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White Paper

The Intelligent Way to Evaluate Fetal Heart : HeartAssist™

HERA W10

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Introduction

Background

Second trimester ultrasonography combined with fetal echocardiography are the methods of choice for the identification of congenital heart diseases (CHDs). However, their detection rate is still far to be optimal despite the efforts in standardization of the technique and improvements in technology [1,2,3]. Further, there are considerable heterogeneity within geographical area in proportion of diagnosis of CHDs ranging from 13 to 87% for severe cases [4].

A recent analysis examining why CHD is missed during prenatal diagnosis found that in the majority of cases, either the sonographic plane was not correctly obtained, or despite the defect was clearly evident on screen, the operator failed its recognition [5].

Artificial Intelligence (AI) has demonstrated potential to improve medical diagnosis in similar conditions, but few data are up now available on its application to prenatal diagnosis [6,7].

The application of AI in accuracy improvement of obstetric ultrasound may include at least three different aspects: structure identification, automatic and standardize measurements, and classification diagnosis.

Samsung Healthcare have recently introduced to the market of ultrasound equipment AI-driven obstetric ultrasound products. These softwares aim to enhance sonographer's skills in identifying ultrasonographic structures, performing automatic biometric measurements and faster workflow.

The application of AI in accuracy improvement of obstetric ultrasound may include at least two different aspects: structure identification, automatic and standardize measurements. The purpose of this white paper is to assess the diagnostic performance of HeartAssist™ in the study of the fetal heart in both these aspects.

Methods

Population

In a prospective observational study including consecutive singleton pregnancies attending the antenatal clinic of the Department of Obstetrics and Gynecology of the Università Roma Tor Vergata for second trimester ultrasonographic examination at 19–24 weeks of gestation [8.9]. Only women with a known gestational age as assessed by crown-rump length at the 11–14 weeks scan were included in the study. Cases with chromosomal, genetic, or structural anomalies detected at either first or second trimester ultrasound assessment, women with pre (chronic hypertension, pre gestational diabetes autoimmune diseases) or pregnancy complications (gestational diabetes, gestational hyper-tension, preeclampsia) and those lost at follow-up were excluded. The study was approved by our Institutional Ethical Board (RS 45.22 29 March 2022) and all the included women signed an informed consent.

Ultrasound examination

All the ultrasound examinations were performed by physicians trained to perform routine second trimester prenatal ultrasound assessment (ME P and P M), using a HERA W10 Ultrasonographic system (Samsung Medison Co., Ltd., Seoul, South Korea) equipped with transabdominal volumetric probe.

All women underwent a detailed evaluation of fetal growth and anatomy according to the local, ISUOG and AIUM guidelines.

Evaluation of fetal heart included assessment of the following cardiac views:

(1) four-chamber view
(2) left ventricular outflow tract
(3) right ventricular outflow tract
(4) three vessels trachea view

All the images related to the different cardiac views and considered of adequate quality by the two physicians were stored on a dedicated electronic database and retrospectively evaluated by an expert in fetal echocardiography who performed a further quality assessment, using a scoring system reported in Table 1 [8].

Table 1 : Criteria followed for quality assessment by visual examination.

Four chamber view

Complete depiction of both atria

Complete depiction of both ventricles

Cardiac crux visible

Clear visualization of both AV valves

Clear visualization of ventricular septum

Left ventricle outflow tract

Perimembranous septum visible

Complete long-axis from LV apex to ascending aorta visible

Right ventricle outflow tract

Upper part of RV visible

Pulmonary artery visible from RV to arterial duct

Three Vessels trachea view

True transverse plane through chest

Clear visualization of the pulmonary artery

Clear visualization of aorta

Clear visualization of right superior vena cava Clear visualization of the trachea

Only images fulfilling all these reported criteria were considered of adequate quality.

Finally, the image stored were retrieved and assessed with the HeartAssist™ software (Samsung Medison Co., Ltd., Seoul, South Korea). As shown in Figure 1-4, the software recognizes the adequacy of the different cardiac views and annotates the anatomic structures using a proprietary algorithm.

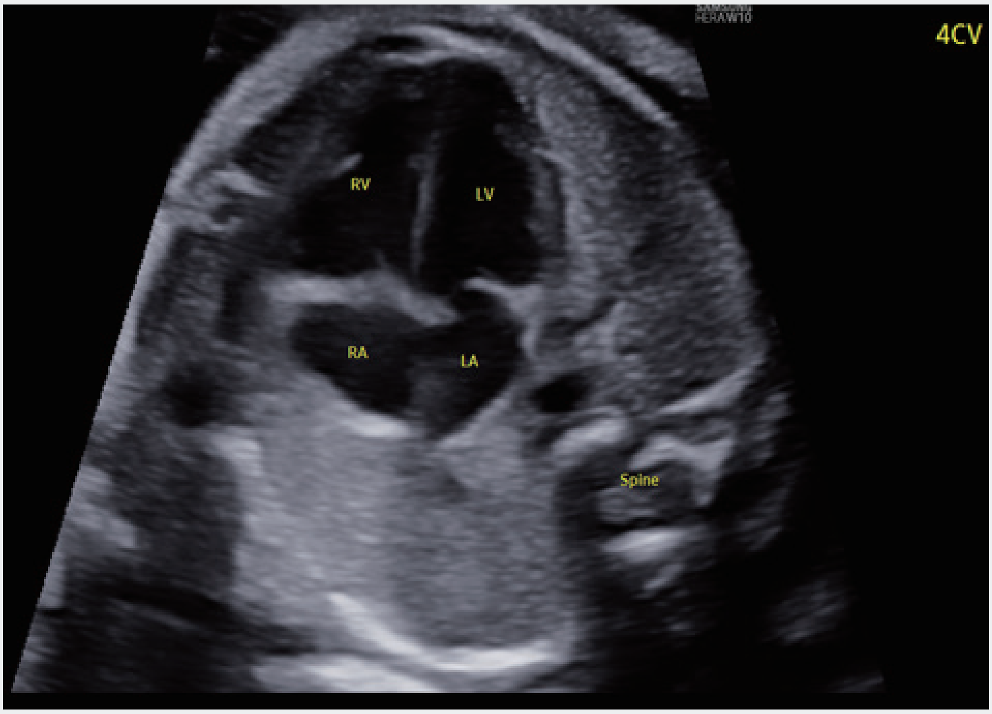

Figure 1. Transverse view of the fetal thorax showing the four chamber view (4CV). HeartAssist™ identifies the right ventricle (RV), left ventricle (LV), right (RA) and left (LA) atria and fetal spine.

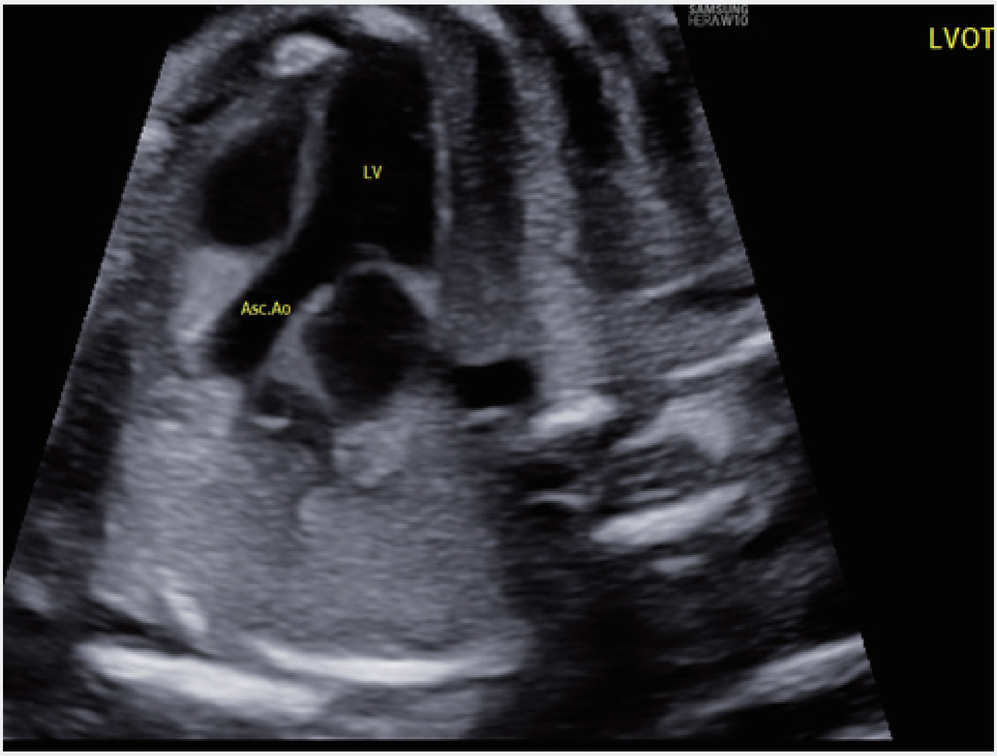

Figure 2. View of the fetal thorax showing the left ventricle outflow tract (LVOT). HeartAssist™ identifies the left ventricle (LV) and ascending aorta (Asc Ao).

Figure 3. View of the fetal thorax showing the right ventricle outflow tract (RVOT). HeartAssist™ identifies the pulmonary artery (PA), the aorta (Ao) and the right branch of pulmonary artery (RPA).

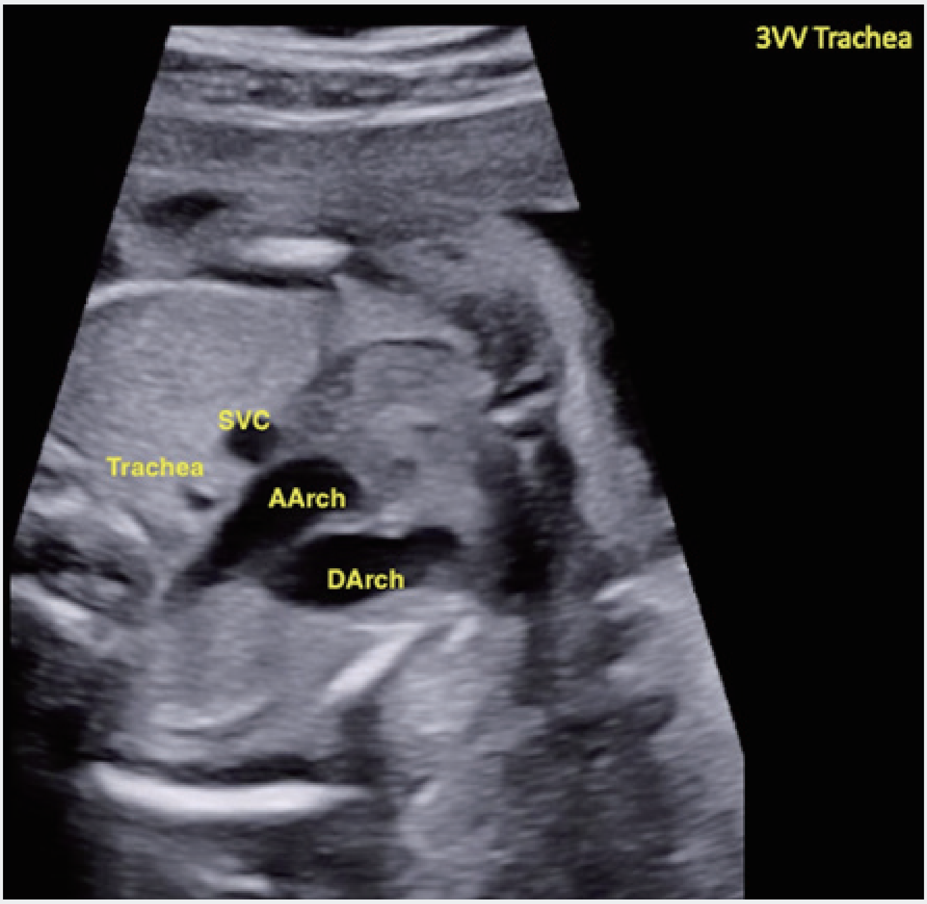

Figure 4. View of the fetal thorax showing three vessel trachea view (3VVT). HeartAssist™ identifies the ductal arch (DArch), the aortic arch (AAarch), the superior vena cav (SVC) and the trachea

In order to evaluate the accuracy in evaluating cardiac biometry and cardiac axis two observers on freezed images and blinded to each other performed the measurements of software calibrated on the size markers of the ultrasonographic images. Then the HeartAssist™ software was activated and measurements were obtained automatically (Figure 5-7) [9].

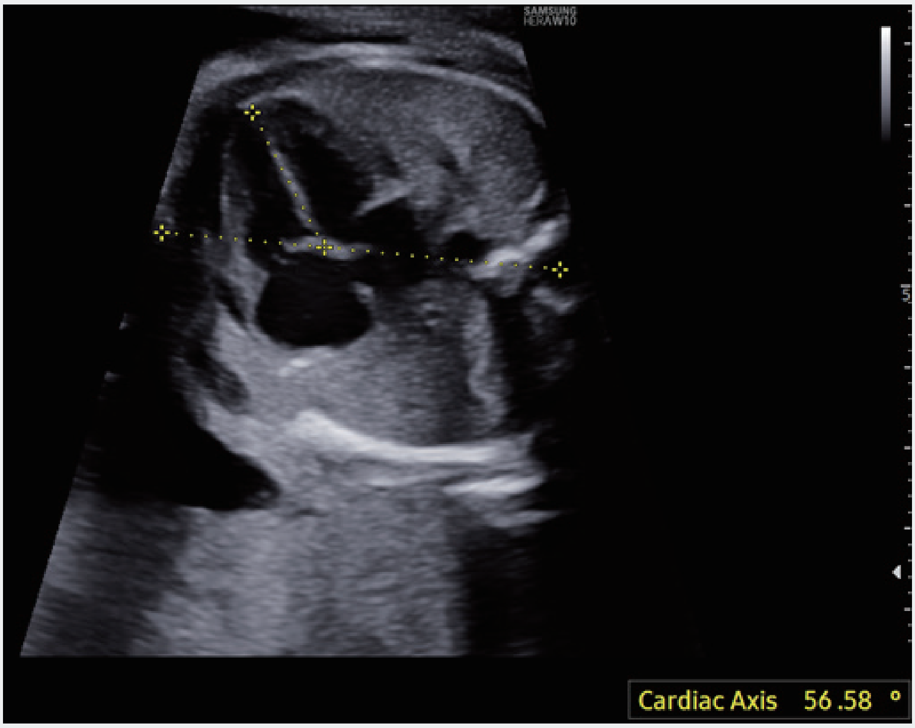

Figure 5. View of the fetal thorax at the level of four chamber view. HeartAssist™ automatically calculates the cardiac axis.

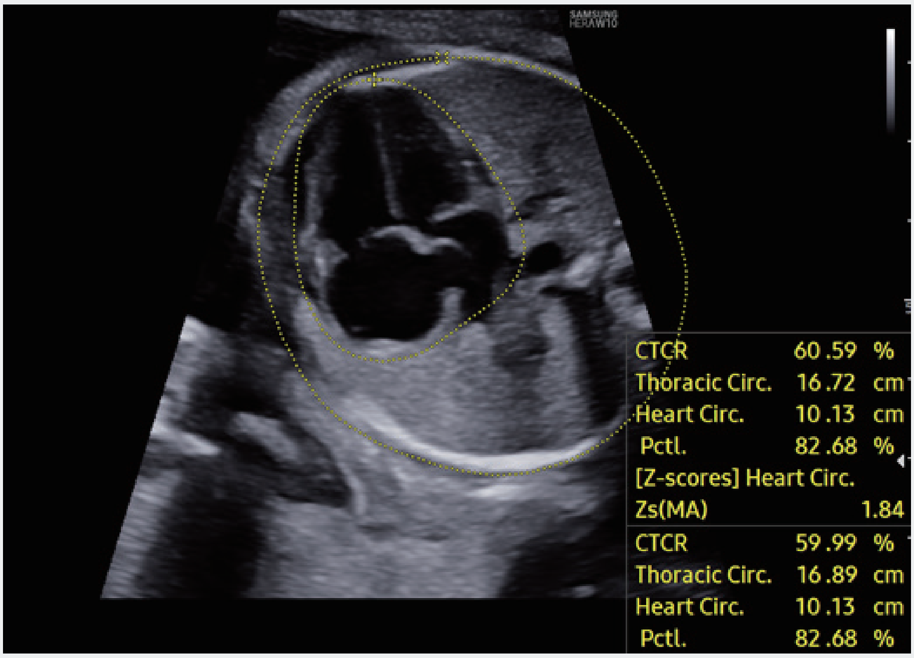

Figure 6. View of the fetal thorax at the level of four chamber view. HeartAssist™ automatically calculates the thoracic and cardiac area and evaluated their ratio (CTCR).

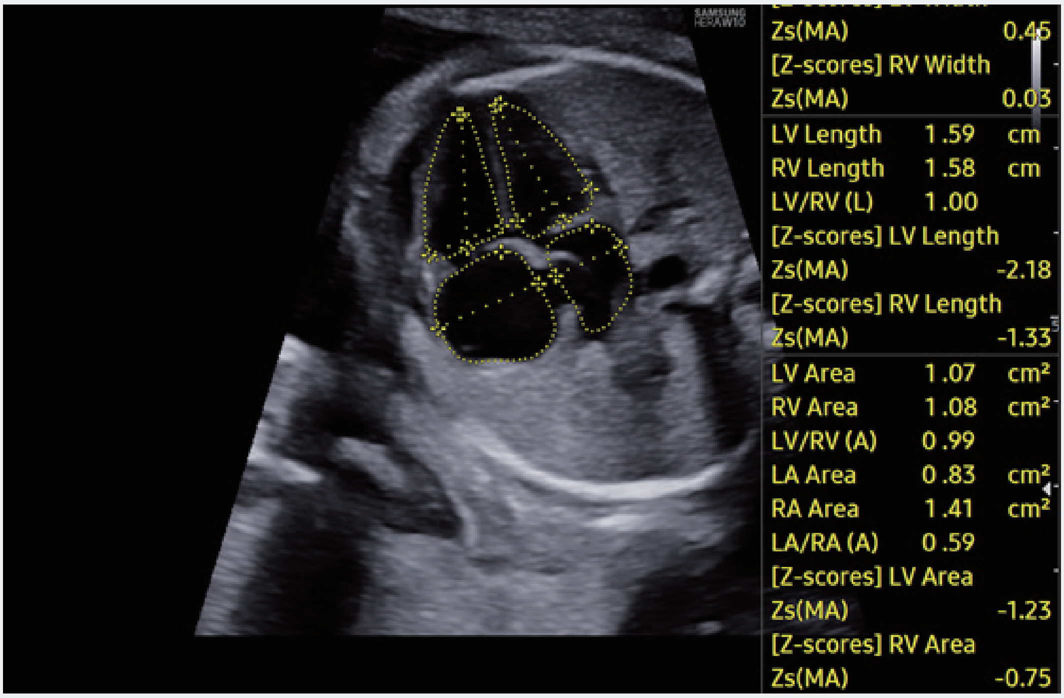

Figure 7. View of the fetal thorax at the level of four chamber view. HeartAssist™ automatically calculates the length, width and area of the atria and ventricles.

Data analysis

The Cohen's κ coefficient was used to evaluate the agreement rates between the visual and automatic evaluation of cardiac view recognition.

The agreement between (inter-observer) and among (intra-observer) the two examiners in the cardiac biometric evaluation was quantified, calculating the intraclass correlation coefficient (ICC) and its 95% confidence interval (CI). Similarly, the inter-method agreement (manual vs. HeartAssist™) was evaluated by ICC. Bland Altman plot were used to assess systematic bias between measurements.

The time necessary to obtain each measurement manually was calculated with a digital chronometer and compared with HeartAssist™.

Results

One hundred and twenty consecutive women attending second trimester ultrasound assessment for fetal anomalies were included in the analysis. There were no significant differences between the prevalence of adequate visualization between the two techniques for all the cardiac views.

The Cohen's κ coefficient values were for the four- chamber view 0.827 (95 % CI 0.662–0.992), 0.814 (95 % CI 0.638– 0.990) for left ventricle outflow tract, 0.838 (95 % CI 0.683–0.992) and three vessel trachea view 0.866 (95 % CI 0.717–0.999), indicating a good agreement between the two techniques.

When the cardiac measurements were considered, the ICC values between the two observes were 0.931 (0.879- 0.961) for TC, 0.944 (95% CI: 0.9221-0.975) for CC, and 0.939 (0.924-0.974) for CC/TC.

The analysis of inter-method agreement of the mean between the two operators and heart assistance measurements resulted in ICC values of 0.929 (0.901-0.942) for CC, 0.933 (95% CI: 0.919-0.944) for TC, and 0.930 (0.919-0.947) for CC/TC. The differences were 0.11 for CC, 0.14 for TC, and –0.06 for the C/T ratio.

The time necessary was significantly lower for the measurements obtained by HeartAssist™ than with the manual method as reported in Figure 8, for the combined measurement of atria and ventricles.

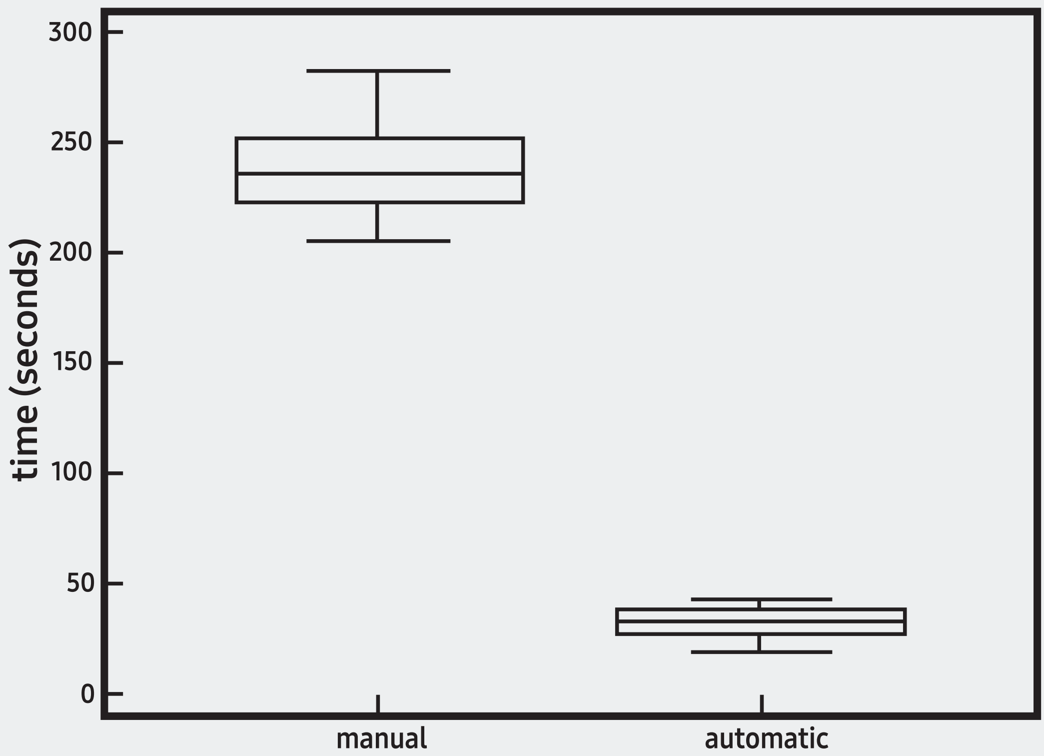

Figure 8. View of the fetal thorax at the level of four chamber view. HeartAssist™ automatically calculates the length, width and area of the atria and ventricles.

Discussion

Our findings from this study showed that HeartAssist™ can assess the adequateness of fetal cardiac plane with a good agreement with that provided by a subjective visual assessment provided by expert sonographers. The inter-rater agreement was >0.81 for all the fetal cardiac views assessed in this study, thus indicating a good agreement between the two techniques.

Introduction of AI in medical imaging has the potential to profoundly impact the field of diagnostic medicine. The potential application of AI based tools for image recognition embraces several imaging modalities, including X-ray, computerized tomography, magnetic resonance imaging, retinal optical coherence tomography and ultrasound. The role of such tools is to provide clinicians increased productivity through the automatic recognition of specific structures, to perform an automated screening assessment and to assist in diagnosis of specific disease, which can in turn optimize clinical management.

In view of its potential contribution in assisting complex imaging assessment and improve imaging diagnosis, it is not surprising the growing application of AI software in prenatal ultrasound. Prenatal diagnosis of structural anomalies, especially CHDs, is still affected by a significant proportion of cases undetected until birth. Furthermore, ultrasound assessment of a fetus requires specific training and skills which cannot be largely present in all clinical settings. In this scenarios, automatic assessment of fetal structures can improve the productivity of prenatal diagnostic services and help the sonographer or physician in promptly identified those cases with a higher suspicion of structural anomalies to promptly refer them to detailed ultrasound assessment. The present study confirms the potential clinical usefulness of AI assessment of fetal heart, demonstrating the good agreement between automatic and expert evaluation of fetal heart using different imaging views, at least in the second trimester of pregnancy.

Conclusions

HeartAssist™ allows to obtain the automatic evaluation of fetal cardiac views, and reached the same accuracy as that of expert visual assessment or manual measurements. HeartAssist™ is faster than manual and has the potential to become the preferred technique to obtain cardiac biometry.

The findings from this study demonstrates the potential clinical applicability of automatic evaluation of fetal heart during second trimester screening assessment for fetal anomalies. Further studies assessing the role of automatic algorithms of image recognition in fetuses with cardiac anomalies or at early or late gestational ages are needed in order to confirm their potential usefulness in the daily clinical practice.

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