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ORIGINAL ARTICLE

Reproducibility of automated fetal heart rate measurement using a novel technique with two-dimensional tracking

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Abstract

Purpose To assess the accuracy of automated fetal heart rate measurement using two-dimensional tracking (AutoFHR) by comparison with the conventional free-angle M-mode (M-mode) and pulsed-waved Doppler (PWD) methods.

Methods A multicenter prospective comparative study was conducted. AutoFHR is a novel technique for the automatic calculation of fetal heart rate using a two-dimensional speckle-tracking method. The fetal heart rate (FHR) obtained by AutoFHR was compared with that obtained by the conventional M-mode and PWD. Statistical analysis was performed on the correlation between the FHR measured by AutoFHR and that determined by M-mode and PWD.

Results Data from 326 singleton pregnancies were analyzed, and all the data and the data from 178 cases were compared with M-mode and PWD, respectively. The intraobserver ICC was 0.96 (95% CI: 0.93–0.98), whereas the interobserver ICC was 0.97 (95% CI: 0.95–0.99). Systematic bias was not observed between M-mode and PWD, based on the Bland–Altman plots. Analyses of the relationships among the FHRs yielded by each method revealed that AutoFHR was strongly associated with M-mode ($r_s = 0.99$, $p < 0.001$) and PWD ($r_s = 0.86$, $p < 0.001$).

Conclusion Evaluation of FHR by AutoFHR was proved to be equivalent to evaluation by the conventional M-mode and PWD. AutoFHR can be employed with only B-mode data, making FHR measurement easier and safer.

Keywords Automated fetal heart rate measurement · Two-dimensional tracking method

Introduction

In recent years, it has become standard procedure to decide the pregnancy follow-up strategy and optimal delivery time by evaluating fetal well-being through the measurement of fetal heart rate (FHR) using ultrasound diagnostic devices [1]. In daily practice, although auscultation of the fetal heartbeat is used for assessing fetal well-being, it has certain limitations, including confounding fetal heartbeats due to the pulsation of maternal vessels. To avoid such confusion, measurement methods such as the conventional free-angle M-mode (M-mode) and the pulsed Doppler (PWD) mode are extensively used for FHR measurement [2]. However, these two methods require the physician to operate an ultrasound machine, in addition to the B-mode. Furthermore, there are concerns for fetal safety owing to the usage of ultrasound in the M-mode or PWD [3, 4]. Theoretically, as the B-mode uses less ultrasound energy than the other methods, it would be more suitable for the fetus if FHR measurement can be made using the B-mode alone.

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An automatic FHR measuring method (AutoFHR), which uses a two-dimensional (2D) speckle-tracking technique for tracking fetal heart motion, was recently invented [5], wherein the FHR can be calculated automatically. However, it is unclear, whether this novel technique can be utilized in daily clinical practice.

In this study, we utilize this novel AutoFHR technique and determine whether it is optimal for achieving simple and stable FHR measurement by examining its feasibility and reliability in comparison with the conventional M-mode and Doppler mode.

Methods

Study population

This study was conducted as a multicenter prospective study on normal singleton pregnancies that underwent fetal ultrasound examination between 8 and 40 weeks of gestation, from April 2015 to March 2016, at six institutions. In all the pregnancies, the gestational age (GA) was corrected by the crown–rump length in the first trimester. Informed consent was obtained from all pregnant women, and the study protocol was approved by the institutional ethics committee (No. A16047). The exclusion criteria included multiple pregnancies and fetal structural or chromosomal abnormalities. This study was retrospectively registered with the Japanese Clinical Trial Registry, "UMIN-CTR," on 10 March 2017 (http://www.umin.ac.jp/ctr/index-j.htm); its trial ID number is UMIN000026503.

AutoFHR

AutoFHR is a technique that automatically calculates the FHR using a 2D speckle-tracking method. In this technique, the examiner sets up a region of interest (ROI-1) on the fetal cardiac region for calculating the FHR automatically; the surrounding region is then used as ROI-2 to track the entire fetal heart movement caused by gross fetal movement or maternal breathing. Therefore, it becomes possible to track and analyze the fetal heartbeats on ROI-1 automatically using a pattern matching method [5].

Specifically, the examiner initially sets up ROI-1 for collecting image data of the fetal heartbeat. Considering the fetal heart size, according to the gestation week, and the contrast resolution, depending on the size of the heart, the ROI size is set up to cover the entire cardiac area in early gestation. On the other hand, in middle and late gestation, it is set up to surround the entire left ventricular area (Fig. 1a, b). In mid to late pregnancy, the left ventricle stretches and contracts centripetally, so it is easy to detect the change by 2D tracking. In contrast, the right ventricle expands and contracts in the long axis direction in addition to the centripetal effect, so it is difficult to capture the movement of the wall by 2D tracking. Furthermore, ROI-2 is automatically generated outside ROI-1 to track the gross fetal movement by a pattern matching method. As the heart region may be partially included within ROI-2 in certain cases, ROI-2 is divided into multiple parts to calculate the average luminance; the divided region of interest that mainly contains the extra-cardiac tissue region is set up to track the gross fetal movement (Fig. 2). These techniques render it possible to obtain various information for recognizing fetal movement and enable the predetermined ROI-2 to be used as a

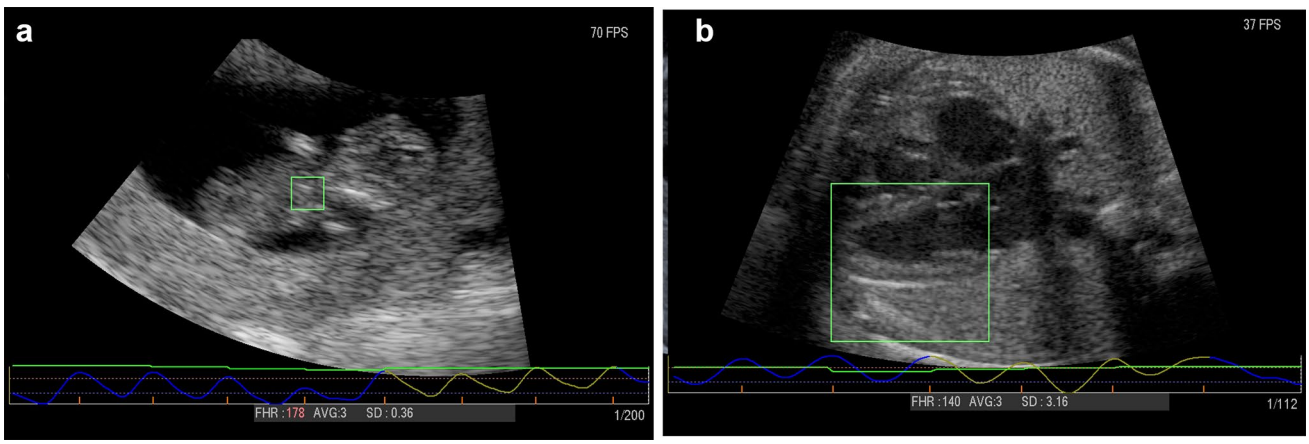

Fig. 1 Setting ROI-1. ROI set-up, covering **a** the entire cardiac area in early gestation and **b** the entire left ventricular area in middle and late gestation

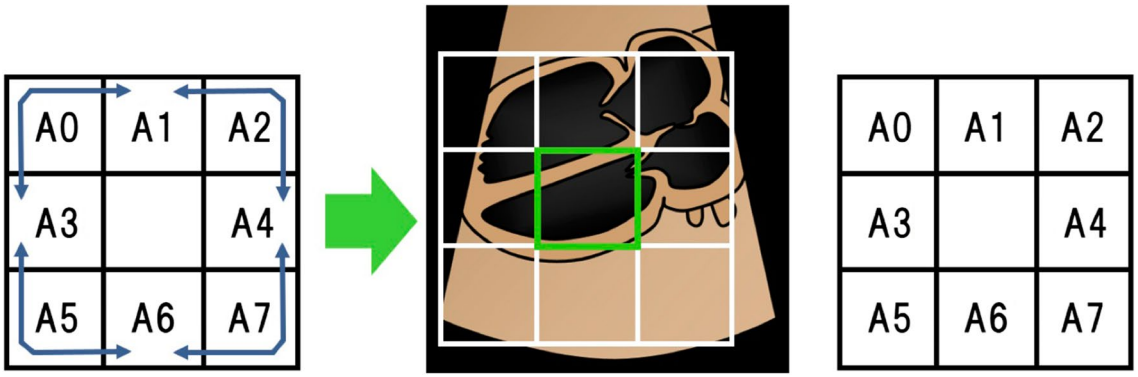

Fig. 2 Dividing ROI-2. The center of the matrix is ROI-1, and the subareas (A0–A7) surrounding ROI-1 are ROI-2 (right matrix). In this case, ROI-2 is divided into five areas (A3–A0–A1, A1–A2–A4, A4–A7–A6, A6–A5–A3, and A0–A7). When ROI-1 (within the green frame) is set to cover the left ventricle, subarea A4–A7–6 is mainly used as the fetal movement compensation template because it contains non-heart tissue

template for tracking the 2D gross movement of the fetal heart (Fig. 3).

To obtain FHR information, ROI-1 is first divided into several subareas to calculate the feature values, and the temporal changes of both the amplitude and average brightness cycle in each divided subarea in ROI-1 are computed (Fig. 4). Furthermore, a cross-correlation function between the heartbeat waveform in each divided region, derived using the above-mentioned method, and the basic sine waveforms is used; the heartbeat waveform with the greatest correlation is then selected and defined as the FHR. During this calculation, the cross-correlation function and root mean square (RMS) between the basic waveform and heartbeat waveform in each region of the divided ROI-1 are utilized for ensuring stable results by adopting the heart rate within the region, where the RMS is maximum, as that of the subject fetus.

FHR measurement

All the ultrasound examinations were performed using an ARIETTA 60 or 70 ultrasound machine containing the AutoFHR application, with a C35 convex transducer (2–8 MHz) (Hitachi, Ltd., Tokyo, Japan). Transvaginal ultrasonography was performed when the FHR was not clearly detected with transabdominal ultrasonography between 8 and 10 weeks gestation. Data were analyzed offline. Measurement algorithms were installed in measuring instruments. To assess the feasibility and reliability of the AutoFHR, the M-mode and PWD methods were also used to calculate the FHR for comparison. When M-mode was used, the wall motion of the left ventricle was visualized with a cross-section perpendicular to the long axis of the heart. The time between the peaks of the wall motion was measured and the heart rate was calculated. When PWD was used, the cursor was set across the tricuspid valve so that the blood flow waveform became sharpest. When performing Doppler

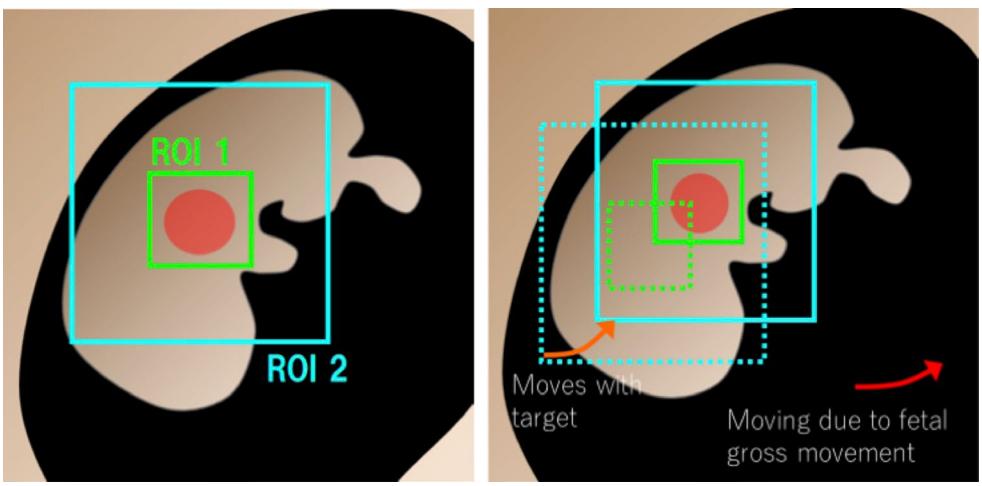

Fig. 3 Canceling fetal movement. As ROI-2 (blue frame) tracks the fetal movement, ROI-1 (green frame) is always set to the fetal heart

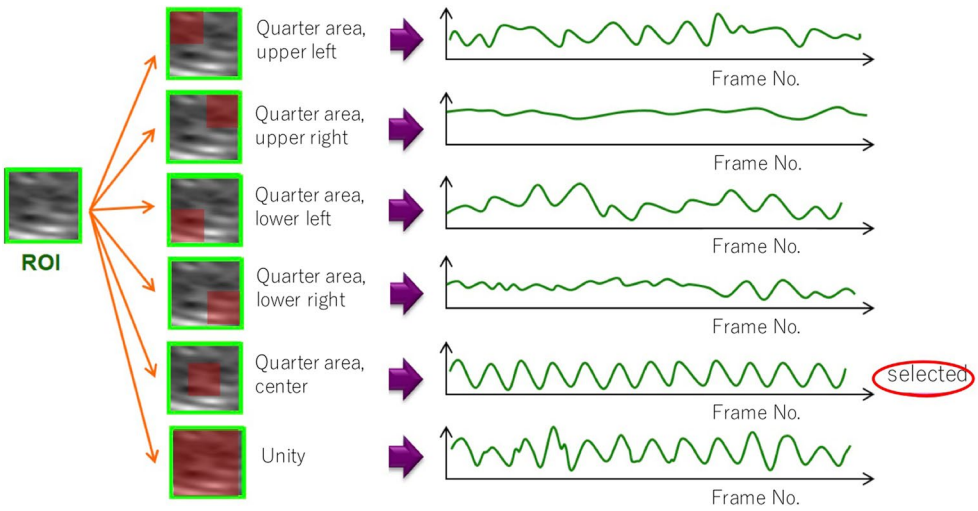

Fig. 4 Dividing ROI-1 into six subareas. FHR calculation method: ROI-1 is divided into six subareas, and the periodical change in each subarea is analyzed. The correlation between the heartbeat waveform in each of the six divided ROI-1 areas and each sinusoidal basic waveform is calculated. The heart rate of the heartbeat waveform with the highest correlation is determined to be the heart rate of the fetus

imaging, it should be performed at the lowest possible energy level (e.g., TI ≤ 1.0, no longer than 5–10 min and not exceeding 60 min). All the measurements were performed when the FHR was stable. The measurement algorithm is affected by the frame rate. To minimize the influence, the frame rate was set to at least 60/sec. In this study, the FHR was assessed only once in each case.

Statistical analysis

The normality of the data distribution was determined using the Shapiro–Wilk test. Because none of the variables was normally distributed, medians and non-parametric tests were used for analysis. The Spearman correlation coefficient was calculated to assess the relationship between the FHR measured by AutoFHR, and that determined by M-mode and PWD, respectively. For assessing the reproducibility, the intra- and interobserver variability of the FHR measured by the AutoFHR method were assessed, using the intraclass correlation coefficients (ICC), with a 95% confidence interval (CI). To assess the intraobserver ICC by one-way classification, 30 subjects were randomly selected and AutoFHR measurements were performed thrice (by one operator: M.N.). The interobserver ICC was also assessed by a two-way random model by selecting 30 subjects randomly and performing the measurements thrice (by three operators: S.N., M.T., and M.N.). For comparing the FHR obtained using two different methods, the AutoFHR and the M-mode or PWD, Bland–Altman analysis was performed [6].

The relationship between the gestational age (GA) and FHR determined by each method was assessed using the Spearman correlation coefficient, and separate linear, cubic, and logarithmic reciprocal regression models were fitted. We selected the best-fitting model for each variable. p values < 0.05 were considered statistically significant throughout. The statistical package for the social sciences software version 20.0 (IBM Corp., Armonk, NY, USA) was used for statistical analyses.

Results

The AutoFHR measurements of all the 325 singleton pregnancies included in this study were successful. The intraobserver ICC was 0.96 (95% CI: 0.93–0.98), and the interobserver ICC was 0.97 (95% CI: 0.95–0.99). The Bland–Altman plots of the difference versus the mean of the paired measurements between the AutoFHR method and each conventional method are depicted in Fig. 5. Systematic bias was not observed between each group. We analyzed data obtained by AutoFHR and M-mode in 326 cases, and data obtained by AutoFHR and PWD in 178 cases. The numbers of cases examined by AutoFHR and M-mode were 103, 104, and 119 in the 1st, 2nd, and 3rd trimester, respectively. Regarding PWD, 65, 50, and 63 women were included in the 1st, 2nd, and 3rd trimester, respectively. The median GA of the FHR measurements determined by AutoFHR and M-mode was 22.4 weeks (range: 8.1–40.9 weeks), whereas that of the FHR determined by PWD was 19.9 weeks (range: 8.1–40.6 weeks). The FHR measured by AutoFHR exhibited a strong negative correlation with the GA ($r_s = -0.77$, $p < 0.001$) (Fig. 6). The regression equation is as follows: FHR by AutoFHR $= 237.3 - 9.2 \times GA + 0.31 \times GA^2 - 0.004 \times GA^3$ ($R^2 = 0.64$).

The analyses of the relationships among the FHRs measured by each method revealed that the AutoFHR was highly similar to the M-mode ($r_s = 0.99$, $p < 0.001$) and PWD ($r_s = 0.86$, $p < 0.001$) (Fig. 7a, b).

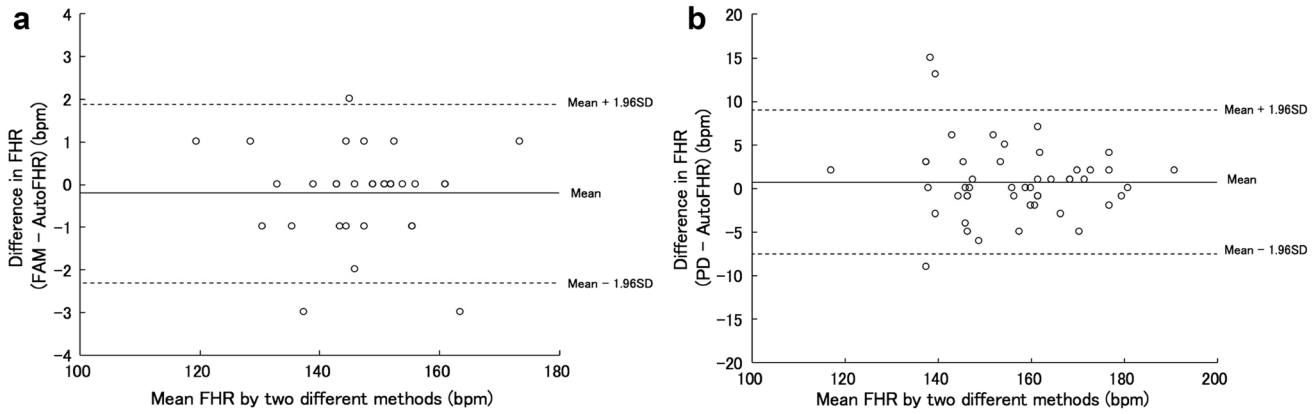

Fig. 5 Evaluation of systematic bias by Bland–Altman method. Bland–Altman plots of the difference versus the mean of the AutoFHR method and other methods (M-mode or PWD), with the difference and 95% agreement limit. **a** Analysis of AutoFHR and M-mode. **b** Analysis of AutoFHR and PWD

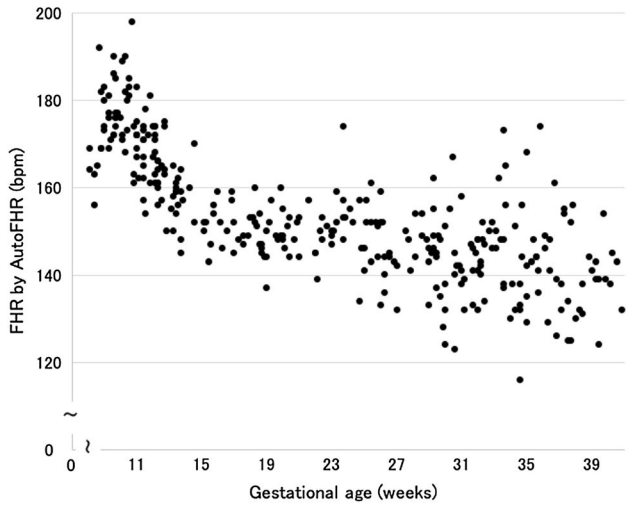

Fig. 6 Scatter plots of GA and FHR measured by AutoFHR. The FHR is plotted for a GA of 8–40 weeks. The FHR measured by AutoFHR exhibits a strong negative correlation with the GA ($r_s = -0.77$, $p < 0.001$) (FHR by AutoFHR $= 237.3 - 9.2 \times GA + 0.31 \times GA^2 - 0.004 \times GA^3 [R^2 = 0.64]$)

Discussion

This study demonstrated that the novel AutoFHR method can become a reliable method for measuring the FHR throughout gestation. Furthermore, AutoFHR exhibited a strong correlation with conventional methods such as M-mode and PWD mode.

This method enables us to calculate the FHR using B-mode only after 8 weeks of gestation. Furthermore, it can be utilized for tracking the gross fetal movement. FHR is generally measured by the conventional PWD or M-mode. In the case of M-mode, the heart rate can be measured by checking the given time interval of the M-mode waveforms, using the luminance values on a line set up by the examiner. As the border of a structural object on an ultrasound image is often unclear, particularly in the case of early gestation due to a minute heart, measurement based on the M-mode waveform is difficult. The same applies for the PWD method. Furthermore, these two conventional methods are often hampered by fetal movement or maternal breathing. In the AutoFHR method, we generated two ROIs for FHR measurement; one was for calculation of the FHR (ROI-1), whereas the other was for tracking the fetal heart (ROI-2). By setting ROI-2 around ROI-1, tracking of the gross fetal movement became possible, and stable signal changes from ROI-1 could be obtained. To the best of our knowledge, this is the first method for calculating the FHR by analyzing the periodical change in the brightness of the ROI. In early gestation, it is difficult to calculate the FHR by conventional methods because the periodical change of the M-mode waveforms cannot be observed due to the minute fetal heart; the PWD signals are also weak. Many physicians are experiencing the fact that the FHR cannot be measured even though the fetal heart beat can be confirmed with the naked eye. This new method analyzes only the periodical change of the brightness in ROI-1, enabling FHR calculation, even in early gestation, when neither M-mode nor PWD can be used.

With respect to safety, the thermal index in bone (TIB) should be considered whenever an ultrasound examination is to be performed during pregnancy. The TIB is an index of the sound power, which becomes significantly higher compared to that during B-mode [4, 7]. Even in ultrasound examinations, which are regarded to be relatively less invasive compared to other imaging modalities such as computed tomography, it is necessary to use the lowest ultrasound

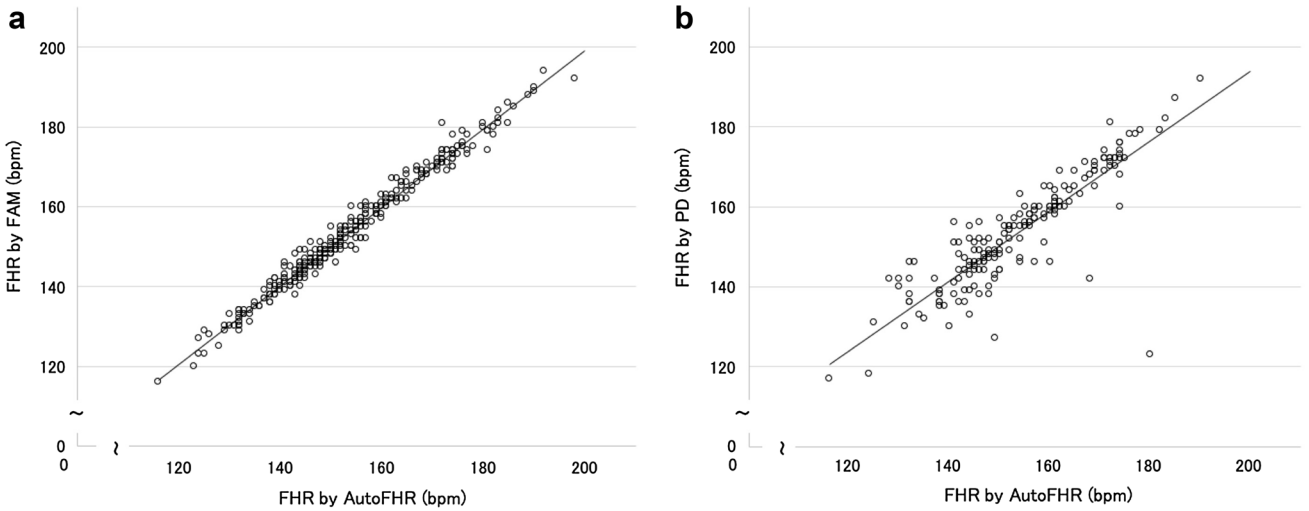

Fig. 7 Scatterplots of FHR measured by AutoFHR and conventional methods in normal fetuses. The graphs demonstrate the correlation between the FHR measured by AutoFHR and that determined by **a** M-mode and **b** PWD

energy possible to obtain the required medical care information. Hence, ultrasound examinations are required to comply with the so-called "as low as reasonably achievable (ALARA)" principle, in which ultrasound irradiation is not performed when diagnosis is not needed, including examinations with the purpose of showing something to the pregnant woman [4, 8]. As it has become a trend to refrain from using PWD mode in routine examinations due to concerns regarding its impact on the fetal heart under development, AutoFHR, which is capable of measuring the FHR using B-mode alone, can be regarded as a suitable examination method for the fetus because it minimizes the invasiveness.

Although the 2D speckle-tracking method has been one of the most reliable methods for evaluating cardiac function in adults, AutoFHR features are considerably different from those of the others in terms of assessing cardiac function because they only detect the FHR. While the other methods detect the wall motion of the heart using a pattern matching method, AutoFHR converts the cardiac wall motion into a sinusoidal wave form and derives the heart rate from the wave pattern.

The relationship between FHR and congenital disorders is determined in early gestation [9] and methods for evaluating the risk of acquiring fetal chromosomal aneuploidy have been established. In addition, the opportunities for conducting fetal ultrasonography are expected to increase, from the beginning of pregnancy, due to improvements in and popularization of reproductive technology. AutoFHR can be an important tool for fetal assessment because the FHR can be evaluated with less invasion.

A limitation of this study is that the analyses are based on a small number of observations. In addition, from a clinical perspective, AutoFHR in the first trimester and its relationship with clinical prognosis such as subsequent miscarriages or fetal chromosomal abnormalities should be assessed. Thus, further extensive studies are required to establish the clinical importance of AutoFHR as a fetal prognosis indicator. Although AutoFHR is not yet common technology, we expect that AutoFHR will become a common technology in the near future and will expand from the research level to the actual clinical level.

Conclusion

We demonstrated that AutoFHR, a novel method using 2D tracking that requires only B-mode, has a strong correlation with conventional M-mode and PWD. Thus, AutoFHR can be considered as a new candidate for FHR measurement.

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Compliance with ethical standards

Conflict of interest Ryuhei Nagai, Susumu Miyashita, Susumu Murata, Yuichiro Takahashi, Atsushi Tajima, Sumito Nagasaki, and Mayumi Takano declare that they have no conflicts of interest. Masahiko Nakata reports grants from JSPS KAKENHI during the conduct of the study. In addition, Nakata has a patent from the Japan Patent Office licensed to 5386001.

Ethical statement All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1946 and later versions.

Informed consent Informed consent was obtained from all patients whose identifying information is included in this article.

References

1. Committee on Practice B-O, the American Institute of Ultrasound in M. Practice bulletin no. 175: ultrasound in pregnancy. Obstet Gynecol. 2016;128:e241–56.
2. Reed KL, Sahn DJ, Marx GR, et al. Cardiac Doppler flows during fetal arrhythmias: physiologic consequences. Obstet Gynecol. 1987;70:1–6.
3. Abramowicz JS, Kossoff G, Marsal K, International society of ultrasound in obstetrics and gynecology (ISUOG), et al. Safety statement, 2000 (reconfirmed 2003). Ultrasound Obstet Gynecol. 2003;21:100.
4. Salvesen K, Lees C, Abramowicz J, et al. ISUOG statement on the safe use of Doppler in the 11–13 + 6-week fetal ultrasound examination. Ultrasound Obstet Gynecol. 2011;37:628.
5. Murashita K, Kasahara E, Matsushita N, et al. Development of technique to detect fetal heart rate automatically. Medix. 2015;63:35–9 **(in Japanese)**.
6. Bland JM, Altman DG. Applying the right statistics: analyses of measurement studies. Ultrasound Obstet Gynecol. 2003;22:85–93.
7. Barnett SB, Ter Haar GR, Ziskin MC, et al. International recommendations and guidelines for the safe use of diagnostic ultrasound in medicine. Ultrasound Med Biol. 2000;26:355–66.
8. Bhide A, Acharya G, Bilardo CM, et al. ISUOG practice guidelines: use of Doppler ultrasonography in obstetrics. Ultrasound Obstet Gynecol. 2013;41:233–9.
9. Liao AW, Snijders R, Geerts L, et al. Fetal heart rate in chromosomally abnormal fetuses. Ultrasound Obstet Gynecol. 2000;16:610–3.