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Non-Inferiority Analysis of Electrocardiography Analysis Application vs. Point-of-Care Ultrasound for Screening Left Ventricular Dysfunction

Jin Hee Kim[1], Jae Yun Jung[1], Joonghee Kim[2,3], Youngjin Cho[3,4], Eunkyoung Lee[2,3], and Dahyeon Son[2,3]

[1]Department of Emergency Medicine, Seoul National University Hospital, Seoul;
[2]Department of Emergency Medicine, Seoul National University Bundang Hospital, Seongnam;
[3]ARPI Inc., Seongnam;
[4]Cardiovascular Center, Department of Internal Medicine, Seoul National University Bundang Hospital, Seongnam, Korea.

Purpose: Point-of-care ultrasound (POCUS) is widely used for heart function evaluation in emergency departments (EDs), but requires specific equipment and skilled operators. This study evaluates the diagnostic accuracy of a mobile application for estimating left ventricular (LV) systolic dysfunction [left ventricular ejection fraction (LVEF) <40%] using electrocardiography (ECG) and tests its non-inferiority to POCUS.

Materials and Methods: Patients (aged ≥20 years) were included if they had both a POCUS-based EF evaluation and an ECG within 24 hours of their ED visit between January and May 2022, along with formal echocardiography within 2 weeks before or after the visit. A mobile app (ECG Buddy, EB) estimated LVEF (EF from EB) and the risk of LV dysfunction (LV-Dysfunction score) from ECG waveforms, which were compared to NT-proBNP levels and POCUS-evaluated LVEF (EF from POCUS). A non-inferiority margin was set at an area under the curve (AUC) difference of 0.05.

Results: Of the 181 patients included, 37 (20.4%) exhibited LV dysfunction. The AUCs for screening LV dysfunction using POCUS and NT-proBNP were 0.885 and 0.822, respectively. EF from EB and LV-Dysfunction score outperformed NT-proBNP, with AUCs of 0.893 and 0.884, respectively (p=0.017 and p=0.030, respectively). EF from EB was non-inferior to EF from POCUS, while LV-Dysfunction score narrowly missed the mark. A subgroup analysis of sinus-origin rhythm ECGs supported the non-inferiority of both EF from EB and LV-Dysfunction score to EF from POCUS.

Conclusion: A smartphone application that analyzes ECG image can screen for LV dysfunction with a level of accuracy comparable to that of POCUS.

Key Words: LV dysfunction, heart failure, point-of-care ultrasound, digital biomarkers, ECG analysis application, emergency department

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Co-corresponding authors: Jae Yun Jung, MD, PhD, Department of Emergency Medicine, Seoul National University Hospital, 101 Daehak-ro, Jongno-gu, Seoul 03080, Korea.
E-mail: matewoos@gmail.com and
Joonghee Kim, MD, PhD, Department of Emergency Medicine, Seoul National University Bundang Hospital, 82 Gumi-ro 173beon-gil, Bundang-gu, Seongnam 13620, Korea.
E-mail: joonghee@snubh.org

•Joonghee Kim, MD, PhD developed the algorithm. He also founded a start-up company, ARPI Inc., where he serves as the CEO. Youngjin Cho, MD, PhD works for the company as a research director. Eunkyoung Lee and Dahyeon Son work for the company as clinical researchers. The other authors have no conflict of interests.

INTRODUCTION

Many emergencies, including respiratory distress or shock, require quick assessment of cardiac function for effective treatment. Point-of-care ultrasound (POCUS) is often used for this purpose, providing rapid evaluations of important cardiac parameters such as left ventricular ejection fraction (LVEF). Research shows that POCUS has a sensitivity of 96%–100% for identifying pericardial effusions and an 84%–93% agreement rate with cardiology sonographers for LVEF assessment.[1]

The implementation of POCUS in cardiovascular assessments has multiple advantages. It allows clinicians to quickly correlate sonographic data with patient history and physical examination, streamlining the diagnostic process. This can also contribute to healthcare cost savings by reducing the need for additional, more expensive tests. However, the technique has limitations. It requires expensive devices and skilled operators, and the quality can vary based on the devices used and level of expertise, which can be challenging especially in resource-limited settings.

Artificial intelligence (AI) is increasingly being used to analyze electrocardiograms (ECGs) for screening variety of conditions, including myocardial infarction, heart failure, and electrolyte abnormalities.[2-12] This technology could be particularly useful for rapid evaluation of cardiac functions in emergency departments (EDs) where POCUS exam is not feasible. To make this technology more accessible, we previously developed a mobile application, ECG Buddy (EB), which can analyze printed ECGs using a smartphone camera (Fig. 1).[2-8]

The purpose of the current study is to compare the accuracy of EB to that of POCUS exam in screening for LV dysfunction. Specifically, we compared four key predictors: EF from POCUS exam, EF from EB, LV-Dysfunction score, and NT-ProBNP, evaluating their performance in identifying LV dysfunction. We conducted a non-inferiority analysis to assess whether the software can serve as a reliable alternative to POCUS for the rapid assessment of cardiac function in emergency settings.

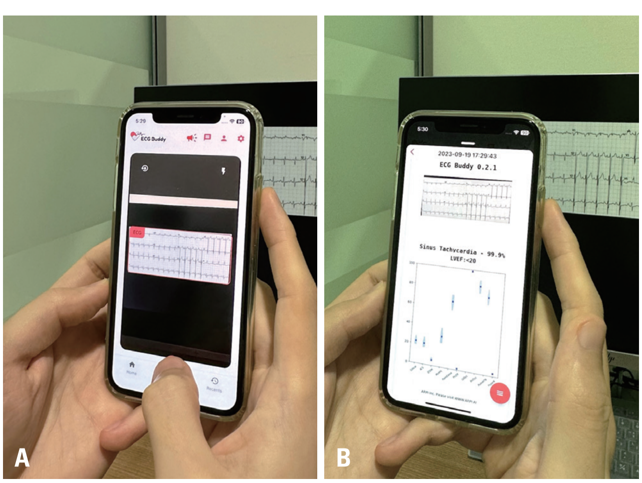

Fig. 1. The operating screen of the evaluated artificial intelligence software, "ECG Buddy." (A) ECG image input. (B) ECG image analysis result. ECG, electrocardiography.

MATERIALS AND METHODS

Study design

This was a retrospective observational study using the ED POCUS registry of Seoul National University Hospital from January 2022 to May 2022. The registry is a collection of recorded ultrasound images and interpretations performed by emergency physicians as part of the diagnostic and management process for patients presenting to the ED. The aim of the study was to compare the diagnostic accuracy of EB with that of POCUS exam in screening for LV dysfunction (LVEF <40%). Specifically, the study compared four predictors: EF from POCUS exam, EF from EB, LV-Dysfunction score, and NT-ProBNP. The primary goal was to determine whether EB is non-inferior to POCUS exam in ED settings.

Study population

We included adult patients (age ≥20 years) who visited the ED and met the following criteria:

1) Both POCUS-based LVEF evaluation and 12-lead ECG were performed within 24 hours of their ED visits.

2) A formal echocardiographic assessment by a cardiologist was conducted within 2 weeks either before or after the ED visits.

Exclusion criteria included electronic pacemaker rhythms, ventricular tachycardia, or undetermined rhythms. These exclusions were consistent with the software's user manual.

Data collection

Demographic and POCUS-evaluation data were obtained from the registry, including patient age, sex, examiner level, days to ECG, and the LVEF measured during the POCUS examination. Additional information, including the LVEF measured in formal echocardiography, initial NT-proBNP levels (within 24 hours of ED visit), and capture images of initial ECG waveforms, were obtained from the hospital's electronic health record.

EF from POCUS was measured by emergency physicians of varying experience levels, including residents, fellows, and professors, using handheld or portable ultrasound devices. The POCUS exam was recommended to be performed during the initial resuscitation phase in the study's ED. The methods for calculating EF varied among operators, ranging from visual estimation to more quantitative approaches, such as volume percentage measurements.

Application evaluated

The EB application uses a smartphone camera to capture the images of 12-lead ECGs, and its deep learning-based algorithms

Table 1. Patient Characteristics by the Presence of LV dysfunction (n=181)

	EF ≥40% (n=144)	EF <40% (n=37)	*p* value
Age (yr)	71.0 (61.5–79.0)	74.0 (64.0–81.0)	0.307
Sex			>0.999
Female	64 (44.4)	17 (45.9)	
Male	80 (55.6)	20 (54.1)	
Chief complaints			0.667
Chest discomfort	31 (21.5)	7 (18.9)	
Dyspnea	66 (45.8)	20 (54.1)	
Others	47 (32.6)	10 (27.0)	
Weight (kg)	63.0±14.1	60.2±13.6	0.286
Height (cm)	161.4 (154.0–170.0)	160.6 (153.8–169.0)	0.569
Operator grade			0.903
PGY1	6 (4.2)	3 (8.1)	
PGY2	46 (31.9)	13 (35.1)	
PGY3	22 (15.3)	4 (10.8)	
PGY4	14 (9.7)	3 (8.1)	
FELLOW	14 (9.7)	3 (8.1)	
Professor	42 (29.2)	11 (29.7)	
Days to ECG			>0.999
Same	138 (95.8)	36 (97.3)	
Next day	6 (4.2)	1 (2.7)	
Days to POCUS			>0.999
Same	132 (91.7)	34 (91.9)	
Next day	12 (8.3)	3 (8.1)	
Days to NT-proBNP			0.799
Same	123 (96.9)	32 (100)	
Next day	4 (3.1)	0 (0.0)	
Days to echocardiography	1.0 (1.0–3.0)	1.0 (1.0–2.0)	0.032
Heart rhythm			
Sinus rhythm	69 (47.9)	11 (29.7)	
Sinus tachycardia	33 (22.9)	16 (43.2)	
Atrial fibrillation	22 (15.3)	6 (16.2)	
Atrial flutter	4 (2.8)	2 (5.4)	
Sinus arrhythmia	3 (2.1)	0 (0.0)	
Complete heart block	2 (1.4)	1 (2.7)	
Sinus bradycardia	2 (1.4)	0 (0.0)	
Accelerated junctional rhythm	2 (1.4)	0 (0.0)	
Frequent PVCs	1 (0.7)	1 (2.7)	
Escape bradycardia	1 (0.7)	0 (0.0)	
Focal atrial tachycardia	1 (0.7)	0 (0.0)	
Non-conducted APC	1 (0.7)	0 (0.0)	
PSVT	1 (0.7)	0 (0.0)	
Supraventricular bigeminy	1 (0.7)	0 (0.0)	
Wandering atrial pacemaker	1 (0.7)	0 (0.0)	
Reference LVEF	57.2 (54.0–63.0)	30.0 (26.0–33.0)	<0.001
EF-POCUS	55.0 (45.0–55.0)	30.0 (25.0–40.0)	<0.001
EF-ECG	58.5 (54.7–61.2)	38.1 (31.2–47.8)	<0.001

Table 1. Patient Characteristics by the Presence of LV dysfunction (n=181) (continued)

	EF ≥40% (n=144)	EF <40% (n=37)	*p* value
LVDys score	8.6 (3.4–22.4)	64.1 (42.0–81.2)	<0.001
NT-proBNP	261.0 (79.0–670.5)	1521.5 (1304.0–4140.0)	<0.001

APC, atrial premature contraction; ECG, electrocardiography; EF, ejection fraction; LVDys, left ventricular dysfunction; LVEF, left ventricular ejection fraction; PGY, post graduate year; POCUS, point-of-care ultrasound; PSVT, paroxysmal supraventricular tachycardia; PVC, premature ventricular contraction.
Values are expressed as n (%), mean (interquartile range), or mean±standard deviation.

analyze the images to provide 10 digital biomarkers, termed Quantitative ECG (QCG™) scores, for various emergencies, cardiac dysfunctions, and hyperkalemia.[2,4-8] It has been approved as a second-degree medical device in South Korea and is available in app stores for public use.[13] The parameters evaluated included the LVEF estimation (available only in its development version), ranging from 20 to 65 (EF from EB), and LV-Dysfunction score (a risk score for LV systolic dysfunction, defined as LVEF <40%), ranging from 0 to 100. The reference LVEF values for evaluation were based on LVEF recorded during formal echocardiography closest to the time of the ED visit.

Statistical analysis

The performance of the application in screening for LV dysfunction was assessed using the area under the receiver operating characteristic curve (AUC-ROC). The AUC values for the different diagnostic methods were compared using the DeLong method. Sensitivity and specificity were determined by binning the parameters based on the thresholds that maximize their Youden's index. A non-inferiority test was conducted with an AUC difference of 0.05 as the non-inferiority margin to compare the software's performance to that of POCUS.[4,14,15] A subgroup analysis was conducted for patients with sinus rhythms (normal sinus rhythm, sinus bradycardia, and sinus tachycardia) to assess the software's performance without being influenced by arrhythmia. Statistical significance was established at a *p*-value <0.05, and R software version 4.1.0 was used for data analysis.

Ethics statement

This study was approved by the IRB of Seoul National University Hospital (IRB No: 2211-141-1381). Informed consent was waived due to the retrospective nature of the study.

RESULTS

A total of 181 adult patients were included. Among these, 37 patients (20.4%) were identified to have LV dysfunction based on their formal echocardiographic reports. Table 1 shows the population characteristics. There was no significant difference

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Table 2. Diagnostic Performance of EF-POCUS, EF-ECG, LVDys Score, and NT-ProBNP

Methods	AUC	Threshold	Sensitivity	Specificity	*p*-difference against NT-proBNP
EF-POCUS	0.885 (0.820–0.949)	41.3	89.2	80.6	0.049
EF-ECG	0.893 (0.825–0.961)	51.2	91.9	81.9	0.017
LVDys score	0.884 (0.820–0.948)	28.0	89.2	78.5	0.030
NT-proBNP	0.822 (0.735–0.908)	1276.5	78.1	86.2	-

AUC, area under the curve; ECG, electrocardiography; EF, ejection fraction; LVDys, left ventricular dysfunction; POCUS, point-of-care ultrasound.

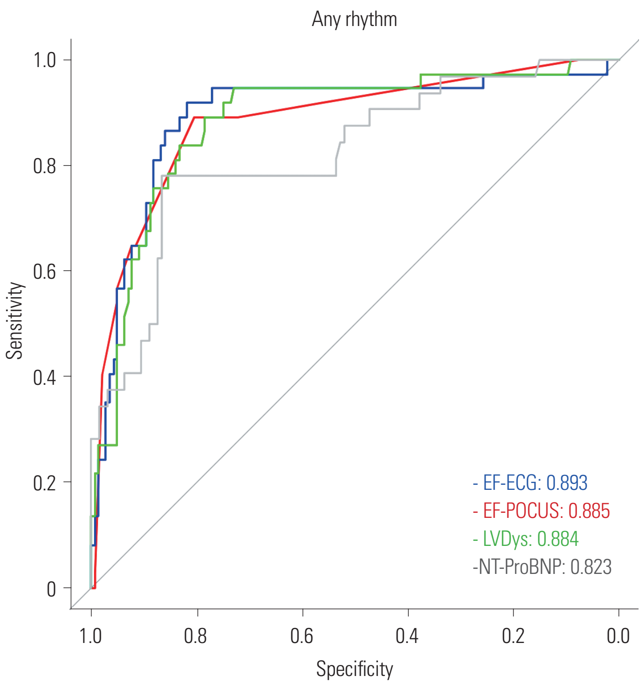

Fig. 2. ROC curves in LV dysfunction prediction in any rhythm. EF-ECG (blue), EF-POCUS (red), LVDys (green), and NT-ProBNP (grey). EF-ECG had the highest AUC, which was significantly higher than that of EF-POCUS. ROC, receiver operating characteristic; AUC, area under the curve; ECG, electrocardiography; EF, ejection fraction; LVDys, left ventricular dysfunction; POCUS, point-of-care ultrasound.

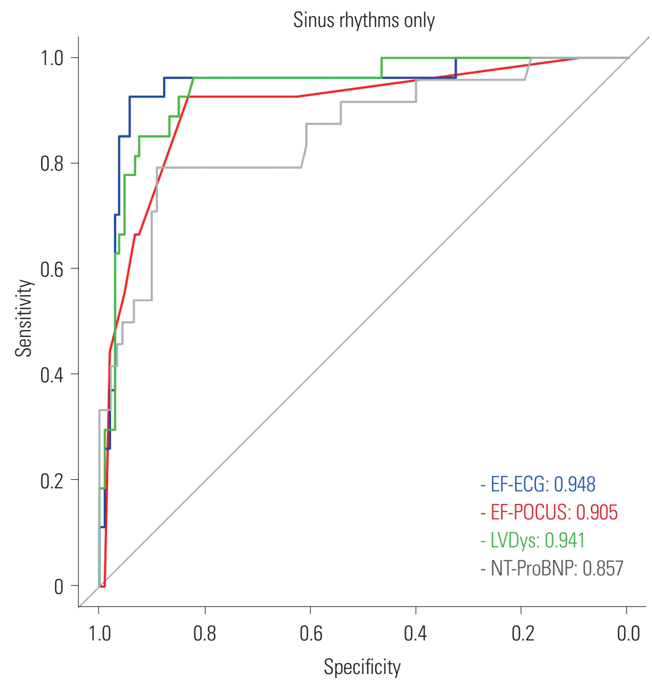

Fig. 3. ROC curves in LV dysfunction prediction in sinus rhythm only. EF-ECG (blue), EF-POCUS (red), LVDys (green), and NT-ProBNP (grey). EF-ECG had the highest AUC, which was significantly higher than that of EF-POCUS. ROC, receiver operating characteristic; AUC, area under the curve; ECG, electrocardiography; EF, ejection fraction; LVDys, left ventricular dysfunction; POCUS, point-of-care ultrasound.

in demographic information between those with and without LV dysfunction, except for the days to echocardiography, which was 1.0 [interquartile range (IQR): 1.0–3.0] day for those without LV dysfunction and 1.0 (IQR: 1.0–2.0) day for those with LV dysfunction (p=0.032). In contrast, there were significant differences in EF from the POCUS exam, EF from EB, LV-Dysfunction score, and NT-proBNP measurements (all p<0.001).

Table 2 details the diagnostic performance of EF from POCUS exam, NT-proBNP, EF from EB, and LV-Dysfunction score in the study population. EF from POCUS exam had an AUC of 0.885 [95% confidence interval (CI), 0.820–0.949], sensitivity of 89.2%, and a specificity of 80.6% (Fig. 2). On the other hand, NT-proBNP demonstrated an AUC of 0.822 (95% CI, 0.735–0.908) with a sensitivity of 78.1% and a specificity of 86.2%. EF from EB exhibited an AUC of 0.893 (95% CI, 0.825–0.961), a sensitivity of 91.9%, and a specificity of 81.9%. Lastly, LV-Dysfunction score had an AUC of 0.884 (95% CI, 0.820–0.948), with a sensitivity of 89.2% and a specificity of 78.5%. Both EF from EB and LV-Dysfunction score were superior to NT-proBNP, with p-values for differences of 0.017 and 0.030, respectively.

We performed the same analysis in the subset of 134 (74.0%) patients with sinus rhythms, as presented in Table 3. EF from POCUS exam had an AUC of 0.905 (95% CI, 0.837–0.973), a sensitivity of 92.6%, and a specificity of 83.2% (Fig. 3). NT-ProBNP showed an AUC of 0.857 (95% CI, 0.764-0.949), a sensitivity of 79.2%, and a specificity of 88.6%. EF from EB exhibited an AUC of 0.948 (95% CI, 0.895–1.000), a sensitivity of 92.6%, and a specificity of 94.4%. LV-Dysfunction score had an AUC of 0.941 (95% CI, 0.894–0.988), a sensitivity of 96.3%, and a specificity of 82.2%. Both EF from EB and LV-Dysfunction score were superior to NT-proBNP, with p-values of 0.018 and 0.032, respectively.

Non-inferiority tests comparing the application's performance against POCUS exam were conducted in the entire study population and the sinus rhythm subgroup (Table 4). In the overall study population, EF from EB was confirmed to be

Table 3. Diagnostic Performance of EF-POCUS, EF-ECG, LVDys Score, and NT-ProBNP in Patients with Sinus Rhythms

Methods	AUC	Threshold	Sensitivity	Specificity	*p*-difference against NT-ProBNP
EF-POCUS	0.905 (0.837–0.973)	41.3	92.6	83.2	0.196
EF-ECG	0.948 (0.895–1.000)	50.5	92.6	94.4	0.018
LVDys score	0.941 (0.894–0.988)	20.8	96.3	82.2	0.032
NT-ProBNP	0.857 (0.764–0.949)	1300.5	79.2	88.6	-

AUC, area under the curve; ECG, electrocardiography; EF, ejection fraction; LVDys, left ventricular dysfunction; POCUS, point-of-care ultrasound.

Table 4. Results of Non-Inferiority Tests

Population	Comparison	EF-ECG	EF-POCUS	95% CI of difference	Non-inferiority
Whole rhythms	EF-ECG vs. EF-POCUS	0.893 (0.825–0.961)	0.885 (0.820–0.949)	(-0.043–0.066)	Established
	LVDys score vs. EF-POCUS	0.884 (0.820–0.948)	0.885 (0.820–0.949)	(-0.056–0.056)	Not established
Sinus rhythms	EF-ECG vs. EF-POCUS	0.948 (0.895–1.000)	0.905 (0.837–0.973)	(-0.006–0.106)	Established
	LVDys score vs. EF-POCUS	0.941 (0.894–0.988)	0.905 (0.837–0.973)	(-0.015–0.100)	Established

CI, confidence interval; ECG, electrocardiography; EF, ejection fraction; LVDys, left ventricular dysfunction; POCUS, point-of-care ultrasound.

non-inferior to EF from POCUS exam, with a 95% CI for the AUC difference ranging from -0.043 to 0.066. However, the non-inferiority of LV-Dysfunction score was not established in the population, as the 95% CI for the AUC difference was -0.056 to 0.056. In the sinus rhythm population, both biomarkers were also confirmed to be non-inferior to EF from POCUS exam, with 95% CIs for the AUC differences ranging from -0.006 to 0.106 and -0.015 to 0.100, respectively.

To identify the factors influencing the accuracy of EB in predicting LV dysfunction, we compared the clinical characteristics between patients with correct and incorrect predictions (Supplemental Table 1, only online). Among the variables analyzed, only the type of rhythm being sinus-origin rhythm was significantly associated with correct predictions (80.9% vs. 37.9%, $p<0.001$). Specifically, correct predictions were more likely to be associated with sinus-origin rhythm. Other factors, including age, sex, presenting complaint, body weight, height, operator grade, days to ECG, days to POCUS exam, days to formal echocardiography, and reference LVEF, did not show a statistically significant association with correct predictions.

DISCUSSION

In the current study, we assessed the diagnostic efficacy of four predictors—EF from POCUS exam, NT-proBNP, EF from EB, and LV-Dysfunction score—for identifying LV dysfunction in ED patients. The results indicated that EF from EB and LV-Dysfunction score demonstrated higher diagnostic performance compared to NT-proBNP. Additionally, EF from EB proved to be non-inferior to EF from POCUS exam in both the overall patient population and the subset with sinus rhythms. These findings suggest that ECG-based digital biomarkers could serve as reliable alternatives or supplements to traditional screening methods, such as NT-proBNP and POCUS exam, in emergency settings.

The importance of quick and accurate cardiac function assessment in EDs is well-established, particularly for patients presenting with chest pain, dyspnea, or signs of shock.[16] Timely diagnosis guides a range of immediate treatment options, from fluid resuscitation to the administration of diuretics or vasodilatory medications. Our study indicates that a smartphone application can offer a practical alternative to POCUS for evaluating LV function. However, it remains uncertain whether app-guided initial patient management improves patient outcomes. Therefore, further studies, preferably prospective ones, are needed to validate this approach and support its widespread adoption.

BNP and NT-proBNP have long been standard tools for heart failure screening in EDs.[17-19] However, these biomarkers have limitations, including variable turnaround times and susceptibility to confounding factors such as age and renal function.[20-23] These limitations can be particularly impactful in emergency settings where quick decision-making is essential. In contrast, ECG-based AI models can offer immediate insights into LV function. This can be particularly advantageous in emergency scenarios, facilitating quicker treatment decisions. The mobile deployment of such AI adds a layer of convenience and accessibility, potentially offering a more cost-effective solution.

In this study, the sensitivity and specificity for detecting LV dysfunction using POCUS exam performed by emergency physicians were 89.2% and 80.6%, respectively. This is consistent with the results of a previous study, where the meta-analysis of POCUS exams conducted by emergency physicians showed sensitivity and specificity for assessing LV systolic function to be 89% (95% CI, 80%–94%) and 85% (95% CI, 80%–89%), respectively.[24] This consistency with established research gave us a reliable point of comparison when evaluating the performance of ECG analysis application.

It is worth noting that POCUS is a much more comprehensive tool. For example, POCUS can also assess pulmonary edema and sometimes detect aortic dissections—capabilities not yet achievable with the application. However, these limitations could be mitigated by integrating chest X-ray (CXR)-based AI models that can identify pulmonary edema or aortic

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dissection.[25,26] This combination of functional data from ECGs and structural data from CXRs could potentially rival POCUS in diagnostic utility.

Despite the encouraging results, our study had several limitations. It was a retrospective study conducted at a single center, which may affect the generalizability of the findings. The sample size, particularly the number of patients with LV dysfunction, was relatively small, constrained by the availability of data in the POCUS registry at the time of study design. Additionally, we did not perform a priori sample size estimation, which is typically recommended in non-inferiority trials. While we included all available cases to maximize the robustness of our findings, future studies should incorporate formal sample size calculations.

There is potential variability in LVEF measurements due to time differences between the POCUS, ECG, and formal echocardiography exams. Although POCUS and ECG were conducted within a day of each other, formal echocardiography was performed up to 2 weeks before or after the ED visit, which may introduce variability in EF assessments.

Furthermore, the variability in operator experience and techniques used for POCUS exams may lead to inconsistencies in LVEF measurements. Although standardized training was provided, differences in experience among operators could affect diagnostic accuracy, reflecting real-world clinical practice. These factors should be considered when interpreting the study's findings

In conclusion, using only 12-lead ECG images, a smartphone application can screen LV dysfunction with a level of accuracy comparable to POCUS, offering a potential alternative for cardiac assessment when POCUS is not readily available.

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AUTHOR CONTRIBUTIONS

Conceptualization: Jin Hee Kim and Jae Yun Jung. Data curation: Jin Hee Kim, Eunkyoung Lee, and Dahyeon Son. Formal analysis: Jin Hee Kim, Joonghee Kim, Eunkyoung Lee, and Dahyeon Son. Funding acquisition: Jae Yun Jung and Youngjin Cho. Investigation: Jin Hee Kim and Joonghee Kim. Methodology: Jae Yun Jung, Joonghee Kim, and Youngjin Cho. Project administration: Eunkyoung Lee and Dahyeon Son. Resources: Jae Yun Jung and Youngjin Cho. Software: Joonghee Kim and Youngjin Cho. Supervision: Jae Yun Jung and Youngjin Cho. Validation: Jae Yun Jung and Youngjin Cho. Visualization: Jin Hee Kim and Joonghee Kim. Writing—original draft: Jin Hee Kim and Joonghee Kim. Writing—review & editing: Jae Yun Jung and Youngjin Cho. Approval of final manuscript: all authors.

ORCID iDs

Jin Hee Kim	https://orcid.org/0000-0002-8936-1317
Jae Yun Jung	https://orcid.org/0000-0003-2994-6900
Joonghee Kim	https://orcid.org/0000-0001-5080-7097
Youngjin Cho	https://orcid.org/0000-0001-8106-3713
Eunkyoung Lee	https://orcid.org/0000-0003-0691-5909
Dahyeon Son	https://orcid.org/0009-0000-2339-432X

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