Scientific Research Publishing

Open Journal of Obstetrics and Gynecology, 2018, 8, 513-520
http://www.scirp.org/journal/ojog
ISSN Online: 2160-8806
ISSN Print: 2160-8792

# The Diagnostic Accuracy of Automated Fetal Heart Echocardiography by Five Dimensional Compared to Two-Dimensional Ultrasound in the Second Trimester of Pregnancy

**Rehab M. Abdelrahman[1*], Ahmed R. M. Ramy[1], Amr M. Abdelhady[2]**

[1]Department of Obstetrics and Gynecology, Maternity Hospital, Ain Shams University, Cairo, Egypt
[2]Fetal Care Unit, Ain Shams University, Cairo, Egypt
Email: *rehababdulrahman.rm@gmail.cm

**How to cite this paper:** Abdelrahman, R.M., Ramy, A.R.M. and Abdelhady, A.M. (2018) The Diagnostic Accuracy of Automated Fetal Heart Echocardiography by Five Dimensional Compared to Two-Dimensional Ultrasound in the Second Trimester of Pregnancy. *Open Journal of Obstetrics and Gynecology*, **8**, 513-520.
https://doi.org/10.4236/ojog.2018.85058

**Received:** April 8, 2018
**Accepted:** May 15, 2018
**Published:** May 18, 2018



## Abstract

**Objective:** To compare the diagnostic accuracy of Fetal Intelligent Navigation Echocardiography (FINE) method by Five-Dimensional Ultrasound in automated fetal heart examination to conventional fetal heart examination by Two-Dimensional ultrasound in second trimester pregnancy. **Methods:** 90 normal singleton pregnancies at the second trimester were enrolled in this prospective study. Fetal heart was examined by Two-Dimensional Ultrasound (2D US) and Five-Dimensional Ultrasound (FINE). Paired numerical data were compared using the paired samples t test. Inter-method agreement for the rating of the quality of cardiac views by 2D US or 5D US was assessed by calculation of the prevalence-adjusted and bias-adjusted kappa coefficient (PABAK). **Results:** There was no statistical significant difference between fetal heart echocardiography assessment using 2DUS or 5DUS(FINE) ($p$-value > 0.05). The overall inter-method agreement between 2D US and 5D US was 0.92. The difference in % of satisfactory views between 2D and 5D US was 1.73%, (95% CI - 0.5% to 3.33%) ($P$-value = 0.144). **Conclusion:** Our findings indicate the accuracy of 5DUS (FINE) echocardiography in evaluation of normal heart in the second trimester of pregnancy.

## Keywords

Fetal Heart Echocardiography, Fetal Intelligent Navigation Echocardiography, 5DUS

## 1. Introduction

Congenital fetal heart disease is more prevalent compared to neural tube defects

and fetal chromosomal aberration [1] [2]. 20% of neonatal passing from congenital malformations is attributed to cardiovascular anomalies [3].

To make the matter more challenging, it is estimated that nearly 90% of congenital cardiac defects are present in low risk pregnancy [4]. The need for an accurate method to detect fetal cardiac anomalies in low and high risk pregnant women is obvious, still routine antenatal ultrasound examination has a sensitivity of almost 50% only fordetection of fetal cardiac anomalies [5], in majority of cases, this is attributed to lack of sonographer experience to detect these cardiac defects [6].

Two DUS offers several benefits as it is a real time imaging with no ionizing radiation exposure. The operator moves the transducer to find appropriate plane for measurement which is a disadvantage as it makes it an operator-dependent method [7].

The Spatiotemporal Image Correlation (STIC) available with 4DUS was found to be useful in detection of fetal heart anomalies [8].

With the development of 5DUS technology which is a form of automation that brings the results of 3D and 4DUS in an automated form to reduce the effect of Operator bias [4].

Fetal Intelligent Navigation Echocardiography (FINE) was recently invented and used to create the 9 fetal echocardiography standard views for the hearts of normal fetuses in an automatic way by coupling the intelligent navigation to STIC findings [9].

The aim of the current study is to evaluate and compare the findings pf conventional to 2DUS echocardiography in normal fetuses with no congenital heart diseases in second trimester with FINE results of the same fetuses and to calculate the percentage of agreement between the two techniques.

## 2. Methods

### 2.1. Study Population

This study included 90 singleton pregnancies at the second trimester of pregnancy attending the Fetal Care Unit, Ain Shams University Maternity Hospital, Cairo, Egypt from January 2016 to august 2016. Multiple pregnancies, fetuses with cardiac or other anomalies, and gestational age less than 20 weeks were all excluded from the study. The study protocol was approved by the hospital protocol and ethical committee. The participants were councelled and written informed consents were obtained from all participants. All the ultrasound measurements were done by a single highly experienced sonographer to avoid inter and intra operator variations.

### 2.2. 2D Ultrasound Fetal Heart Examination

2D ultrasound was done first to examine fetal heart in both sagittal Views and transverse views: Four chamber view, Five chamber view, Lt outflow tract, Rt outflow tract, 3 vessels and Trachea View, Abdomen/Stomach, Ductal arch, Aor-

tic arch and Bicaval view.

### 2.3. 5D Ultrasound Fetal Heart Examination

4D STIC volume data set of the fetal heart were obtained through an apical four chamber view using Samsung-UGEO-WS80A machine as described by Garcia M *et al.*, 2016 [4]. The FINE technology was used first to evaluate the anatomical landmarks for the standard echocardiography 7 views (Figure 1). After making the seven anatomical heart structures, the operator used the anatomical box and performed the necessary calculations to reconstruct the fetal heart in three dimensions and accordingly nine views were generated and displayed as shown in Figure 2. 5DUSecho is satisfactory if the nine views appear after marking the 6anatomical sites of the fetal heart detected in the study. If the 5D US echosoft ware give the nine views with the marks away from their anatomical sites in the fetal heart so it is unsatisfactory.

### 2.4. Sample Size Calculation

The required sample size was calculated using G*Power software version 3.1.7 (Universitat Dusseldorf, Germany). The primary outcome was to measure the accuracy of 2D US versus 5D US for assessment of fetal heart. The difference in the accuracy in the estimation methods will be tested on the mean absolute (unsigned) error. A total sample size of 90 patients were chosen to achieve a power of 80% and to detect a statistically significant difference between the overall accuracy of both methods for a small to medium effect size (Cohen's dz) of 0.3 with a confidence level 95%. The effect size (dz) is calculated as follows: dz= mean difference/SD of the difference. This effect size has been chosen as it can be regarded as a clinically relevant difference in this exploratory study.

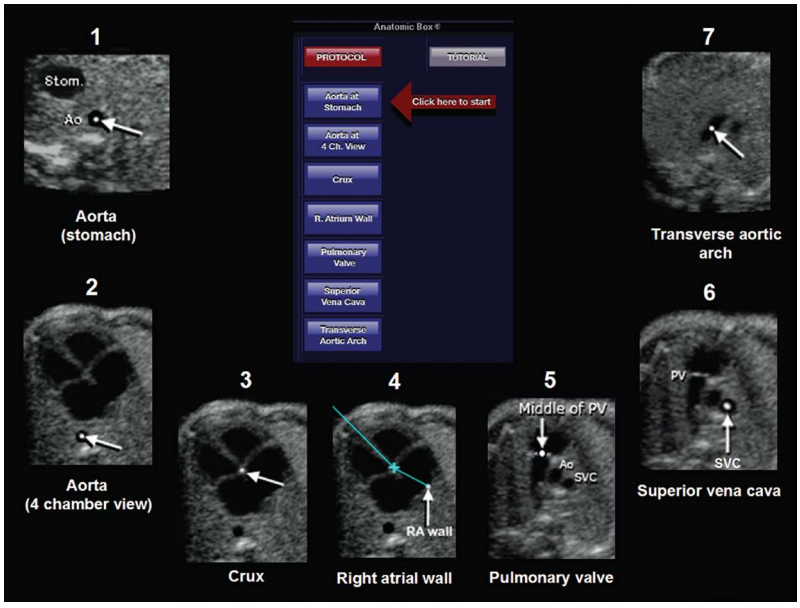


Figure 1. Seven anatomical structures within the heart that are marked using Anatomic Box.

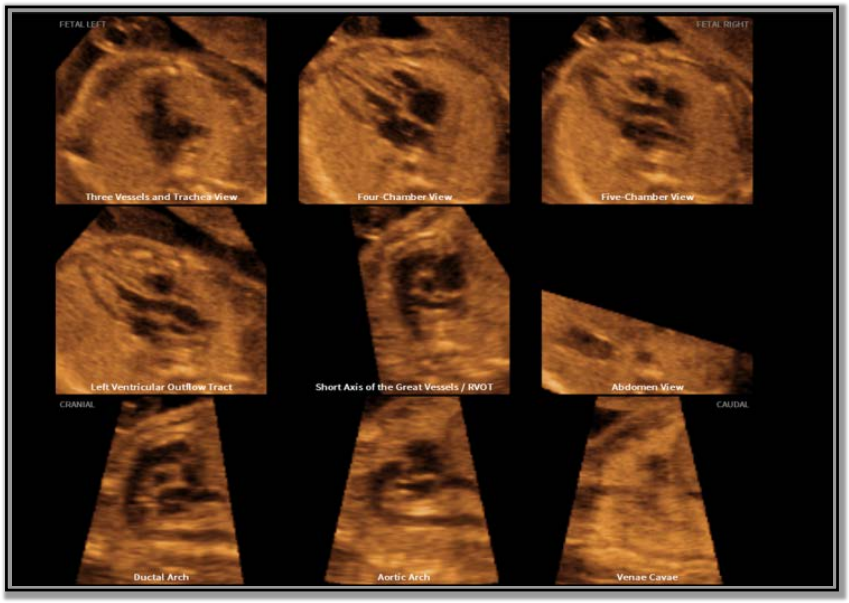


**Figure 2.** The feature Anatomic Box was performed and generated nine views fetal echocardiography.

## 2.5. Statistical Analysis

Data were analyzed using MedCalc© version 15.8 (MedCalc© Software bvba, Ostend, Belgium). Numerical variables were presented as mean ± SD and categorical variables as number and percentage. Paired numerical data were compared using the paired-samples t test. The Mc Nemar exact test was used to compare paired categorical variables. Inter-method agreement for the rating of the quality of cardiac views by 2D US or 5D US was assessed by calculation of the prevalence-adjusted and bias-adjusted kappa coefficient (PABAK), which is statistical measures described and used in diagnostic imaging for expressing observer agreement in regard to categorical data. Prevalence-adjusted bias-adjusted kappa values is used as additional indicators to measure observer agreement and it is used to characterize the reliability of imaging methods and the reproducibility of disease classifications and, occasionally with great care, as the surrogate for accuracy.

# 3. Results

One hundred patients were initially included in this study; ten patients were excluded (one had suspected cardiac anomaly, three with twin pregnancy, two cases were excluded due to failure of STIC accusation from excessive fetal movement, one case had marked oligohydramnios and three patients were reluctant to participate). The remaining 90 pregnant women had a mean age of 25 years (range 18 - 36). Their mean gestational age was 24 weeks (range 20 - 28). Fetal heart assessment using 2DUS showed satisfactory rating in 93.3% - 100% in the nine views (Table 1) while 5DUS FINE showed satisfactory rating in 95.6% - 100% in the nine views (Table 2).

**Table 1.** Rating of the 9 views by 2D US.

| 2D US | Rating | N | % |
|---|---|---|---|
| **View 1** | Satisfactory | 88 | 97.8% |
| 4-chamber | Unsatisfactory | 2 | 2.2% |
| **View 2** | Satisfactory | 88 | 97.8% |
| 5-chamber | Unsatisfactory | 2 | 2.2% |
| **View 3** | Satisfactory | 90 | 100.0% |
| LOT | Unsatisfactory | 0 | 0.0% |
| **View 4** | Satisfactory | 86 | 95.6% |
| ROT | Unsatisfactory | 4 | 4.4% |
| **View 5** | Satisfactory | 86 | 95.6% |
| 3VT | Unsatisfactory | 4 | 4.4% |
| **View 6** | Satisfactory | 90 | 100.0% |
| Abdomen/Stomach | Unsatisfactory | 0 | 0.0% |
| **View 7** | Satisfactory | 84 | 93.3% |
| Ductal arch | Unsatisfactory | 6 | 6.7% |
| **View 8** | Satisfactory | 84 | 93.3% |
| Aortic arch | Unsatisfactory | 6 | 6.7% |
| **View 9** | Satisfactory | 90 | 100.0% |
| Bicaval view | Unsatisfactory | 0 | 0.0% |

LOT: left outflow tract, ROT: right outflow tract, 3VT: 3 vessels and trachea.

**Table 2.** Rating of the 9 views by 5D US.

| 5D US | Rating | N | % |
|---|---|---|---|
| **View 1** | Satisfactory | 90 | 100.0% |
| 4-chamber | Unsatisfactory | 0 | 0.0% |
| **View 2** | Satisfactory | 90 | 100.0% |
| 5-chamber | Unsatisfactory | 0 | 0.0% |
| **View 3** | Satisfactory | 90 | 100.0% |
| LOT | Unsatisfactory | 0 | 0.0% |
| **View 4** | Satisfactory | 88 | 97.8% |
| ROT | Unsatisfactory | 2 | 2.2% |
| **View 5** | Satisfactory | 90 | 100.0% |
| 3VT | Unsatisfactory | 0 | 0.0% |
| **View 6** | Satisfactory | 90 | 100.0% |
| Abdomen/Stomach | Unsatisfactory | 0 | 0.0% |
| **View 7** | Satisfactory | 86 | 95.6% |
| Ductal arch | Unsatisfactory | 4 | 4.4% |
| **View 8** | Satisfactory | 86 | 95.6% |
| Aortic arch | Unsatisfactory | 4 | 4.4% |
| **View 9** | Satisfactory | 90 | 100.0% |
| Bicaval view | Unsatisfactory | 0 | 0.0% |

Inter-method agreement for the rating of the quality of cardiac views by 2DUS or 5DUS was assessed by calculation of the prevalence-adjusted and bi-as-adjusted kappa coefficient (PABAK). The overall inter-method agreement between 2DUS and 5DUS was 0.92, The difference in % of satisfactory views between 2D and 5D US was 1.73%, (95% CI - 0.5% to 3.33%) (Table 3), and P-value is 0.144 (insignificant) (Table 4).

The mean examination time was significant higher in 2DUS compared to FINE ($P < 0.0001$) (Table 5).

## 4. Discussion

The present study showed that conventional 2DUS was able to get satisfactory rating at nine structured fetal echocardiography views in 93.3% - 100% of the study population, while 5DUD FINE method yielded a satisfactory rating for the nine chamber views in 95.6% - 100% of the cases studied. The overall in-ter-method agreement between 2DUS and 5DUS FINE was 0.92. The difference

Table 3. Agreement between 2D US and 5D US.

| | | 5D US | | |
|---|---|---|---|---|
| **VIEW** | **2D US** | **Satisfactory** | **Unsatisfactory** | **PABAK** |
| **View 1** | Satisfactory | 88 | 0 | 0.96 |
| 4-chamber | Unsatisfactory | 2 | 0 | |
| **View 2** | Satisfactory | 88 | 0 | 0.96 |
| 5-chamber | Unsatisfactory | 2 | 0 | |
| **View 3** | Satisfactory | 90 | 0 | NA |
| LOT | Unsatisfactory | 0 | 0 | |
| **View 4** | Satisfactory | 84 | 2 | 0.87 |
| ROT | Unsatisfactory | 4 | 0 | |
| **View 5** | Satisfactory | 86 | 0 | 0.91 |
| 3VT | Unsatisfactory | 4 | 0 | |
| **View 6** | Satisfactory | 90 | 0 | NA |
| Abdomen/Stomach | Unsatisfactory | 0 | 0 | |
| **View 7** | Satisfactory | 80 | 4 | 0.78 |
| Ductal arch | Unsatisfactory | 6 | 0 | |
| **View 8** | Satisfactory | 80 | 4 | 0.78 |
| Aortic arch | Unsatisfactory | 6 | 0 | |
| **View 9** | Satisfactory | 90 | 0 | NA |
| Bicaval view | Unsatisfactory | 0 | 0 | |
| **Overall** | Satisfactory | 776 | 10 | 0.92 |
| | Unsatisfactory | 24 | 0 | |

PABAK, prevalence-adjusted and bias-adjusted kappa coefficient; NA, could not be estimated. LOT: left outflow tract, ROT: right outflow tract, 3VT: 3 vessels and trachea.

**Table 4.** Comparison of the overall percentage of satisfactory views for 2D and 5D US.

| | Rating of 2D US views | | | | | |
|---|---|---|---|---|---|---|
| Rating of 5D US views | Satisfactory | Unsatisfactory | Column Total | Difference in % of satisfactory views between 2D and 5D US | 95% CI | *p*-value |
| Satisfactory | 776 | 24 | 800 (98.77%) | 1.73% | −0.5% to 3.33% | 0.144 |
| Unsatisfactory | 10 | 0 | 10 (1.23%) | | | |
| Row total | 786 (97.04%) | 24 (2.96%) | 810 | | | |

95% CI, 95% confidence interval.

**Table 5.** Comparison of the number of satisfactory views and examination time for 2D and 5D US.

| Variable | 2D US | 5D US | t | DF | *p*-value |
|---|---|---|---|---|---|
| Number of satisfactory views | 8.7 ± 0.8 | 8.9 ± 0.4 | 1.459 | 44 | 0.152 |
| Examination time (s) | 264 ± 67 | 204 ± 40 | 4.968 | 44 | <0.0001 |

t, t statistic; DF, degree of freedom. Paired t test.

in the percentage of satisfactory rating views between the two methods was 1.73% (95% CI, 0.5% - 3.33%) with *P* value of 0.144 which is insignificant.

Our results showed a strong agreement with other investigators as Garcia M *et al.* [4], who found that FINE was successful to generate the nine planes in 98% - 100% of cases and also Veronese *P et al.* [10] who found that FINE was successful to generate the nine planes in 96% - 100% of cases.

The current study also showed that there was no statistical significant difference between the number of satisfactory views by both 2DUS (8.7 ± 0.8) compared to 5DUS FINE (8.9 ± 0.4), $P = 0.152$ which indicates a perfect agreement.

An advantage for the FINE over 2DUS Echocardiography was found in the current study as there was a significant reduction in examination time needed in the FINE method (204 ± 40 seconds) compared to (264 ± 67) seconds in the 2DUS method, $P < 0.0001$, which gives an advantage for FINE compared to conventional 2DUS method.

Points of strength in this study are; first it is one of very few studies done to evaluate FINE method used to study fetal heart echocardiography in second trimester normal pregnancy to validate its future usage on large scale, second, our study also compared FINE technology with the gold standard 2DUS echocardiography in this aspect.

The limitation of our study is that FINE method is not tested to evaluate its accuracy in cases of suspected or proved congenital fetal heart diseases which may be a topic of future research.

## 5. Conclusion

5DUS FINE method is comparable in accuracy to 2DUS echocardiography in

normal fetuses in second trimester; it has more advantages as less examination time, non-operator dependent compared to 2DUS echocardiography.

## Conflict of Interest

The authors declared no conflict of interest associated with this manuscript.

## Synopsis

5DUS FINE method is as accurate as 2DUS echocardiography in normal fetuses in second trimester with less examination time and non-operator dependent.

## References

[1] Carvalho, J.S., Mavrides, E. and Shineboume, E.A. (2002) Improving the Effectiveness of Routine Prenatal Screening for Major Congenital Heart Defects. *Heart*, **88**, 387-391. https://doi.org/10.1136/heart.88.4.387

[2] Barboza, J.M., Dajani, N.K., Glenn, L.G. and Angtuaco, T.L. (2002) Prenatal Diagnosis of Congenital Cardiac Anomalies: A Practical Approach Using Two Basic Views. *Radiographics*, **22**, 1125-1137. https://doi.org/10.1148/radiographics.22.5.g02se171125

[3] Panchal, S. and Grag, R. Fetal Echocardiography in Malhotra, N., Shah, P.K. and Divakan, H. (2014) Principles and Practice of Obstetrics and Gynecology for Postgraduates. Fourth Edition. Jypee Brothers' Medical Publishers, New Delhi, 243-261.

[4] Garcia, M., Yeo, L., Romero, R., Haggerty, D., Giardina, I., Hassan, S.S., Chaiworapongsa, T. and Hernandez-Andrade, E. (2016) Prospective Evaluation of the Fetal Heart Using Fetal Intelligent Navigation Echocardiography (FINE). *Ultrasound in Obstetrics & Gynecology*, **47**, 450-459. https://doi.org/10.1002/uog.15676

[5] Friedberg, M.K., Silverman, N.H., Moon-Grady, A.J., Tong, E., Nourse, J., Sorenson, B., Lee, J. and Hornberger, L.K. (2009)Prenatal Detection of Congenital Heart Disease. *Journal of Pediatrics*, **155**, 26-31. https://doi.org/10.1016/j.jpeds.2009.01.050

[6] Allan, L. (2000) Antenatal Diagnosis of Heart Disease. *Heart*, **83**, 367-370. https://doi.org/10.1136/heart.83.3.367

[7] Benacerraf, B.R., Shipp, T.D. and Bromley, B. (2006) Three-Dimensional US of the Fetus: Volume Imaging. *Radiology*, **238**, 988-996. https://doi.org/10.1148/radiol.2383050636

[8] Zhang, M., Pu, D.R., Zhou, Q.C., Peng, Q.H. and Tian, L.Q. (2010) Four-Dimensional Echocardiography with B-Flow Imaging and Spatiotemporal Image Correlation in the Assessment of Congenital Heart Defects. *Prenatal Diagnosis*, **30**, 443-448.

[9] Yeo, L. and Romero, R. (2013) Fetal Intelligent Navigation Echocardiography (FINE): A Novel Method for Rapid, Simple, and Automatic Examination of the Fetal Heart. *Ultrasound in Obstetrics & Gynecology*, **42**, 268-284. https://doi.org/10.1002/uog.12563

[10] Veronese, P., Bogana, G., Cerutti, A., Yeo, L., Romero, R. and Gervasi, M.T. (2017) A Prospective Study of the Use of Fetal Intelligent Navigation Echocardiography (FINE) to Obtain Standard Fetal Echocardiography Views. *Fetal Diagnosis and Therapy*, **41**, 89-99. https://doi.org/10.1159/000446982