Artificial intelligence–based screening for cardiomyopathy in an obstetric population: A pilot study

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BACKGROUND Cardiomyopathy is a leading cause of pregnancy-related mortality and the number one cause of death in the late postpartum period. Delay in diagnosis is associated with severe adverse outcomes.

OBJECTIVE To evaluate the performance of an artificial intelligence–enhanced electrocardiogram (AI-ECG) and AI-enabled digital stethoscope to detect left ventricular systolic dysfunction in an obstetric population.

METHODS We conducted a single-arm prospective study of pregnant and postpartum women enrolled at 3 sites between October 28, 2021, and October 27, 2022. Study participants completed a standard 12-lead ECG, digital stethoscope ECG and phonocardiogram recordings, and a transthoracic echocardiogram within 24 hours. Diagnostic performance was evaluated using the area under the curve (AUC).

RESULTS One hundred women were included in the final analysis. The median age was 31 years (Q1: 27, Q3: 34). Thirty-eight percent identified as non-Hispanic White, 32% as non-Hispanic Black, and 21% as Hispanic. Five percent and 6% had left ventricular ejection

fraction (LVEF) <45% and <50%, respectively. The AI-ECG model had near-perfect classification performance (AUC: 1.0, 100% sensitivity; 99%–100% specificity) for detection of cardiomyopathy at both LVEF categories. The AI-enabled digital stethoscope had an AUC of 0.98 (95% CI: 0.95, 1.00) and 0.97 (95% CI: 0.93, 1.00), for detection of LVEF <45% and <50%, respectively, with 100% sensitivity and 90% specificity.

CONCLUSION We demonstrate an AI-ECG and AI-enabled digital stethoscope were effective for detecting cardiac dysfunction in an obstetric population. Larger studies, including an evaluation of the impact of screening on clinical outcomes, are essential next steps.

KEYWORDS Cardiomyopathies; ECG; Heart failure; Obstetrics; Pregnancy; Postpartum

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Introduction

Cardiomyopathy is a leading cause of pregnancy-related mortality and the number one cause of death in the late postpartum period.[1,2] In addition, any form of pregnancy-associated cardiomyopathy is known to be associated with a high risk of severe complications.[3] Antepartum diagnosis of cardiomyopathy is challenging owing to the overlap between pregnancy physiology–related symptoms and those

suggestive of cardiomyopathy or heart failure,[4,5] and a delay in diagnosis is believed to be an important contributor to mortality.[6] As such, the need to develop scalable and effective tools for routine cardiomyopathy screening in the obstetric population is imperative.

Prior studies have demonstrated the effectiveness of an artificial intelligence (AI)–enabled electrocardiogram (AI-ECG) for detection of left ventricular dysfunction in unselected patient populations.[7–11] This AI-ECG model, based on a standard 12-lead ECG recording, has been validated in an emergency room setting,[12] racial and ethnic subgroups,[13] a retrospective community-based cohort,[14] a retrospective

sample of pregnant and postpartum women,[15] and in a clinical trial among patients seen for routine primary care.[16]

In a bid to evaluate potentially scalable and portable cardiomyopathy screening options, an AI-enabled single-lead ECG recording from a digital stethoscope has also been shown to be effective for detection of left ventricular dysfunction,[17,18] and more recently, the digital stethoscope single-lead AI-ECG model has been revised to incorporate data from recorded phonocardiograms as well. In addition, a smartwatch-enabled ECG demonstrated similar performance[19] in a prospective study.

However, these AI models and digital tools have yet to be prospectively evaluated in the obstetric population. Pregnant and postpartum women are an ideal group for targeted screening owing to reported delays in cardiomyopathy diagnosis and a high risk of cardiomyopathy-associated mortality with the current standard of care. In addition, failure to identify symptoms of heart disease during pregnancy, which can be difficult to distinguish from normal physiological changes of pregnancy, is an important driver of health inequities in the obstetric population.[5] The goal of this study was to prospectively evaluate the effectiveness of an AI-ECG and AI-enabled digital stethoscope to screen for left ventricular systolic dysfunction (LVSD) in a pilot study of pregnant and postpartum women.

Methods
Study design
We conducted a single-arm, prospective study among pregnant and postpartum women (up to 12 months following delivery) between October 28, 2021, and October 27, 2022, with follow-up for outcomes through November 21, 2022. The study was approved by the Mayo Clinic Institutional Review Board (IRB). A written or electronic consent was obtained from each study participant in accordance with IRB guidance.

Study population
Consecutive consenting study participants were enrolled at 3 sites: Mayo Clinic, Jacksonville, Florida; Agape Family Health Clinic, Jacksonville, Florida; and Mayo Clinic, Rochester, Minnesota, to ensure that a racially and ethnically diverse group of women were included. To meet this goal, we aimed to have at least 30% of the study sample be Black/African American. As such, enrollment of White participants was halted after 38 were enrolled in the study. Study participants included patients receiving care, hospital/clinic staff, and visitors. Inclusion criteria were female sex, aged 18–49 years, and pregnant or within 12 months postpartum. We excluded participants with complex congenital heart disease (status post complex cardiac surgery, single-ventricle physiology, or significant shunts with cardiac structural changes) or significant conduction abnormalities on a resting ECG (paced ECGs or presence of a left ventricular assist device). Study participants completed a standard 12-lead ECG recording, a digital

stethoscope ECG recording, a questionnaire (including demographic variables and clinical symptoms), and a comprehensive transthoracic echocardiogram on the same day or within 24 hours. Over a 12-month enrollment period, 126 women agreed to participate and 101 were able to make it to a scheduled research appointment. We excluded 1 participant who did not complete all required baseline tests or the questionnaire (Figure 1).

Standard 12-lead ECGs were acquired by trained personnel at a sampling rate of 500 Hz using GE ECG machines (MAC 5500, MAC 7, and MAC VU360), were stored and clinically interpreted using the MUSE ECG data management system (GE Healthcare, Chicago, IL), and digital XML files were exported for AI analysis. Digital stethoscope ECG and phonocardiogram recordings were performed by study staff; 15-second recordings at 3 locations across the chest were obtained, as follows: (1) placed vertically at the left sternal border (V2), (2) angled across the left upper chest (angled), and (3) placed horizontally over the left subclavicular area (subclavicular) (Figure 2).

All echocardiograms were performed by trained sonographers at a Mayo Clinic site using standard image acquisition protocols and clinically interpreted by a board-certified cardiologist according to the American Society of Echocardiography guidelines.[20] All echocardiogram images and measurements were also reviewed by the study lead (DA). Quantitative measures including left ventricular ejection fraction (LVEF) were extracted from the echocardiogram reports.
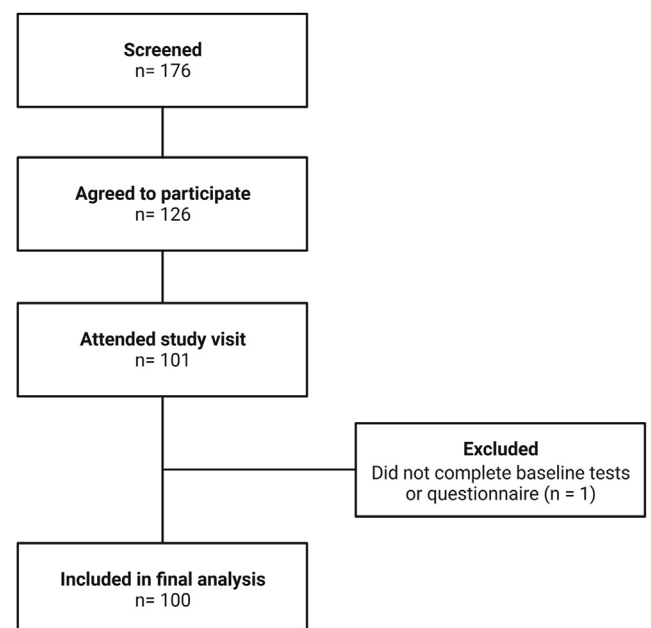

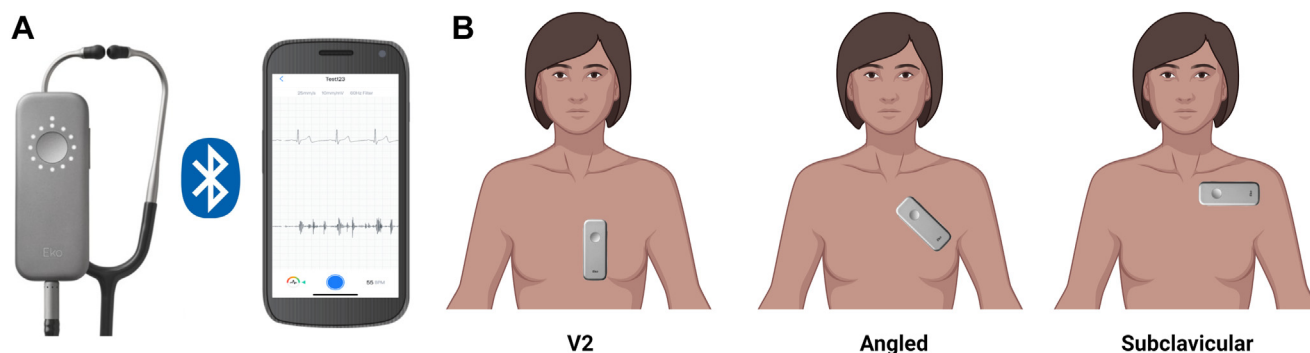**Figure 1**   Flow diagram for study participants.

Figure 2   Digital stethoscope positions. **A:** Digital stethoscope connects to mobile app via Bluetooth. **B:** Fifteen-second single-lead electrocardiogram recordings were obtained at 3 locations across the chest: placed vertically at the left sternal border (V2), angled across the left upper chest (angled), and placed horizontally over the left subclavicular area (subclavicular).

ECG preprocessing

Standard 12-lead ECGs

Standard 12-lead ECGs were uploaded from GE ECG machines to the MUSE ECG database management system (GE Healthcare). Following clinical interpretation, digital XML files were exported to a secure research server, after which they were processed and decoded from GE's proprietary format to a NumPy object using an open source R package[21] and Mayo Clinic's AI-ECG algorithm for detection of left ventricular dysfunction[7] was used to generate predictions.

Digital stethoscope ECG and phonocardiogram recordings

Single-lead digital ECGs and phonocardiograms were extracted from the cloud server by Eko Health (Emeryville, CA). The phonocardiogram signal is run through a Butterworth low-pass filter with a cutoff frequency of 800 Hz and then through a Butterworth high-pass filter with a cutoff frequency of 30 Hz. The single-lead ECG signal is first run through a notch filter to remove interference from the main power supply (60 Hz in the United States or 50 Hz in the UK/other countries), then it is run through a bandpass filter with a lower cutoff of 0.5 Hz and an upper cutoff of 40 Hz. AI predictions based on the ECG combined with phonocardiogram recordings were provided by Eko Health to the Mayo Clinic study team for each study participant (up to 3 for each participant based on recording location on the chest wall, Figure 2). Digital stethoscope data linkage to echocardiogram results and area under the receiver operating characteristic curve analyses were performed at Mayo Clinic.

Measures

Our primary study endpoint was detection of LVSD, defined as LVEF <50% using the AI-ECG (based on a standard 12-lead ECG recording) and an AI-enabled digital stethoscope. Our secondary study endpoint was detection of LVEF <45% using the AI-ECG (based on a standard 12-lead ECG recording) and an AI-enabled digital stethoscope. LVEF <45% was selected as a secondary outcome, being a clinically relevant threshold for identification of peripartum cardiomyopathy in the obstetric population. LVEF measurements were assessed using multiple methods in this order: 2D-biplane > 2D-linear > visual assessment. For echocardiographic images with more than 1 segment not clearly seen, an ultrasound-enhancing agent was used.

Statistical analysis

This study was designed as a single-arm study to provide an understanding of subject accrual rate, feasibility of obtaining standard 12-lead and portable ECGs using US Food and Drug Administration–approved devices in pregnant and postpartum women, and the performance of the AI-enabled ECG algorithm in this patient population. For sample size justification, assuming a ratio of positive to negative of 1:19 (based on a retrospective analysis of obstetric patients who had cardiovascular testing at Mayo Clinic[15], a sample size of 100 cases would be expected to have >90% power to reject the null hypothesis that the area under the curve (AUC) = 0.5 at the alpha = 0.05 level of significance provided the AUC is at least 0.90. From prior AI algorithms for left ventricular dysfunction, this level of discrimination was expected.

Diagnostic performance for detection of LVSD was evaluated for the AI-ECG and digital stethoscope using the AUC and other measures of diagnostic accuracy, including sensitivity, specificity, positive and negative predictive values, with 95% confidence intervals calculated. We used a previously validated AI-ECG deep learning model originally developed for identification of LVEF $\leq 35\%$[7,16,22] without any modifications to analyze the 12-lead ECGs obtained in this study. The digital stethoscope had up to 3 separate AI model predictions based on the device position on the chest wall at the time of data acquisition (Figure 2). Model performance was summarized for each lead configuration along with 2 global measures: the mean of the model outputs and the maximum model output. The maximum value was taken as the primary summary for the digital stethoscope, as it would represent the most sensitive summary using the device. The research reported in this paper adhered to the Standards for Reporting of Diagnostic Accuracy Studies guidelines. P values <.05 were considered statistically

Table 1 Demographics and clinical characteristics of the study sample

	Normal LV systolic function (n=94)	LV systolic dysfunction[†] (n=6)	Overall	P values
Age	31.6 (27.5, 34.8)	30.9 (25.6, 35.2)	31.6 (27.5, 34.9)	.828
Body mass index	29.0 (24.1, 32.8)	26.4 (24.2, 28.4)	28.5 (24.1, 32.7)	.411
Race/ethnicity				
Non-Hispanic White	34 (36.2%)	4 (66.7%)	38 (38.0%)	.204
Non-Hispanic Black	30 (31.9%)	2 (33.3%)	32 (32.0%)	
Hispanic or Latino	21 (22.3%)	0 (0%)	21 (21.0%)	
Asian	6 (6.4%)	0 (0%)	6 (6.0%)	
Native Hawaiian/Pacific Islander	1 (1.1)	0 (0%)	1 (1.0%)	
Multiracial	2 (2.1%)	0 (0%)	2 (2.0%)	
Recruitment site				
Mayo Clinic Florida	46 (48.9%)	5 (83.3%)	51 (51.0%)	.067
AGAPE Clinic	41 (43.6%)	0 (0%)	41 (41.0%)	
Mayo Clinic Rochester	7 (7.5%)	1 (16.7%)	8 (8.0%)	
Pregnancy status				
Pregnant	76 (80.9%)	2 (33.3%)	78 (78.0%)	.02[‡]
- First trimester	9 (9.6%)	1 (16.7%)	10 (10.0%)	
- Second trimester	37 (39.4%)	0 (0.0%)	37 (37.0%)	
- Third trimester	30 (31.9%)	1 (16.7%)	31 (31.0%)	
Postpartum	18 (19.2%)	4 (66.7%)	22 (22.0%)	
Vital signs				
Systolic blood pressure	113.0 (105.3, 120.0)	106.0 (93.3, 118.0)	113.0 (104.8, 120.0)	.186
Diastolic blood pressure	70.0 (64.0, 75.0)	68.5 (62.3, 76.3)	70.0 (63.0, 75.3)	.788
Heart rate	76.0 (68.3, 85.0)	98.5 (84.3, 109.0)	76.5 (69.0, 86.3)	.01
Echocardiographic parameters				
LV end-diastolic diameter (mm)	46.0 (43.0, 49.0)	60.0 (57.3, 64.3)	46.0 (43.0, 50.0)	<.001
LV end-systolic diameter (mm)	30.0 (28.0, 33.0)	54.0 (49.3, 59.5)	30.0 (28.0, 33.0)	<.001
LV septal wall thickness (mm)	8.0 (8.0, 9.0)	7.5 (7.0, 8.8)	8.0 (8.0, 9.0)	.283
LV relative wall thickness (%)	38.0 (33.3, 42.0)	27.0 (25.3, 28.0)	37.0 (33.0, 42.0)	<.001
LV mass index (g/m^2)	73.0 (61.0, 80.0)	98.5 (86.3, 119.0)	73.5 (61.8, 82.3)	.008
LV posterior wall thickness (mm)	9.0 (8.0, 10.0)	8.0 (8.0, 8.0)	9.0 (8.0, 10.0)	.244
Mitral valve early diastolic filling velocity – E (m/s)	0.8 (0.7, 0.9)	1.1 (0.9, 1.3)	0.8 (0.7, 1.0)	.033
Medial mitral annulus velocity by tissue Doppler – e' (m/s)	0.11 (0.09, 0.12)	0.07 (0.07, 0.08)	0.10 (0.08, 0.12)	.001
Mitral valve E/e' ratio	7.8 (6.4, 9.0)	16.3 (11.3, 18.6)	7.8 (6.4, 9.2)	.001
Cardiac output – Doppler method (L/min)	5.6 (4.1, 6.2)	5.3 (4.9, 5.5)	5.6 (4.9, 6.1)	.437
Cardiac index – Doppler method (L/min/m^2)	3.0 (2.7, 3.4)	2.9 (2.7, 3.0)	3.0 (2.7, 3.4)	.379
Peak tricuspid valve regurgitation velocity (m/s)	2.0 (1.8, 2.3)	2.9 (2.7, 3.1)	2.1 (1.8, 2.3)	.007
Left atrial volume index (mL/m^2)	25.0 (21.0, 28.3)	28.0 (26.0, 31.0)	25.0 (21.0, 29.0)	.266
Right atrial volume index (mL/m^2)	19.0 (15.0, 23.1)	16.5 (14.0, 29.0)	18.9 (15.0, 23.2)	.943
LV global longitudinal systolic strain	-19.0 (-21.0, -18.0)	-9.5 (-10.8, -8.0)	-19.0 (-21.0, -18.0)	.001
LV geometry				
Normal	61 (64.9%)	2 (33.3%)	63 (63.0%)	.006
Concentric remodeling	23 (24.5%)	0 (0%)	23 (23.0%)	
Eccentric hypertrophy	9 (9.6%)	4 (66.7%)	13 (13.0%)	
Concentric hypertrophy	1 (1.1%)	0 (0%)	1 (1.0%)	
Diastolic function				
Normal	87 (92.6%)	2 (33.3%)	89 (89.0%)	.001
Abnormal	4 (4.3%)	2 (33.3%)	6 (6.0%)	
Indeterminate	3 (3.2%)	2 (33.3%)	5 (5.0%)	
Medical history				
Chronic hypertension	3 (3.2%)	0 (0%)	3 (3.0%)	1
Gestational hypertension	1 (1.1%)	2 (33.3%)	3 (3.0%)	.009
Preeclampsia	2 (2.1%)	2 (33.3%)	4 (4.0%)	.017
Gestational diabetes	5 (5.3%)	2 (33.3%)	7 (7.0%)	.055
Small for gestational age	3 (3.2%)	0 (0%)	3 (3.0%)	1
Preterm birth	2 (2.1%)	1 (16.7%)	3 (3.0%)	.171
Other	22 (23.4%)	2 (33.3%)	24 (24.0%)	.628
Pregnancy outcome				

(Continued)

Table 1   *(Continued)*

	Normal LV systolic function (n=94)	LV systolic dysfunction[†] (n=6)	Overall	*P* values
Live birth (single)	77 (81.9%)	5 (83.3%)	82 (82.0%)	.139
Live birth (multiple)	1 (1.1%)	1 (16.7%)	2 (2.0%)	

Median, 25th percentile (Q1), and 75th percentile (Q3) reported for all numeric variables.
Frequency counts and percentages reported for categorical variables.
LV = left ventricular.
[†]LV systolic dysfunction is defined as left ventricular ejection fraction <50%.
[‡]Fisher's exact *P* value computed for the comparison of pregnant vs postpartum. The enumeration of the stage of pregnancy was not used in the analysis.

significant. All analysis were performed using R version 4.0.3 (Vienna, Austria).[23]

Results

One hundred pregnant and postpartum women were included in the final analysis. At the time of enrollment, 78% were pregnant and 22% were within 12 months postpartum. Summary sample characteristics are provided in Table 1. The median age of participants was 31 years (Q1: 27, Q3: 34). Thirty-eight percent identified as non-Hispanic White, 32% as non-Hispanic Black, 21% as Hispanic, and 9% as other (comprising 6% Asian, 2% multiracial, and 1% Native Hawaiian/Pacific Islander). Five percent and 6% had LVEF <45% and <50%, respectively.

Twelve-lead ECG

The AI-ECG model had excellent classification performance for detection of cardiomyopathy at both LVEF categories (<45% and <50%), correctly identifying all cases of LVSD in our study sample and achieving near-perfect discrimination (Figure 3A–3D, Supplemental Table 1). At the LVEF <50% threshold, all 100 participants were correctly classified (AUC 1.0, sensitivity and specificity were 100%). At LVEF <45%, AUC was 1.0, sensitivity was 100%, and specificity was 98.9%. Overall accuracy was 99% (99/100; 95% CI: 94.6%–100.0%), with the 1 misclassified individual having an LVEF of 49% and classified as a false positive. Standard 12-lead ECG tracings are shown in Figure 4 for a patient with LVEF of 35% and another with LVEF 66%. These are shown side by side to demonstrate the similarity between both ECGs on visual appreciation. Although minor differences are appreciated on the ECGs, a formal cardiologist's clinical interpretation of the ECGs would be insufficient for definite determination of low LVEF status.

Digital stethoscope with AI-enabled single-lead ECG and phonocardiogram

Across all 3 stethoscope positions, diagnostic performance was robust. The number of evaluable ECGs by position, however, varied, with 99, 98, and 96 participants providing ECG signals for the V2, angled, and subclavicular positions, respectively. Of the 3 positions, the angled position for the digital stethoscope provided the numerically highest discrimination, with AUC of 0.987 (95% CI: 0.967, 1.00) for both

the detection of LVEF <50% (Supplemental Table 2) and LVEF <45% (Supplemental Table 3). To provide predictions for all participants, the diagnostic performance for the mean and maximum model outputs over the 3 positions was also considered. For the maximum model output, which would have the highest sensitivity of any of the combinations of positions, the AUC, sensitivity, and specificity were 0.968 (95% CI: 0.934, 1.000), 100.0% (95% CI: 54.1%, 100.0%), and 90.4% (85/94; 95% CI: 82.6%, 95.5%) for LVEF <50% (Supplemental Figure 1A and 1B). Model performance metrics for all other stethoscope positions and LVEF thresholds are provided in Supplemental Tables 2–4. A subgroup analysis was performed and showed stable performance of the AI model by age and race/ethnicity categories (Supplemental Figure 2) at both LVEF thresholds (<45% and <50%). The model outputs from both the 12-lead ECG and digital stethoscope recordings appear to be appropriately correlated with LVEF and other lead/device configurations (Supplemental Figure 3).

Discussion

This pilot prospective study of an AI-powered screening tool for LVSD among pregnant and postpartum women had 3 main findings. First in this US-based population, pregnancy-related cardiomyopathy was relatively common, impacting 6% of consecutive women enrolled in the study (4 diagnosed with peripartum cardiomyopathy and 2 with dilated cardiomyopathy). Second, a standard 12-lead ECG, a ubiquitous, inexpensive test that is integrated in clinical workflows, was a powerful screening test for LVSD among pregnant and postpartum women with the addition of AI analysis, demonstrating near-perfect discrimination in this cohort (AUC = 1.0). Third, a digital stethoscope with single-lead ECG recording capability combined with a phonocardiogram recording had a similarly strong performance (AUC = 0.987). These findings, if confirmed in larger studies, would support widespread screening for this important condition that impacts young women and children.[24]

The frequency and clinical impact of LVSD occurring during pregnancy or postpartum is incompletely understood. Studies have suggested that peripartum cardiomyopathy is likely under-recognized and underdiagnosed.[25] Its incidence varies in different patient populations, with the highest estimates reported in predominantly Black populations (1 in 100 deliveries in Nigeria and 1 in 300 deliveries
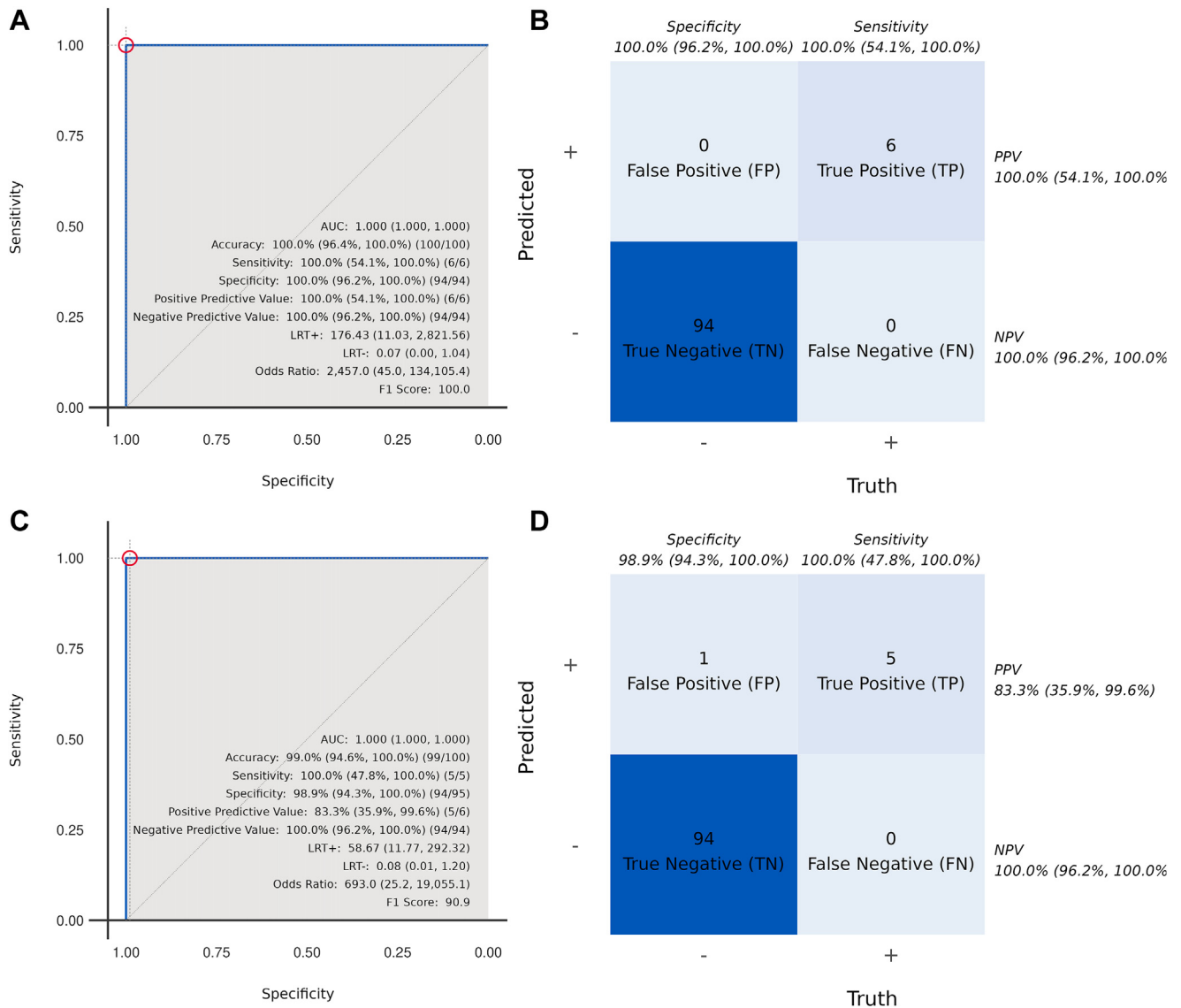
Figure 3   Twelve-lead electrocardiogram (ECG) receiver operating characteristic (ROC) curves and confusion matrix. **A, B:** ROC curve (**A**) and confusion matrix (**B**) for detection of left ventricular ejection fraction (LVEF) <50% using a 12-lead artificial intelligence–enabled ECG (AI-ECG) algorithm among pregnant and postpartum women. **C, D:** ROC curve (**C**) and confusion matrix (**D**) for detection of LVEF <45% using 12-lead AI-ECG algorithm among pregnant and postpartum women. The 1 false-positive case had an ejection fraction of 49%.

in Haiti).[25,26] The incidence of peripartum cardiomyopathy in the United States was estimated at approximately 1 in 850 live births based on the National Inpatient Sample (NIS) data from 2011, which is up from approximately 1 in 1200 in 2004.[26] Among women aged 40 and older, the incidence is reported to be as high as 1 in 270 live births.[27] It is important to detect and initiate appropriate therapy for cardiomyopathy early owing to the high risk (up to 13%) for severe maternal morbidity (left ventricular assist device placement or heart transplantation) and mortality,[28] with important implications for the infant as well. Novel clinical approaches and tools, such as the AI-powered ECG, are needed to help identify disease sooner in an effort to help decrease maternal and fetal morbidity and mortality related to this condition. The presented screening approach, which leverages the ECG enhanced with AI and confirmatory eval-

uation by echocardiogram if an AI-positive flag is obtained, has been demonstrated to be cost effective.[29]

Current guidelines from the American College of Cardiology and the American College of Obstetrics and Gynecology (ACOG) do not recommend routine screening for any cardiomyopathy in the obstetric population. This may in part reflect the current need for expensive imaging tests (echocardiogram, computed tomography, or magnetic resonance imaging) that can include radiation or high-magnetic-force exposure to mother and fetus, making such screening impractical. The availability of an ECG-based AI screen may change the equation. This study provides important preliminary data supporting the use of AI-powered tools for cardiovascular screening during pregnancy.

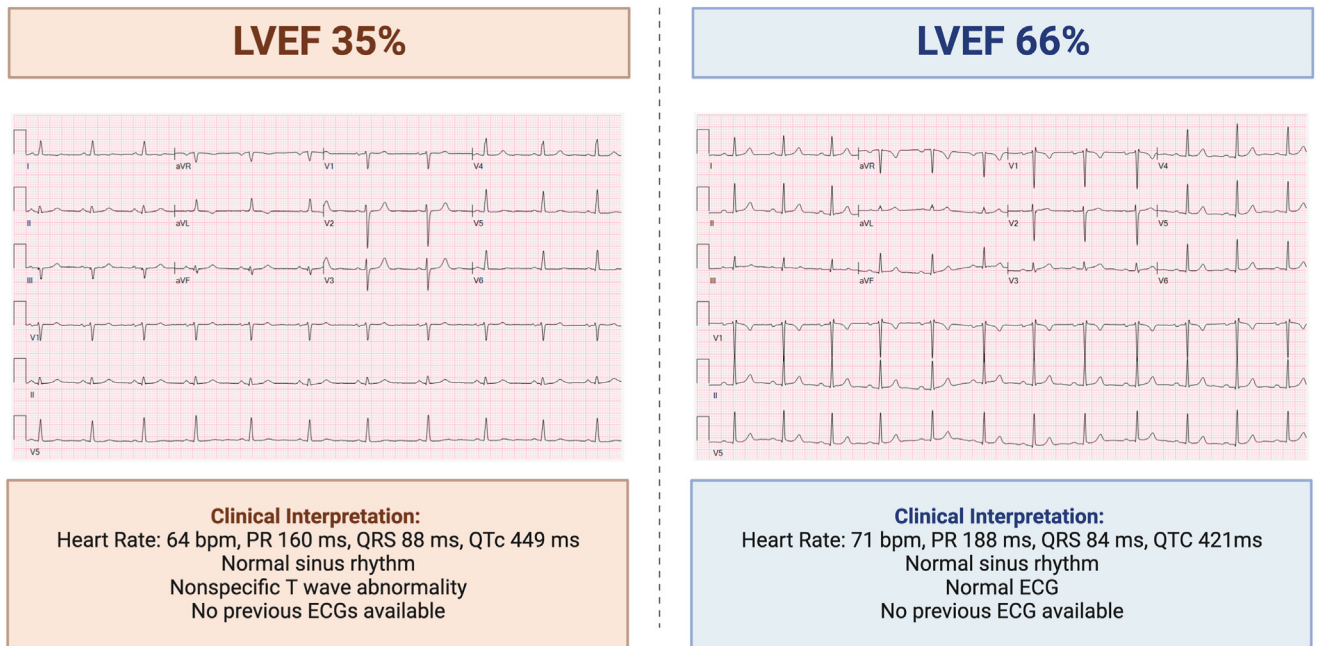The performance of both the 12-lead ECG and digital stethoscope significantly exceeded the strong performance

Figure 4 Standard 12-lead electrocardiogram (ECG) examples. ECG tracings for 2 patients in our study sample, with clinical interpretations: 1 with left ventricular ejection fraction (LVEF) of 35% (AI-predicted probability 0.796) and the other with LVEF of 66% (AI-predicted probability 0.180). The previously determined AI-predicted probability threshold for a positive flag is 0.256.

previously reported in retrospective[7] and prospective[16] studies of the same algorithm that included older, general patient populations. In contrast to previous studies, in which individuals with normal ventricular function (control) had many comorbidities such as hypertension, diabetes, hyperlipidemia, and renal dysfunction, the control subjects in the present study were younger and healthier. This likely facilitated the ability of the AI-ECG to powerfully classify normal from abnormal ventricular function. We have previously demonstrated the ability of AI analysis of a single-lead ECG from a watch to detect ventricular dysfunction,[19] with only minimal loss in test performance compared to the 12-lead model. Thus, it was not surprising to find a similar very modest degradation of test performance using the digital single-lead ECG stethoscope recording. Prior to the implementation of AI models in clinical practice, it is essential that they be thoroughly validated in populations in which they are intended for use,[30] with prospective validation studies being an important step, as well as ensuring dataset diversity for model training and validation.[31,32]

While routine screening is not recommended, the ACOG guidelines do recommend a cardiovascular toolkit be used to risk-stratify patients with suspected cardiovascular disease.[5] This toolkit uses a combination of symptoms, vital signs, risk factors from medical history, and physical examination findings to determine risk, and, based on a combination of these, an ECG and natriuretic peptide measurement are the recommended first-line screening tests.[33,34] Clinical interpretation of the ECG alone is insufficient for identification of LVSD, and natriuretic peptide levels are known to vary by pregnancy trimester[35] and can be altered by obesity[36,37] or preeclampsia.[38]

Our study leverages the ECG, a simple, effective, scalable, and cost-effective screening tool to screen for LVSD in the obstetric population. Our team has previously evaluated the effectiveness of the AI-ECG for detection of LVSD in a retrospective sample of pregnant and postpartum women seen at Mayo Clinic, demonstrating its effectiveness (AUC = 0.92) and that it outperformed natriuretic peptides.[15] In addition, the current study evaluated a portable device, the digital stethoscope, as an alternative to the standard 12-lead ECG and showed it remained effective, thus providing an alternate option for obstetric cardiovascular screening in clinical settings, nonclinical settings, and low-resource settings. While 12-lead ECGs are readily available in standard cardiovascular outpatient and in-patient practices, this may not necessarily be the case in obstetric care settings, particularly in the outpatient clinics. As such, the ability to use a portable device in various health care settings as well as for remote/virtual care or in the community can have a profound impact as a public health intervention. The diagnostic performance of the AI-ECG for detection of left ventricular dysfunction is notably impressive when compared to screening tests used in routine clinical care, such as mammography,[39] pap smear,[40,41] and natriuretic peptide screening for heart failure,[19] with AUC values ranging from 0.71 to 0.85. The AI-ECG also demonstrates superior diagnostic performance when compared to commonly used diagnostic tests in cardiovascular medicine, such as SPECT myocardial perfusion imaging for detection of obstructive coronary disease (AUC = 0.87 based on a meta-analysis)[42] and stress echocardiography (AUC = 0.73–0.84).[43]

A key limitation of this study is the relatively small sample size with a low number of participants having LVSD, as

such model performance needs to be interpreted cautiously in this context. In addition, the low number of cases limits subgroup analysis (including age and race categories), with less precise confidence intervals around calculated estimates of diagnostic performance. The sample for this study was intentionally small to allow for the initial examination of the AI-ECG algorithm in pregnant and postpartum women. The sample size justification used a lower threshold of AUC = 0.5 to allow for any discrimination above chance to be considered evidence that the algorithm shows some diagnostic performance in this population. As such, a positive signal in this study would warrant a larger, more comprehensive study.

Strengths include the use of standard and portable ECG recordings for AI-based cardiomyopathy prediction, targeted enrollment of a racially and ethnically diverse group of women, and performance of the ECGs on the same day as or (in 1 patient) within 24 hours of the echocardiogram, which allows for an almost simultaneous assessment of the AI-based predictions with echo-based left ventricular function assessment.

Conclusion

In this pilot prospective study, we found that a 12-lead AI-ECG and an AI-enabled digital stethoscope (single-lead ECG + phonocardiogram) are powerful screening tools for LVSD in obstetric patients, a treatable, under-recognized condition with significant morbidity and mortality. This suggests AI-ECG tools may provide powerful point-of-care screening for pregnant and postpartum women.

Disclosures

Drs Attia and Friedman are co-inventors of several AI algorithms (including screening for low LVEF, QT tool, aortic stenosis, atrial fibrillation detection during normal sinus rhythm). These have been licensed to Anumana, AliveCor, and Eko. Mayo Clinic, Dr Attia, and Dr Friedman may benefit from their commercialization. Dr Noseworthy, Dr Lopez-Jimenez, and Mayo Clinic have filed patents related to the application of AI to the ECG for diagnosis and risk stratification and have licensed several AI-ECG algorithms to Anumana. Dr Noseworthy and Mayo Clinic are involved in potential equity/royalty relationship with AliveCor. Dr Noseworthy is a study investigator in an ablation trial sponsored by Medtronic and has served on an expert advisory panel for OptumLabs. All other authors have no conflicts to disclose.

Role of the Funding Source

Miami Heart Research Institute and Eko Health had no role in the study design and conduct; data collection, management, analysis, and interpretation; manuscript preparation, review, or approval; and decision to submit the manuscript for publication.

Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author. All requests for raw and analyzed data and related materials, excluding programming code, will be reviewed by the Mayo Clinic legal department and Mayo Clinic Ventures to verify whether the request is subject to any intellectual property or confidentiality obligations. Requests for patient-related data not included in the paper will not be considered. Any data and materials that can be shared will be released via a Material Transfer Agreement.

Appendix
Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.cvdhj.2024.03.005.

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