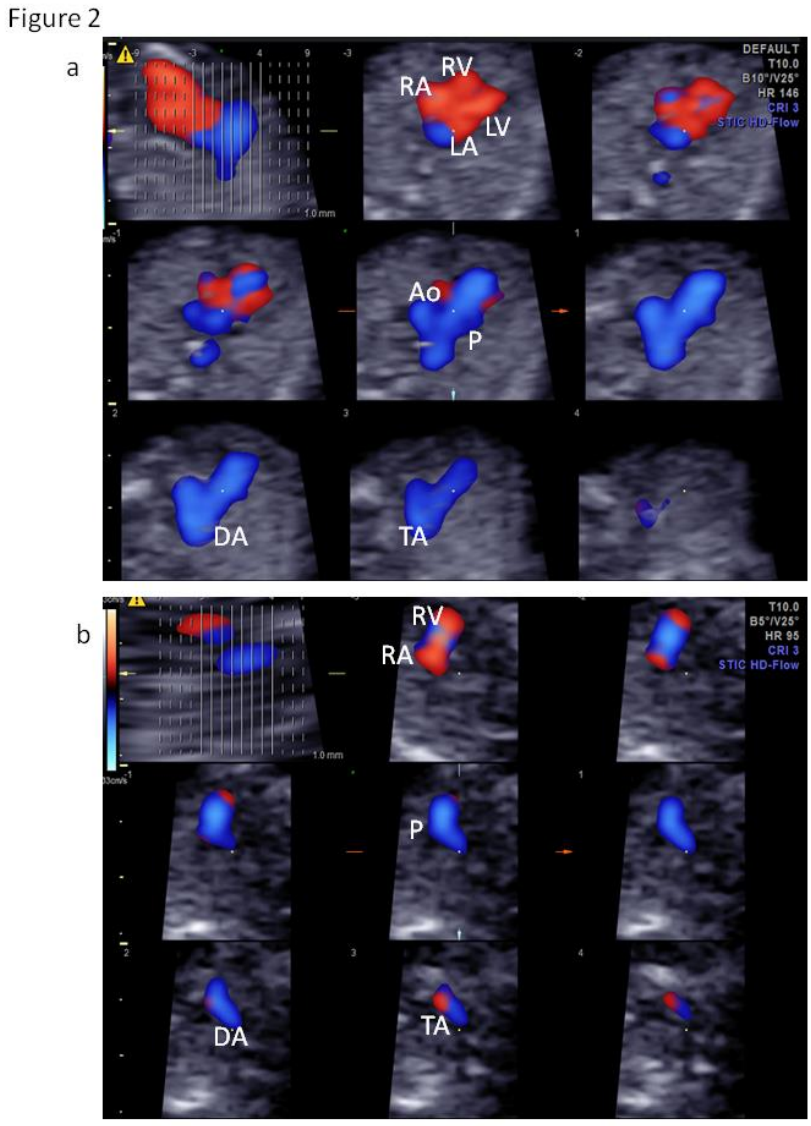

Figure 3: This figure shows cardiac anomalies detected at prenatal and postnatal period. There were 20 abnormal heart diagnoses at first trimester. Thirteen of them were terminated which were marked with ñ*ò Seven cardiac anomalies were confirmed and 2 previously undiagnosed defects were identified during second trimester echo. Out of 9 fetuses with a cardiac anomaly, 3 of them died later in pregnancy, which were marked with ñ#ò The remaining 6 cardiac anomalies were confirmed during the neonatal period. A-v canal: atrio-ventricular canal, R-: right, DORV: double outlet right ventricle, VSD: Ventriclular septal defect, DIV: double inlet ventricle, TGA: transposition of great arteries

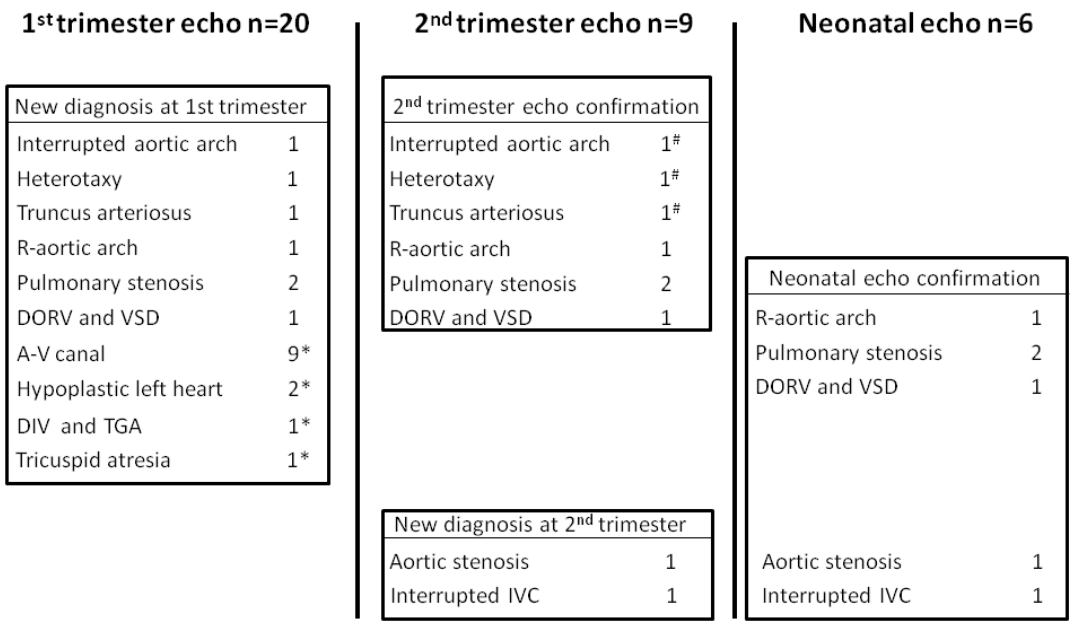

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Table 1. Demographics of the study population

Maternal age	32 (18-46)
Parity	1 (0-8)
BMI	29.2 (17-60)
Race	
Caucasian	66 (43%)
Black	76 (50%)
Asian	7 (5%)
Hispanic	3 (2%)
Fetus #	
1	142 (93%)
2	9 (6%)
3	1 (1%)
Indications	
Maternal pregestational diabetes	77 (44%)
Conception through assisted reproduction	38 (22%)
Tricuspid regurgitation	14 (8%)
Increased NT thickness/DV RAV	23 (13%)
History of congenital heart disease	22 (12%)
History of congenital seizure disorder	2 (1%)
Ultrasound method	
Abdominal	151 (92%)
Vaginal	13 (8%)

Legend: NT= nuchal translucency, DV ductus venosus, RAV=reversed a wave

Data was presented as median (minimum-maximum) and number (%)

Table 2. List of the abnormal TUI findings in 20 fetuses with congenital heart disease

Abnormal TUI findings	
Four chamber view	17 (90%)
Descending aorta	1 (5%)
Heart size	0
Cardiac axis	2 (10%)
Two equally sized atria	7 (35%)
Two equally sized ventricles	9 (45%)
Two opening atrioventricular valves	13 (65%)
Visualization of the two great arteries	11 (55%)
Visualization of crossing of great arteries	8 (40%)
Great arteries with equal diameter	8 (40%)
Arch and duct similar in size	8 (40%)
Forward flow in the ductal and aortic arches	5 (25%)