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An artificial intelligence electrocardiogram analysis for detecting cardiomyopathy in the peripartum period

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ABSTRACT

Background: Peripartum cardiomyopathy (PPCM) is a fatal maternal complication, with left ventricular systolic dysfunction (LVSD; Left ventricular ejection fraction 45% or less) occurring at the end of pregnancy or in the months following delivery. The scarcity of screening tools for PPCM leads to a delayed diagnosis and increases its mortality and morbidity. We aim to evaluate an electrocardiogram (ECG)-deep learning model (DLM) for detecting cardiomyopathy in the peripartum period.

Methods: For the DLM development and internal performance test for detecting LVSD, we obtained a dataset of 122,733 ECG-echocardiography pairs from 58,530 male and female patients from two community hospitals. For the DLM external validation, this study included 271 ECG-echocardiography pairs (157 unique pregnant and postpartum period women) examined in the Ajou University Medical Center (AUMC) between January 2007 and May 2020. All included cases underwent an ECG within two weeks before or after the day of transthoracic echocardiography, which was performed within a month before delivery, or within five months after delivery. Based on the diagnostic criteria of PPCM, we analyzed the area under the receiver operating characteristic curve (AUROC), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) to evaluate the model effectiveness.

Results: The ECG-based DLM detected PPCM with an AUROC of 0.877. Moreover, its sensitivity, specificity, PPV, and NPV for the detection of PPCM were 0.877, 0.833, 0.809, 0.352, and 0.975, respectively.

Conclusions: An ECG-based DLM non-invasively and effectively detects cardiomyopathies occurring in the peripartum period and could be an ideal screening tool for PPCM.

1. Introduction

Peripartum cardiomyopathy (PPCM) is a life-threatening cardiovascular disease linked to pregnancy. It accounts for 23% of maternal deaths from cardiovascular disease in the late postpartum period [1]. However, the pathophysiology of PPCM has not been fully explained. According to previous PPCM criteria [2], PPCM is diagnosed as cardiac failure in the last month of pregnancy or within five months of delivery. In addition, patients' left ventricular ejection function (LVEF) is checked via echocardiography to determine whether it is 45% or less. Later, several studies have shown that cardiomyopathy can occur earlier or later during pregnancy than the previously given time window (one month before and five months after delivery). Therefore, the definition of PPCM was revised by Heart Failure Association of the European Society of Cardiology Working Group in 2010 to remove the former timeline cut-offs to avoid underdiagnosing PPCM. The incidence of PPCM varies by the ethnic composition and local demographics of areas. There is an estimated 1 case per 3000–4000 births in the United States

[3,4]. However, Haiti reported a significantly higher incidence, with 1 case per 300 live births [5] and 1 case per 1741 deliveries in South Korea [6]. Moreover, African ancestry [3,7,8], multi-gestation [9–12], an older age [7,8,13], preeclampsia, and hypertensive disease [2,6,8–10] are all known to be factors that can elevate the risk of PPCM.

Despite such a high prevalence, PPCM has been frequently under-diagnosed because of the under-recognition of the disease and the similarity to signs and symptoms of normal pregnancy and heart failure [14]. The symptoms of PPCM patients overlap with those of women with heart failure after normal delivery, such as shortness of breath on exertion, fatigue, orthopnea, paroxysmal nocturnal dyspnea, edema, and chest tightness. These ambiguous clinical symptoms lead to under-recognition of this disease by both patients and physicians, which prevents on-time diagnosis [14]. A delay in diagnosis contributes to higher mortality and increased risk of preventable complications [13,15,16].

To compensate for the high mortality linked to delayed diagnoses, the American College of Obstetricians and Gynecologists (ACOG) recommends the California CVD Tool Kit algorithm to screen groups at high risk of PPCM in one of its 2019 Practice Bulletins [17]. This algorithm suggests that individuals who are in the high-risk groups should receive an electrocardiogram (ECG) and screening for b-type natriuretic peptide (BNP) levels. However, the few, previous studies present conflicting opinions of ECGs on PPCM diagnosis. Honigberg et al. [18] show that ECG has a low sensitivity for PPCM diagnosis, but a recent study from the Mayo Clinic by Adedinsewo et al. [19] demonstrates the high performance of ECG-based deep learning models in left ventricular dysfunction in perinatal women.

To date, few studies have investigated the utility of ECG-based deep learning models for PPCM. The only previous DLM study for PPCM [19] was not externally validated and included a small subset of individuals of Asian ethnicity. Therefore, our study aims to derivate an ECG-based DLM detecting cardiomyopathies occurring in the peripartum period in a predominantly Asian population with external validation. As per the classic PPCM criteria, only patient echocardiographies done in the last month of pregnancy or within five months of after delivery were included in the analysis.

2. Methods

2.1. Study population and setting

To develop DLMs to detect patients with decreased LVEF, we extracted ECGs and echocardiography data (September 2016 to April 2021) using electronic medical records (EMRs) and picture archiving and communication systems from A and B hospitals [SJHs](A hospital: Bucheon Sejong Hospital, Bucheon, Republic of Korea, B hospital: Mediplex Sejong Hospital, Incheon, Republic of Korea). Patients with decreased LVEF were classified using the modified biplane Simpson's method. The interval between ECG and echocardiography was set to within 14 days before and after either procedure. Data for the DLMs' development included both genders and pregnant women.

To perform external validation of the developed DLM, we included all women over 18 years old who were in the Ajou University Medical Center (AUMC, Suwon, Republic of Korea) delivery registry between January 2007 and May 2020. If a patient delivered more than once, only the first delivery case was used. We extracted ECG XML with 500 Hz waveform from the MUSE ECG data management system (GE healthcare, Wisconsin, USA). We also extracted the LVEF parameter (calculated from modified biplane Simpson's method) from transthoracic echocardiography reports. For the external validation test, women were included if they had an echocardiography within a month before the delivery or within five months after the delivery and had at least one ECG within two weeks before or after the day of transthoracic echocardiography. In addition, a sensitivity analysis was performed with ECG-Echocardiography pairs which has the closet ECG to echocardiography. All diagnosis dates were between January 2007 and May 2020.

We excluded patients with pre-existing or newly confirmed structural heart disease or coronary artery disease. Structural heart disease includes valvular heart disease, congenital heart disease, and chronic heart failure which had been previously diagnosed.

The study was approved by institutional review boards (IRBs) of AUMC (AJIRB-MED-MDB-21-362) and ISH (ISH-2021-0282). The IRBs waived the need for informed consent because of the retrospective nature of the study, the fully anonymized dataset applied, and the minimal risk to the patient.

2.2. Study data and outcomes

Patients' demographics, medical history, laboratory data, and perinatal medication history were all extracted from AUMC's EMR. The primary outcome of this study was the performance of the DLM in identifying PPCM using the clinical cut-off value (LVEF of 45% or less). The secondary outcome of this study was to analyze our DLM with various decreased LVEF cut-offs: 35% or less, 40% or less, and 50% or less. To establish the DLM, we used the PPCM criteria, which was established in 1971: echocardiography performed from one month before childbirth to within five months after childbirth reveals an LVEF of 45% or less without explicit causes, such as previous structural heart disease [2].

2.3. Deep learning models

To accomplish outcomes, we created four types of DLMs with the same architecture but different hyperparameters. The architecture of our DLMs comprises three modules. The first module represents the latent features for ECGs. It consists of multiple residual blocks [20], each of which has two submodules. Each module has two sets of a one-dimensional convolutional neural network (Conv1D), batch normalization (BatchNorm1d), and rectified linear unit activation (ReLU), with a dropout layer (Dropout) at the rear. The first submodule has only skip-connection. The second module has a single fully connected layer (FC) extracting additional latent features for patient information, such as age, sex, weight, and height. The final module also includes a single FC to yield the probability of lower ejection fraction at a cut-off value of 45% using the combination of two latent features (Supplementary file 1).

To train the model to classify patients with decreased LVEF, we used data from two general hospitals (SJHs). Firstly, we split the dataset into a ratio of 8:1:1 and then performed the internal validation. We used an Adam optimizer, a receiver operating characteristic (ROC) loss function [21], and a cosine annealing warm-up restarts scheduler. As preprocessing at the training stage, we down-sampled the sampling rate of ECGs from 500 Hz to 250 Hz and transformed the ECGs using data-augmentation applying diverse noises. All ECGs were normalized. We performed the external validation on the cohort of pregnant women in AUMC using the developed DLMs. Additionally, to investigate the effects of classifications on the decision-making ability of our models, we used gradient-weighted class activation mappings (Grad-CAM) to generate saliency maps [22]. All experiments were conducted on 20 NVIDIA DGX Systems equipped with NVIDIA A100 graphics processing units. All codes were implemented using PyTorch 1.8 and Python 3.8.

2.4. Statistical analysis

The performances of the DLM were measured by sensitivity, specificity, PPV, and NPV with 95% confidence intervals (95% CIs) for primary and secondary outcomes. The calculation for the area under the receiver operating characteristic curve (AUROC) with 95% CIs and the ROC curve analysis was also performed with Youden's J statistics. Variables were compared using Student's *t*-test, Mann–Whitney *U* test, Chi-square test, and Fisher's exact test as appropriate. A *p*-value <0.05 was considered significant. All analyses were performed using the R software, version 4.1.0 (R Foundation for Statistical Computing, Vienna,
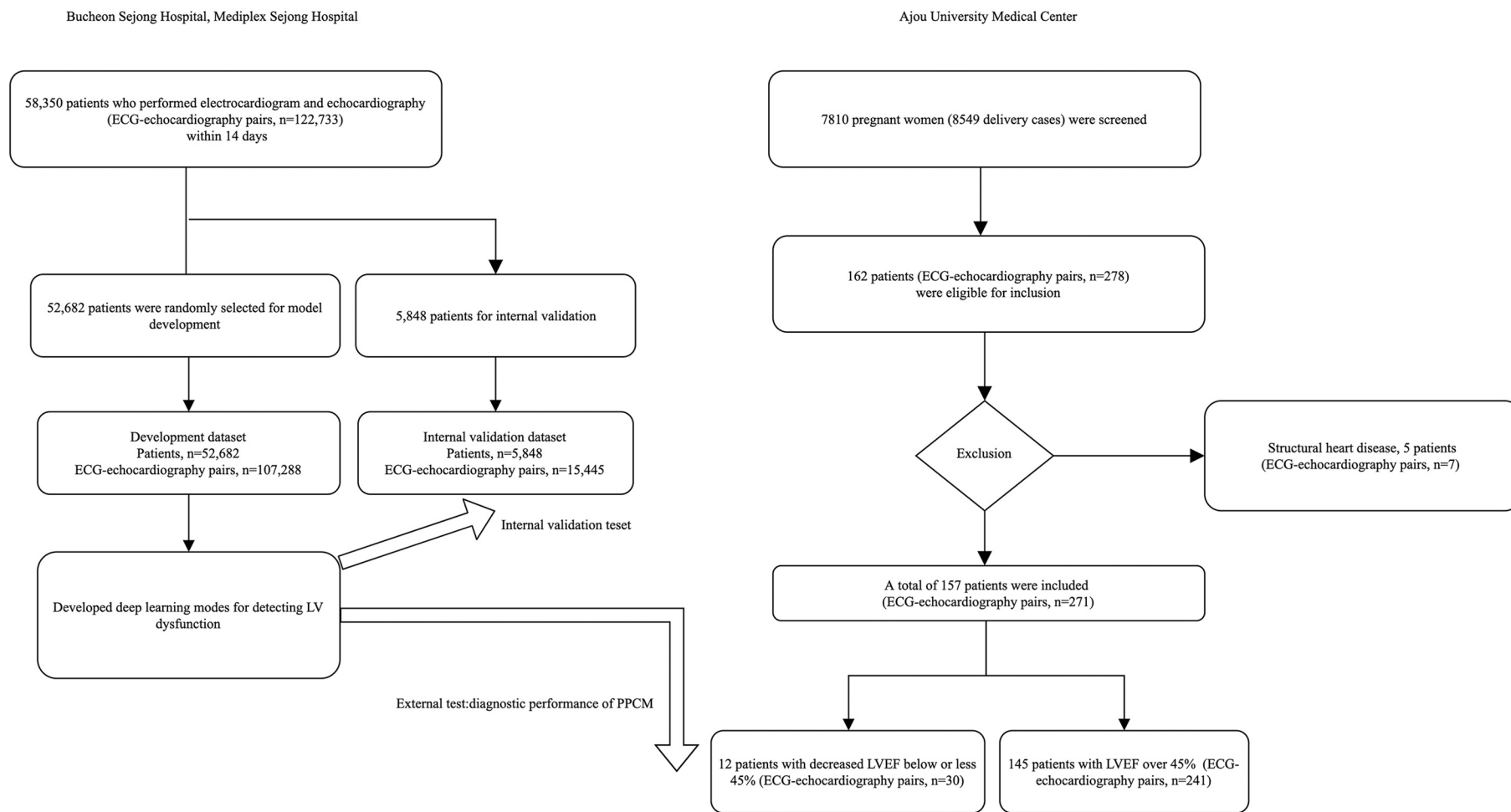
Bucheon Sejong Hospital, Mediplex Sejong Hospital

Ajou University Medical Center

Fig. 1. Study design and patient flow.

Left: study population for DLM development and internal validation in two general hospitals.

Right: study population for DLM in identifying PPCM from AUMC.

AUMC, Ajou University Medical Center; ECG, electrocardiogram; DLM, deep learning model; LV, left ventricular; LVEF, left ventricular ejection fraction; PPCM, peripartum cardiomyopathy.

Table 1
Baseline characteristics.

	Missing	Total (*n* = 157)	LVEF ≤45% (*n* = 12)	LVEF >45% (*n* = 145)	p-value
Demographics					
Age, mean (SD)	0	33.4 (4.3)	32.9 (5.0)	33.5 (4.3)	0.715
Old age (>35 years), n (%)	0	50 (31.8)	3 (25.0)	47 (32.4)	0.753
BMI, kg/m², mean (SD)	0	27.59 (4.5)	27.6 (4.4)	28.1 (5.2)	0.730
Medical history					
Primiparity, n (%)	45	54	6 (66.7)	48 (46.6)	0.309
Multiparity, n (%)		58	3 (33.3)	55 (53.4)	
Cesarean section, n (%)	0	14 (8.9)	2 (16.7)	12 (8.3)	0.291
Normal delivery, n (%)	0	143 (91.1)	10 (83.3)	133 (91.7)	
Preterm labor, n (%)	0	28 (17.8)	3 (25.0)	25 (17.2)	0.450
Diabetes, n (%)	0	10 (6.4)	2 (16.7)	8 (5.5)	0.171
Chronic hypertension, n (%)	0	15 (9.6)	1 (8.3)	14 (9.7)	1.000
Gestational hypertension, n (%)	0	44 (28.0)	4 (33.3)	40 (27.6)	0.740
Preeclampsia, n (%)	0	33 (21.0)	4 (33.3)	29 (20.0)	0.279
Eclampsia, n (%)	0	1 (0.6)	1 (8.3)	0 (0.0)	0.076
Laboratory findings					
BNP, pg/mL, mean (SD)	146	839.1 (1145.6)	1547.0 (1438.2)	249.2 (227.0)	0.114
proBNP, pg/mL, mean (SD)	139	3261.8 (5075.3)	3135.2 (940.9)	3297.9 (5785.7)	0.921
pre-Hb, g/dL, mean (SD)	59	11.4 (2.1)	11.6 (3.1)	11.3 (1.9)	0.830
post-Hb, g/dL, mean (SD)	2	9.9 (1.9)	9.2 (2.4)	9.9 (1.9)	0.362
Medications					
Magnesium sulfate, n (%)	0	53 (33.8)	6 (50.0)	47 (32.4)	0.222
Labetalol, n (%)	0	11 (7.0)	1 (8.3)	10 (6.9)	0.595
Hydralazine, n (%)	0	39 (24.8)	5 (41.7)	34 (23.4)	0.174
Nifedipine, n (%)	0	31 (19.7)	5 (41.7)	26 (17.9)	0.061
Aspirin, n (%)	0	5 (3.2)	1 (8.3)	4 (2.8)	0.332
Ritodrine, n (%)	0	19 (12.1)	0 (0.0)	19 (13.1)	0.363
Atosiban, n (%)	0	4 (2.5)	0 (0.0)	4 (2.8)	1.000

% values exclude missing values.
LVEF, left ventricular ejection fraction; BMI, body mass index; BNP, b-type natriuretic peptide; pre-Hb, pre-delivery.
or pre-operative hemoglobin level; post-Hb, post-delivery or post-operative hemoglobin level; SD, standard deviation.

Austria).

3. Results

3.1. Study flow and baseline characteristics

Among 8549 delivery cases, 278 electrocardiogram-echocardiography pairs were eligible for inclusion during the study period. We excluded seven pairs (five patients). Patients were excluded on the basis of the following conditions, aortic stenosis (*n* = 1), mitral stenosis (*n* = 1), mitral regurgitation or prolapse (*n* = 2), and chronic heart failure with atrioventricular septal defect (n = 1). Finally, we included a total of 271 pairs (157 pregnant and postpartum women) for the main study population (Fig. 1).

The mean age of enrolled patients was 33.4 years, and 50 patients (31.8%) were > 35 years of age. Excluding the 45 patients with no recorded obstetrical history, primiparity and multiparity were 48.2%

and 51.8%, respectively. The demographics and medical history were not significantly different between the non-PPCM group and the PPCM group (Table 1).

3.2. The development and internal validation of DLMs

DLMs were developed using the dataset consisting of 107,288 ECGs of 52,682 male and female patients in SJHs. The internal validation test was conducted using the internal test dataset of 15,445 ECGs from 5848 male and female patients in SJH. (Fig. 1) The baseline characteristics of the development cohort used in developing the DLM are shown in Supplementary file 2. During the internal validation test, the AUROC, sensitivity, specificity, PPV, and NPV of the DLM for the detection of heart failure with LVEF of 45% or less were 0.896 (95% CI, 0.890–0.903), 0.796 (95% CI, 0.781–0.811), 0.841 (95% CI, 0.835–0.848), 0.533 (95% CI, 0.518–0.548), and 0.948 (95% CI, 0.944–0.952), respectively (Supplementary files 3, 4).

3.3. Main outcomes: external validation of DLMs

Regarding the cut-off value for PPCM diagnosis, the AUROC of our DLM to detect PPCM at an LVEF of 45% or less was 0.877 (95% CI, 0.803–0.952) (Fig. 2). In addition, sensitivity, specificity, PPV, and NPV were 0.833 (95% CI, 0.700–0.967), 0.809 (95% CI, 0.760–0.859), 0.352 (95% CI, 0.241–0.463), and 0.975 (95% CI, 0.953–0.997), respectively (Table 2). The performance of the DLM for the secondary outcomes is described in Table 2.

3.4. Sensitivity analysis

Sensitivity analysis was performed within 157 ECG-Echocardiography pairs by selecting only 157 ECGs closest to the time point of echocardiography among all ECGs included in 271 ECG-Echocardiography pairs. In the sensitivity analysis, AUROC, sensitivity, specificity, PPV, and NPV to detect PPCM at an LVEF of 45% or less were 0.863 (95% CI, 0.760–0.966), 0.818 (95% CI, 0.590–1.046), 0.833 (95% CI, 0.772–0.894), 0.273 (95% CI, 0.121–0.425), and 0.984 (95% CI, 0.961–1.006), respectively.

4. Discussion

We developed a DLM to predict cardiomyopathy using a general unselected patient population and then performed an external validation among 157 pregnant and postpartum women. The results of this study are consistent with those of previous studies of ECG-based DLM that effectively detected cardiomyopathy [23,24]. When it comes to cardiomyopathies associated with pregnancy, ECG-based DLM have rarely been performed. During pregnancy, hemodynamic and structural changes occur. Along with the structural changes of the left ventricle, hormonal changes contribute to an increase in plasma volume and cardiac output as well as a decline in systemic vascular resistance [17,25]. ECG changes have also been reported during pregnancy, including increased heart rate, changes in the QRS axis, nonspecific ST-segment changes, and changes in the T-wave axis [26,27]. Given the distinct features of pregnancy, a study was necessary to show the suitability of an ECG-based DLM for pregnant patients compared with its effectiveness for ordinary patients. In August 2021, Adedinsewo et al. conducted a study at the Mayo Clinic and reported that ECG-DLM effectively detects cardiomyopathy related to pregnancy [19]. Our model achieved an AUROC of 0.877 in the external validation test (LVEF 45% or less) compared with Mayo Clinic's AUROC of 0.89 (LVEF <45%); both studies manifest excellent performance of the DLM in the pregnancy group.

We set the three additional cut-off values (EF of 35, 40, and 50%) for secondary outcomes to secure the robustness of this algorithm. In the internal validation test, the lower the LVEF cut-off is, the better DLM
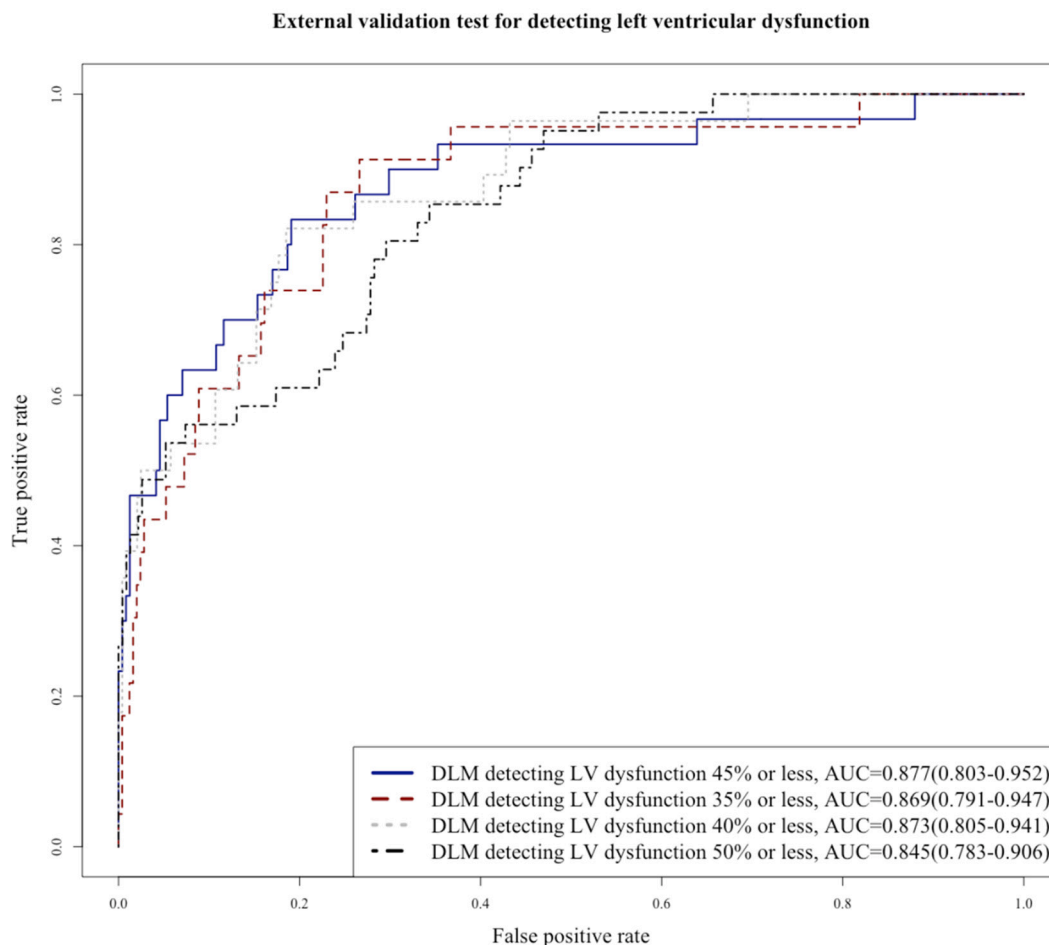
External validation test for detecting left ventricular dysfunction

Fig. 2. DLM performance on primary and secondary outcomes (external validation).
Receiver operating characteristic curves for identification of PPCM at pre-specified LVEF values. Primary outcome: LVEF ≤45%; Secondary outcome: LVEF <35%, 40%, and 50%. AUC indicates area under the receiver operating characteristic curve.
DLM, deep learning model; PPCM, peripartum cardiomyopathy; LVEF, left ventricular ejection fraction.

Table 2
Primary and secondary outcomes (external validation).

		AUROC (95% CIs)	Sensitivity (95% CIs)	Specificity (95% CIs)	PPV (95% CIs)	NPV (95% CIs)
Primary outcome	LVEF 45% or less	0.877 (0.803–0.952)	0.833 (0.700–0.967)	0.809 (0.760–0.859)	0.352 (0.241–0.463)	0.975 (0.953–0.997)
Secondary outcome	LVEF 35% or less	0.869 (0.791–0.947)	0.913 (0.798–1.028)	0.734 (0.679–0.789)	0.241 (0.151–0.331)	0.989 (0.974–1.004)
	LVEF 40% or less	0.873 (0.805–0.941)	0.821 (0.680–0.963)	0.815 (0.766–0.864)	0.338 (0.226–0.451)	0.975 (0.954–0.997)
	LVEF 50% or less	0.845 (0.783–0.906)	0.854 (0.745–0.962)	0.657 (0.595–0.718)	0.307 (0.222–0.392)	0.962 (0.932–0.992)

AUMC, Ajou University Medical Center; AUROC, area under receiver operating characteristic curve; CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value; LVEF, left ventricular ejection fraction.

detects LVSD (Supplementary file 4.). We run this test with these extra cut-offs in pregnant women to see whether this finding is also seen in a different group. However, we failed to detect this trend in the pregnant women. The DLM reveals statistically similar efficacy throughout these cut-offs in pregnant women, yet it shows the highest efficacy at a cut-off value of 35% in a general population of internal validation test. Given the broad 95% CIs range of secondary outcomes in pregnant women, this dissimilarity may be attributed to a small case number.

A major strength of this study compared with the Mayo Clinic study is that the ECG-based DLM was externally validated using an entirely different patient population in a different institution. Moreover, this study population is composed of a homogeneous race: all the women were of Korean nationality. Considering that the prior study included only a small number of Asian women, despite the known racial variance

in AUROC (highest AUROC among Black women: 0.93), this study shows the effectiveness of the DLM in the Asian demographic. Lastly, this study model strictly follows the PPCM criteria. According to an Investigation in Pregnancy Associate Cardiomyopathy (IPAC) study [22], most patients with LVSD recovered within six months after delivery.

Despite multiple previous studies of PPCM patients showing ECG abnormalities: T-wave abnormalities with flattening or inversions [18], ST-T abnormality [28], ECG has been known as an unreliable screening tool for PPCM prediction since normal ECG is also commonly found in PPCM patients [18]. The performance of ECG-DLM in detecting cardiomyopathy in the peripartum period can help clinicians decide whether further evaluation such as echocardiography is indicated. Considering echocardiography - an essential test for the diagnosis of PPCM - is not readily available in most local obstetric centers, this DLM

can be an important screening tool for PPCM using ECG data only. In addition, it can reduce the likelihood that obstetricians or midwives miss the optimal time to refer to cardiologists. In contrast to prior studies of the ECG in PPCM, where a significant number of "normal" ECGs were observed [18], ECG-DLM might have learned nonspecific ECG changes of PPCM patients that physicians might have not noticed.

This study has some limitations. First, because of its retrospective study design, it is vulnerable to selection bias. Second, the sample size of this study was too small to evaluate DLM segregated by several subgroups: advanced maternal age, multi-gestational pregnancy, and co-morbid pre-existing underlying conditions, such as hypertension and diabetes mellitus, which are considered as PPCM risk factors [14]. Moreover, we included overlapped ECG-Echocardiography pairs in the external validation set to amplify the test cases to make up for the small data volume. Therefore, we also performed a sensitivity analysis to compare this amplified pair test model (multiple ECG-Echocardiography pairs per person, $n = 271$) to the unamplified (the one ECG-Echocardiography per person test, $n = 157$). AUROC was comparable in both tests (0.863 in n = 157, 0.877 in n = 271). Although, due to lower number, the one ECG-Echocardiography per person test has a larger 95% CI range than the multiple pair per person test (0.760–0.966 in n = 157, 0.803–0.952 in n = 271). Third, we validated the DLM model using retrospective data. Future multicenter, large clinical trials including prospective studies are required to confirm the feasibility of this model to aid in the early diagnosis of PPCM in various clinical settings. Lastly, the DLM has a technical limitation, the so-called black box. The decision and learning process of the DLM is veiled. Although we applied a gradient map to solve this issue, we could not explain what distinctive features of the ECG contributed to the detection of PPCM. Further research is needed to unveil the black box.

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YJL (Gangdong Miz Women's Hospital), RWP, UJ, SY, and BC (Ajou University School of Medicine) declare no competing interests. JMK, YYJ, and MSL are researchers of Medical AI Co., a medical artificial intelligence company. There are no products in development or marketed products to declare. This does not alter our ability to conduct the study and report its findings without bias.

CRediT authorship contribution statement

Ye Ji Lee: Conceptualization, Methodology, Investigation, Writing – original draft, Writing – review & editing. **Byungjin Choi:** Software, Formal analysis, Data curation, Writing – review & editing. **Min Sung Lee:** Conceptualization, Methodology, Validation, Investigation, Writing – original draft, Writing – review & editing, Supervision, Project administration. **Uram Jin:** Resources. **Seokyoung Yoon:** Resources. **Yong-Yeon Jo:** Software, Formal analysis, Visualization. **Joon-myoung Kwon:** Methodology, Validation, Data curation, Writing – review & editing.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi. org/10.1016/j.ijcard.2022.01.064.

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