



Diagnostic agreement of smartphone-based electrocardiogram with coronary angiography in identifying vessel involvement in patients with myocardial infarction

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ABSTRACT

Background: Acute myocardial infarction (MI) remains one of the major causes of morbidity and mortality throughout the world. The objectives of this study were to determine the diagnostic agreement between the findings from Portable (Spandan Pro) and Conventional Electrocardiogram with coronary angiography (CAG) regarding vessel involvement in MI patients, and to assess related risk factors.

Methodology: This study was an Observational, Single-arm, Cross-sectional study performed on 109 subjects at a local hospital in Dehradun. The study was approved by the Institutional Ethics Committee, and informed consent was obtained from all the participants. For diagnostic agreement, Statistical analyses such as Cohen's κ , weighted κ , prevalence- and bias-adjusted κ (PABAK), and Jaccard index were used.

Results: The mean age of the included patients was 58 ± 11.96 years, with a significant male predominance (88.07%). For overall vessel involvement of ECGs with CAG, portable ECG showed a higher sensitivity (84.76 vs. 78.10%), and for LAD artery, it also showed higher sensitivity (88.46% vs. 82.05%) compared to the conventional ECG. Diagnostic agreement showed substantial agreement with CAG (PABAK 0.68), and according to the Jaccard Index, there was a moderate agreement (approximately 50%) between the ECG-derived findings with CAG across all types of vessel diseases. The most prevalent confounding factor among the participants was smoking (41.9%), followed by Hypertension (39.0%) and diabetes (34.3%).

Conclusion: This study indicates that Portable ECG performed comparably to conventional ECG and had a moderate level of diagnostic agreement with CAG in the detection of vessel involvement in patients with MI.

Introduction

Coronary artery disease (CAD) remains one of the leading causes of mortality worldwide, with an estimated 315 million cases projected in 2022 alone [1,2]. Early diagnosis and timely intervention are critical for preventing adverse outcomes such as myocardial infarction (MI) and ischemia. One of the most typical manifestations of CAD is acute MI [3]. The urgency of revascularization is determined by early identification of infarct-related arterial involvement, and treatment decisions are influenced by Electrocardiogram (ECG) patterns [4]. Percutaneous coronary intervention (PCI), a minimally invasive method to restore blood flow in stenosed or occluded coronary arteries, is widely used for the

management of CAD [1]. Coronary angiography (CAG) remains the gold standard for diagnosing CAD and informing PCI choices [5]. However, limited access to advanced medical infrastructure often delays diagnosis until the symptomatic phase, thus elevating the risk of severe complications and mortality [6].

To address this gap, noninvasive diagnostic modalities have gained popularity due to their ease of use, safety, and effectiveness in providing a diagnosis. Of these, the Conventional 12-lead ECG (Philips PageWriter ECG) is still a cornerstone for the detection of ischemia, arrhythmias, and conduction diseases [7]. It can also be utilized to identify the culprit artery in patients with MI. ECG-based early infarct-related artery (IRA) prediction can identify the extent of myocardium at risk and help

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determine the urgency of revascularization. Making a decision quickly could help with management and prevent complications. The ECG can be a helpful tool in determining which artery is implicated at the first point of care, even if CAG is the “gold standard” for determining the IRA in acute MI. An angiography can be used to verify the ECG prediction. It is impossible to provide early intervention in many centers across our nation. We can predict the artery linked to the infarct and subsequent challenges by examining the ECG [3]. However, the conventional ECG machines are typically confined to hospital settings, restricting timely assessment in rural or resource-limited areas. This underscores the need for portable, accessible ECG solutions that can expand diagnostic reach.

One such advancement is Spandan Pro, a smartphone-based, portable 12-lead ECG device developed by Sunfox Technologies Pvt. Ltd. (Fig. 1). It is designed for real-time cardiac monitoring and offers a cost-effective and user-friendly solution. Prior studies have demonstrated the device's clinical utility in detecting conditions such as ST-elevation myocardial infarction (STEMI), non-ST-elevation myocardial infarction (NSTEMI), arrhythmias, and conduction defects [8–13].

Unlike prior research that typically compares portable ECG devices to Conventional ECG recordings alone, this study extends the investigation to the anatomical level by demonstrating concordance between portable ECG findings and angiographic evidence of coronary artery involvement. To our knowledge, this is one of the first studies to map ECG findings from a portable ECG device directly against CAG results in patients undergoing evaluation for suspected CAD. The strength of this study lies in its direct comparison of portable and conventional ECG recordings with angiographic findings, specifically in the context of MI. By focusing on ST-segment deviations that are associated with specific artery involvement, such as the left anterior descending (LAD), right coronary artery (RCA), and left circumflex artery (LCX). The study introduces novel clinical insights on the reliability and interpretability of portable ECGs in real-world cardiovascular care.

The primary objective of this study is to determine the diagnostic agreement between the ECG findings from the Portable ECG (Spandan Pro) device and a conventional ECG machine, with the CAG findings in identifying the coronary vessel involvement in patients with MI. The secondary objective is to explore the association of coronary vessel disease with patient-specific risk factors.

Methods

Study design and setting

This study has been designed with meticulous care: as an Observational, Single-arm, Cross-sectional study conducted at a local hospital in Dehradun, Uttarakhand, India, from February 15, 2024, to June 4, 2024. Data were collected from the Cardiac Care Unit and Cardiac Intensive Care Unit wards to obtain a comprehensive assessment of patients with chest pain, palpitations, and/or shortness of breath, as well as those who had been referred for CAG testing.

Participants selection

A total of 146 patients aged 20 years presenting with symptoms suggestive of acute coronary syndrome, including chest pain, palpitation and/or shortness of breath, were clinically evaluated by the treating

cardiologist. The decision to diagnose MI (STEMI/NSTEMI) and to refer patients for CAG was made entirely by the treating cardiologist as part of routine clinical care, based on a combination of clinical presentation, standard 12-lead ECG findings, and cardiac biomarker assessment (including cardiac troponin), where available, in accordance with institutional practice. The criteria for MI was defined by the presence of ischemic symptoms, electrocardiographic changes consistent with myocardial ischemia or infarction (ST-segment elevation or depression, new pathological Q waves, or dynamic ST-T changes), and a rise and/or fall in cardiac biomarkers consistent with myocardial necrosis. In cases of acute MI, the diagnostic criteria were the same, except that the presence of new pathological Q waves was not required. ST-segment elevation was assessed on standard 12-lead ECGs recorded at a paper speed of 25 mm/s and a calibration of 10 mm/mV, with measurements taken at the J-point relative to the PR segment baseline. Diagnostic ST-segment elevation was defined as ≥ 2 mm in leads V2–V3 and ≥ 1 mm in at least two contiguous leads in other myocardial territories, representing leads that assess the same myocardial region. The required sample size was estimated initially using the formula by Yamane:

$$n = \frac{N}{(1 + Ne^2)}$$

where n = required sample size, N = estimated population size, and e = margin of error. Approximately 100 patients undergo CAG at our center per month. As trial activities were restricted to regular working hours, we assumed that approximately 40% of these patients would be available for recruitment, resulting in an effective monthly study population of $N = 40$. With a margin of error ($e = 0.05$, 95% CI), Yamane's formula yields $n = 37$ patients per month, and an operational 4-month recruitment target of approximately 148 participants.

However, Yamane's formula is primarily suited for the sampling of finite population proportions and does not offer adequate statistical justification for studies on diagnostic agreement. Therefore, the final sample size justification was based on Cohen's kappa (κ) methodology.

Assuming the binary classification outcome with category prevalence (p) of 0.5, expected chance agreement P_e was estimated as: $P_e = p^2 + (1 - p)^2 = 0.5$. We used a null hypothesis kappa level of $\kappa_0 = 0.40$ and target kappa of $\kappa_1 = 0.60$. The corresponding observed agreements were computed as: $P_{00} = \kappa_0(1 - P_e) + P_e = 0.7$; $P_{01} = \kappa_1(1 - P_e) + P_e = 0.8$.

The respective standard deviations were estimated as: $S_0 = \frac{\sqrt{P_{00}(1-P_{00})}}{1-P_e} = 0.916$, $S_1 = \frac{\sqrt{P_{01}(1-P_{01})}}{1-P_e} = 0.8$.

Using a two-sided 95% confidence level ($Z_{1-\alpha/2} = 1.96$) and 80% power ($Z_{1-\beta} = 0.84$), the required sample size was calculated as:

$$n = \frac{(Z_{1-\alpha/2} \cdot S_0 + Z_{1-\beta} \cdot S_1)^2}{(k_1 - k_0)^2} = 152.3 \text{ (approximately 153)}$$

Thus, a minimum of 153 patients was required to achieve adequate statistical power for kappa-based agreement analysis. The study included only those patients who had been clinically diagnosed with MI (STEMI or NSTEMI) and referred for CAG, ensuring that infarct localization and IRA assessment were performed exclusively in patients with a presumed culprit coronary lesion. Patients with a history of reperfusion therapy, pacemaker rhythms, significant ECG baseline wandering or artefacts, loosened skin or dense chest hair, deep breathing interference, critical illness, pregnancy, patients referred for CAG for non-MI indications or those without a clinical diagnosis of MI or those who refused to participate were excluded to minimize diagnostic dilution and misclassification bias. No unreadable ECG leads, incomplete CAG labels, or missing baseline clinical variables (e.g., diabetes, hypertension, smoking status) were identified. Therefore, the primary analysis set comprised all 109 participants, for whom ECG test reports from both the portable ECG device and conventional 12-lead ECG, along with corresponding CAG reports, were available and deemed eligible for analysis; consequently, no imputation of missing data was required.



Fig. 1. Spandan Pro ECG device.

Ethical approval and consent

The study received ethical approval from the local Institutional Ethics Committee (Approval No.- SRHU/HIMS/E-1/2024/07) with CTIRI No.- CTIRI/2024/07/071055. Written and verbal informed consent was obtained from all the participants.

Data collection and study procedure

Upon presentation of chest pain, palpitation, and/or shortness of breath, the MI patients were referred for the CAG. Patients were screened and enrolled consecutively by the study investigators after admission. The first step was taking participant's consent both verbally and in writing. Trained Clinical trial Assistants completed the Case Report Format (CRF) following study protocols. The CRF includes demographic and clinical data, including age, gender, comorbidities, and relevant medical history. The conventional 12-lead ECG report was collected from the patient's file. Then, each participant undergoes an ECG recording using the Portable smartphone-based ECG device before undergoing CAG. Additionally, the CAG report was also collected after the CAG test was completed. All ECG recordings, including conventional and portable smartphone-based ECGs, were interpreted independently by an experienced cardiologist. The cardiologists were blinded to patient clinical details and CAG results, as well as to the other ECG modality. The interpretations were performed on different days, a minimum of one week apart, in random order, so as to minimize recall bias. This ensured that each ECG reading was truly independent and without bias. But during the CAG complete blinding of the cardiologist to the ECG findings was not feasible due to routine clinical practice. The cardiologists assessed rhythm and conduction parameters and evaluated ischemic changes, recording variables such as heart rate and rhythm, PR interval, QRS duration, QT/QTc, presence of pathologic Q waves, ST-segment deviation (elevation or depression), T-wave inversion, and the anatomic distribution of changes across contiguous lead groups (inferior, anterior, lateral, septal). ST-segment deviation was measured manually at the J-point, and where required at J + 60–80 ms, relative to the PR segment baseline on ECGs recorded at standard calibration (25 mm/s, 10 mm/mV), and categorized by magnitude (mm) and lead contiguity to support MI classification and determination of the affected territory and IRA. This detailed and systematic assessment allowed accurate identification of MI location (anterior, inferior, lateral, septal, or combinations thereof), which was then compared with vessel involvement on CAG.

Time consideration

A maximum gap of 2 days was kept between the recordings of the Conventional ECG test and the Portable ECG device test to minimize any potential biases. This time discrepancy occurred because the Conventional ECG was conducted during patient admission, while the Portable ECG device was performed following the cardiologist's recommendation for a CAG test. Moreover, there was a time gap of less than 8 h between the CAG test and the Portable ECG device. Notably, the mean duration between the ECG recordings of the Conventional ECG with Portable ECG device was approximately 1 day and 7 min and Conventional ECG with CAG was 1 day 3 h.

Statistical analysis

All analyses were performed using Microsoft Excel 2013, IBM SPSS (version 27), and/or MATLAB (version R2025B). Continuous variables were expressed as mean $\pm$ SD or median (IQR), and categorical variables as frequencies and percentages. Diagnostic agreement between the Portable ECG and CAG was assessed using Cohen's κ (with 95% CI) for per-artery analyses (LAD, RCA, LCx) and weighted κ for multi-category agreement (single vessel disease (SVD)/ Double vessel disease (DVD)/

Triple vessel disease (TVD). The primary outcomes were overall diagnostic agreement with CAG and sensitivity for the LAD artery; additional artery-level analyses (LCx and RCA) were conducted using the same methods and interpreted similarly, with these analyses considered secondary and exploratory. To adjust for class imbalance, prevalence- and bias-adjusted κ (PABAK) was calculated. For multivessel disease, patient-level multi-label concordance was quantified using the Jaccard index with 95% CIs. Binary per-artery endpoints were compared with McNemar's test, and Effect size (risk differences) with 95% CIs were reported. Interpretation of κ values followed Landis and Koch (1977) [14]. Diagnostic performance was further evaluated using sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with 95% CIs (Wilson method). Continuous ECG parameters (PR, QRS, QT, QTc) were compared with paired *t*-tests and Bland–Altman plots, while cardiovascular risk factors were compared across angiographic patterns using chi-square tests, with adjusted associations estimated via multinomial logistic regression (Relative risk ratio (RRRs) with 95% CIs).

Data confidentiality, privacy, security, and storage

The hospital ensures stringent data security and privacy by anonymizing all collected information and storing it on a two-step authenticated local server. Additionally, data is securely maintained in a HIPAA-compliant cloud storage system, spreadsheets, and printed records within the hospital. Access is restricted to authorized hospital personnel, with all data transfers being secure and encrypted. To maintain confidentiality and data integrity, no personally identifiable information is included in the analyzed data.

Information about the portable ECG (Spandan Pro) device

The Spandan Pro is a Portable smartphone-based 12-lead ECG is an advanced, Sequential ECG device for rapid cardiac monitoring. It records a full 12-lead ECG in only 1.3 min and has automatic lead switching. The device integrates advanced signal processing features, including noise reduction and precise R-peak detection, ensuring high-quality ECG recordings. Portable ECG records the clearest and most refined ECG traces, compatible with both electrodes and suction bulbs for multi-purpose clinical use.

Guide for using the portable smartphone-based ECG

To record an ECG using the Portable ECG device, we need to ensure it is securely connected to the smartphone with a micro USB cable. Electrode placement follows Goldberger's lead positioning, as explained in the prior study, in order to ensure correct readings [13].

Concordance between ECG findings and angiographic findings

According to Leo Schamroth's *An Introduction to Electrocardiography* [15], the standardized electrocardiographic parameters summarized in Table 1 were used to assess concordance between ECG abnormalities and angiographic findings. In this study, specific ECG leads demonstrating ST-segment elevation were used to localize the MI, while CAG was used to identify the IRA based on anatomical location and severity of luminal narrowing. Percentage stenosis for each major coronary vessel was extracted from the final angiography report, with lesion severity documented as estimated visual narrowing (e.g., distal RCA stenosis ~90%, LAD artery stenosis ~40%, or diffuse disease of the LCX artery). Concordance between electrocardiographic findings and CAG was assessed by determining whether the MI location inferred from ST-segment elevation patterns on the 12-lead ECG corresponded to the IRA identified on CAG. ECG lead groups were mapped to their expected coronary arterial territories (e.g., anterior leads to the LAD artery, inferior leads to the RCA or LCX artery, and lateral leads to the LCX or

Table 1

Diagnostic agreement algorithm of coronary angiography findings and ECG findings.

ECG lead(s) with ST elevations	Coronary angiography finding	ECG findings
Lead V3 and V4	LAD artery Occlusion	Anterior MI
Leads V1 and V2	LAD artery Occlusion	Septal MI
Leads V5, V6, I and avL	LAD artery Occlusion	Lateral MI
Leads II, III, and avF	RCA occlusion, Distal to Right Ventricular, 58% of MI	Inferior MI
II, III, avF, I, avL, V5, and V6	LAD artery and LCX artery occlusion in a L dominant System	Inferolateral MI
V1-V4 (V2 more prominent for septal dominance)	LAD artery (proximal/mid-segment), possible involvement of the first diagonal branch	Anteroseptal MI
V1-V6 (V4-V6 more prominent for lateral involvement)	LAD artery (proximal/mid-segment), possible involvement of LCX artery (circumflex marginal branches)	Anterolateral MI
V1-V4 (V1-V3 more prominent for apical involvement)	LAD artery (distal segment)	Antero apical MI
II, III, avF	RCA (proximal/mid-segment), possible involvement of septal perforator branches	Infero-septal MI

Abbreviations: LAD: Left Anterior Descending artery; RCA: Right Coronary Artery; LCX: Left Circumflex artery.

diagonal branches), and concordance was defined as agreement between the ECG-predicted culprit vessel and the angiographically determined IRA [15–17]. It is important to note that CAG primarily provides anatomical information regarding vessel involvement and does not by itself confirm acute MI; therefore, MI localization (anterior, inferior, lateral, septal, or combined territories) was determined using both conventional 12-lead ECG and smartphone-based ECG, with the primary aim of assessing diagnostic concordance between ECG-based MI localization and CAG-determined vessel involvement, while acknowledging that severe coronary stenosis does not always indicate the artery responsible for the acute infarction. This concordance enables the accurate identification of MI locations, enhancing the Portable ECG's ability to precisely assess CAD and guide clinical decision-making.

For overall vessel involvement, a case was considered a true positive (TP) when the smartphone-based ECG correctly identified at least one coronary artery territory with MI or ischemia that was confirmed by CAG, including cases where CAG showed additional vessel disease. A false positive (FP) occurred when ECG changes were not confirmed by CAG, a true negative (TN) when neither modality detected stenosis or occlusion, and a false negative (FN) when CAG revealed significant obstruction despite a normal ECG or in a different territory. At the per-artery level (LAD, LCX, RCA), a TP was defined when ECG correctly identified MI or ischemia confirmed by CAG in the same artery, an FP when ECG changes were unconfirmed by CAG, a TN when both modalities were negative, and an FN when CAG showed significant obstruction despite a normal ECG. A representative case of anterolateral MI detected by both portable and conventional ECGs, consistent with LAD and first obtuse marginal artery (OM1) stenosis on CAG, is shown in Fig. 2.

Results

All included participants (109) after applying inclusion and exclusion criteria had complete and analyzable data for portable ECG, conventional ECG, and CAG findings. Participant flow from screening to final analysis is illustrated in Fig. 3. No revascularization procedures occurred between ECGs and CAG. However, variable therapy changes, including adjustment or initiation of cardiac medications such as Anti platelet (eg. Aspirin), Anti coagulant (eg. Nicoumalone), Anti anginal (eg. Nitroglycerin), Antihyperlipidemic (Atorvastatin), Antihypertensive (eg. Metoprolol, Ramipril, Telmisartan, Amlodipine), Diuretics (Furosemide) and/or Antiarrhythmic (eg. Digoxin) were observed among patients during the interval between tests. The mean age of the included 109 patients was 58 ± 11.96 years, with 96 (88.07%) being male and 13 (11.93%) being female, and among them, the patients diagnosed with coronary vessel disease were 105, the majority had SVD 40 (38.09%), followed by DVD 35 (33.33%) and TVD 30 (28.57%). Table 2 provides a detailed breakdown of their smoking status, presence of diabetes and hypertension, symptoms, and whether they were advised for coronary artery bypass grafting (CABG) or PCI.

Table 3 demonstrates the Paired *t*-test analysis showed no significant

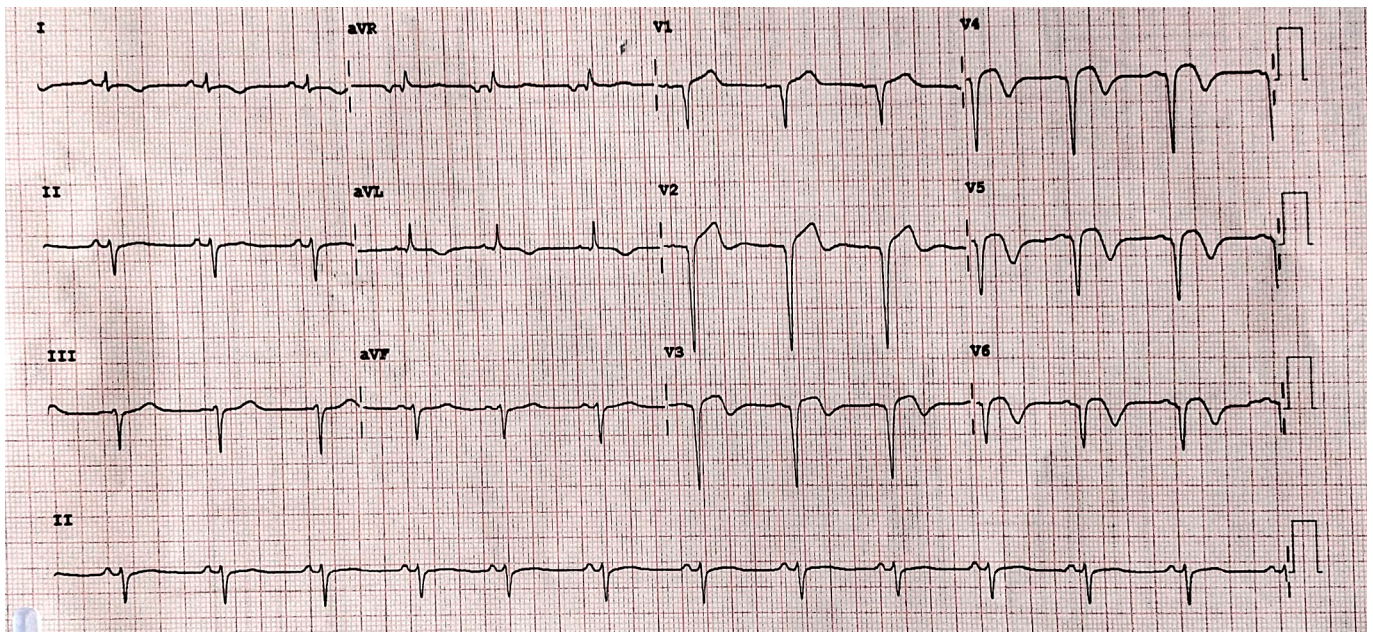


Fig. 2. Case example of anterolateral MI detection. ECGs recorded with (A) conventional and (B) portable devices show concordant anterolateral MI patterns. Coronary angiography (C) revealed 90% stenosis in the LAD and 90% proximal stenosis in OMI, corresponding to the ECG infarct territory, illustrating that the portable ECG can reliably detect ischemic changes comparable to conventional ECG.

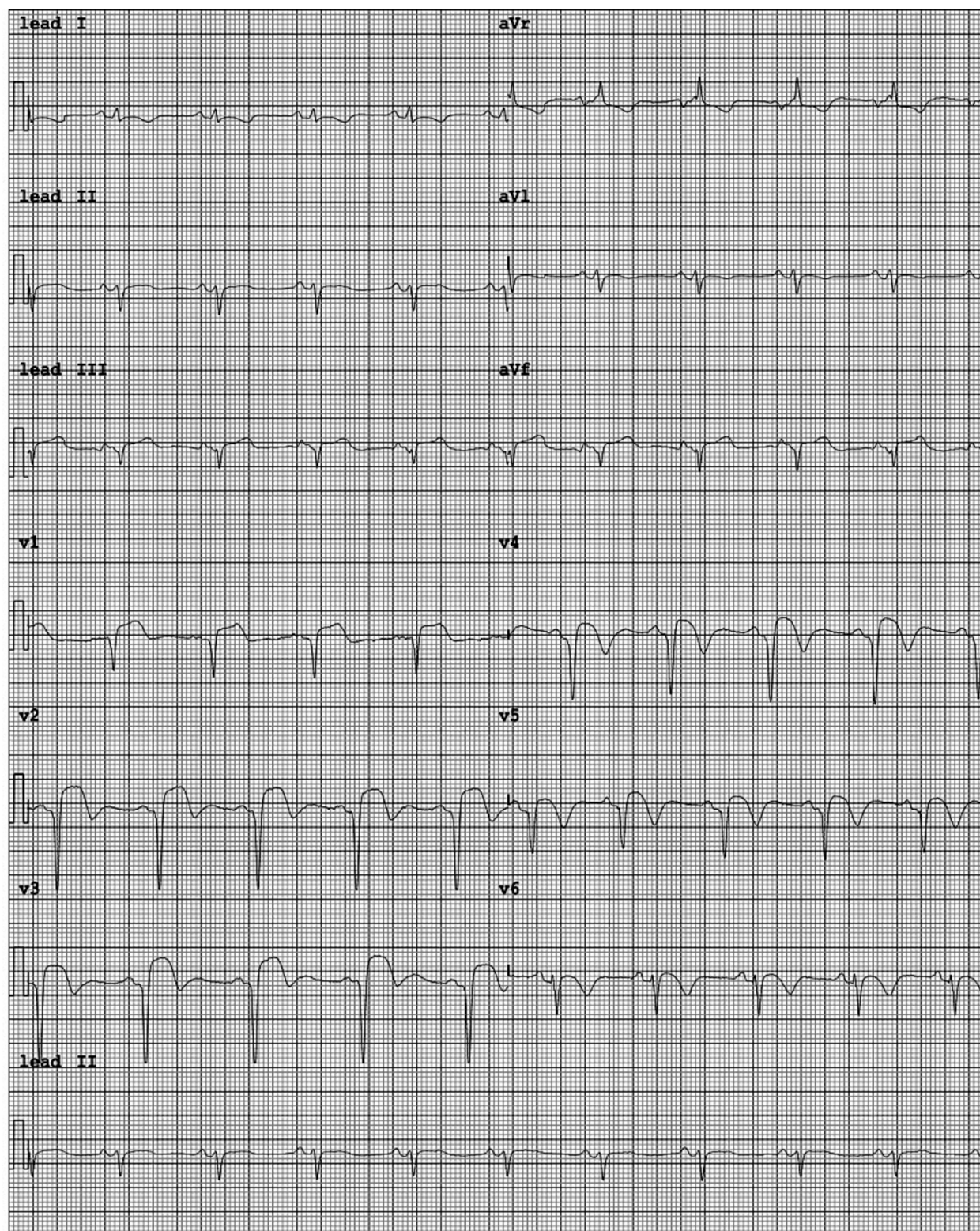


Fig. 2. (continued).

differences in PR, QRS, QT, or QTc intervals between the portable and conventional ECG devices in patients at anytime (all $p > 0.05$), with small mean differences and narrow 95% CIs, indicating good correlation. Similar results were obtained when patients had ≤ 6 h and > 6 h between ECG tests, thus confirming consistency across time intervals.

Bland-Altman plots are available in the Supplementary Appendix (S1-S3). Minimal bias and narrow limits of agreement were observed for

PR and QRS intervals in the overall and subgroup analyses, supporting interchangeability between the portable and conventional ECG measurements.

Table 4 describes the diagnostic performance of portable ECG and conventional ECG in diagnosing coronary artery involvement, with CAG as the reference standard. For overall vessel involvement, portable ECG showed a higher sensitivity (84.76 vs. 78.10%), PPV (98.80% vs.

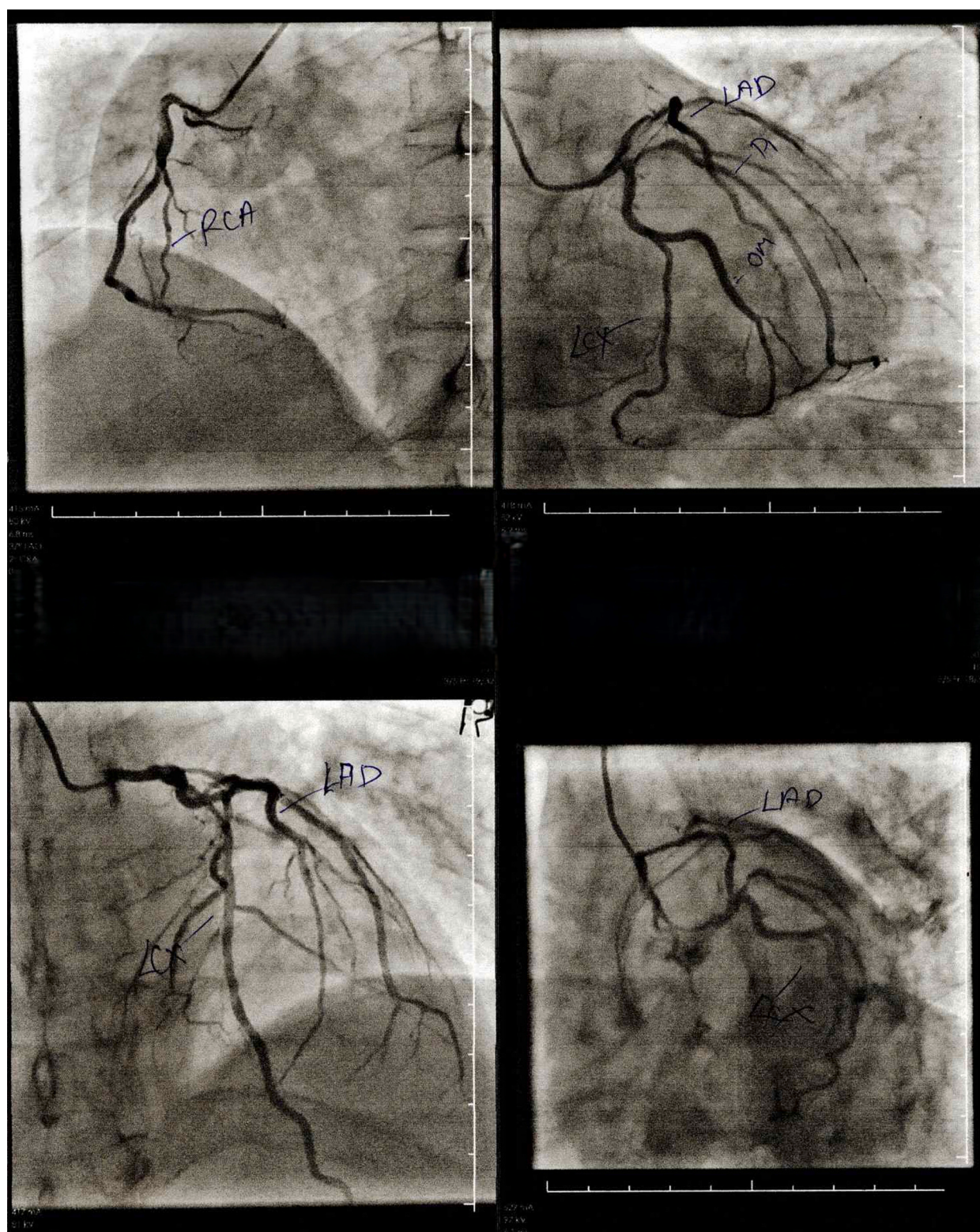


Fig. 2. (continued).

98.70%), and NPV (15.70% vs. 11.53%), and a similar specificity (75% for both) compared to the conventional ECG. Agreement measures indicated substantial agreement with CAG (PABAK 0.68 for portable ECG vs 0.52 for conventional ECG), and weighted κ (quadratic) values showed slight agreement (0.03 for portable ECG vs 0.05 for conventional ECG). For the LAD artery, portable ECG showed higher sensitivity (88.46%) and conventional ECG showed higher specificity (51.61%),

PPV (81.01%), and NPV (53.33%). Agreement of portable ECG and conventional ECG with CAG was moderate for PABAK (0.43 vs. 0.4) and slight to fair for Cohen's Kappa (0.2 vs. 0.34). McNemar's test for Portable ECG showed a statistically significant difference from CAG (0.03), whereas conventional ECG showed no significant difference (1.00). For the effect size portable ECG was more effective than the conventional ECG in detecting MI, with a meaningful and statistically

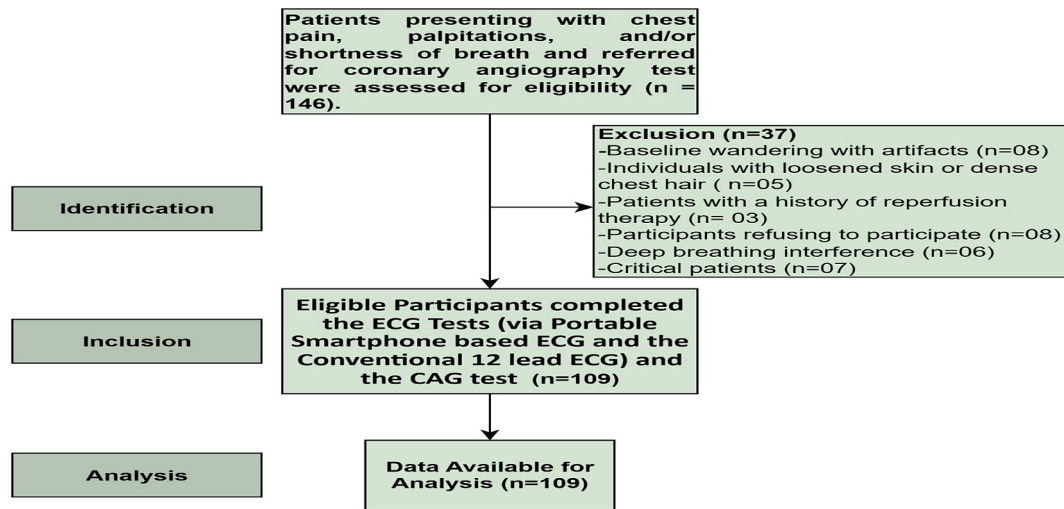


Fig. 3. STORBE flowchart of the study: A flow diagram depicting the participant inclusion process from February 15, 2024, to July 4, 2024, prepared in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Table 2
Baseline characteristics of the participants.

Baseline characteristics		Frequency (n = 109)	Percentage (%)
Gender	Male	96	88.07
	Female	13	11.93
Mean Age $\pm$ Standard Deviation (Years)		58 $\pm$ 11.96 Years	–
Smoker		45	41.28
Diabetic		37	33.94
Hypertension		44	40.37
Diabetes with Hypertension		20	18.35
Symptoms		5	4.59
Symptoms	Chest Pain	88	80.73
	Short of Breath	26	23.85
CABG Advised		10	9.17
PCI Advised		93	85.32

Table 3
Comparison of portable and conventional ECG parameters using paired t-tests across different time intervals.

Parameter	Patient of anytime between the portable vs conventional ECG: paired t-test p-value (mean difference, 95% CI)	Patient with ≤ 6 h between the portable vs conventional ECG: paired t-test p-value (mean difference, 95% CI)	Patient with > 6 h between the portable vs conventional ECG: paired t-test p-value (mean difference, 95% CI)
PR	0.2437 (3.10 ms, –8.35 to 2.14)	0.4416 (–7.67 ms, –13.47 to 28.80)	0.1058 (4.43 ms, –9.82 to 0.96)
QRS	0.1634 (–1.98 ms, –0.82 to 4.78)	0.2535 (–3.17 ms, –2.62 to 8.95)	0.2412 (–1.84 ms, –1.25 to 4.92)
QT	0.6408 (–2.66 ms, –8.61 to 13.93)	0.5919 (–10.42 ms, –31.11 to 51.94)	0.7766 (–1.70 ms, –10.17 to 13.57)
QTc	0.4028 (5.50 ms, –18.50 to 7.49)	0.5922 (–11.92 ms, –35.62 to 59.46)	0.2679 (7.66 ms, –21.30 to 5.99)

significant increase (risk difference 0.12 vs. 0.01). For the LCX artery, both ECGs showed lower sensitivities. Agreement of portable ECG and conventional ECG compared to CAG was slight for both Cohen's Kappa and PABAK (κ 0.03–0 vs. 0.05 and PABAK 0.10 vs. 0.15). For the RCA artery, the conventional ECG showed higher sensitivity, specificity, NPV, and PPV than the portable ECG. Agreement with CAG for both PABAK and Cohen's Kappa was slight for portable ECG and Fair for conventional ECG. For LCX and RCA, McNemar's test for both ECGs showed a statistically significant difference from CAG, and the effect size showed both ECGs significantly reduced missed MI, with the

conventional ECG showing a slightly larger effect. Overall, Portable ECG performed comparably to conventional ECG for overall vessel involvement and LAD detection. Per-patient confusion profiles for handling of multivessel disease are provided to illustrate detection accuracy across different coronary territories. (Supplementary Table 1)

Fig. 4 demonstrates the sensitivity of the portable and conventional ECG at the time intervals between ECG acquisition and CAG: anytime ($n = 109$ in each ECG), ≤ 6 h (Portable ECG, $n = 82$; Conventional ECG, $n = 6$), and > 6 h (Portable ECG, $n = 27$; Conventional ECG, $n = 103$). In the interval of ≤ 6 h, sensitivity was higher for the portable ECG compared to the conventional ECG in the overall artery (83.75% vs. 66.66%) and specifically for the LAD artery (87.95% vs. 80%), while it showed slightly lower sensitivity for the LCX and RCA arteries. In contrast, for the > 6 -h interval, the portable ECG showed higher sensitivity for the overall artery (88.46% vs. 79%), the LAD artery (90% vs. 82.19%), as well as for the LCX and RCA arteries. These findings indicate that the diagnostic performance of the portable ECG is comparable to that of the conventional ECG.

For both the portable and conventional modalities, across all types of vessel diseases, there was generally moderate agreement of ECG-derived findings with CAG results. For SVD, concordance was slightly higher for the conventional ECG at 0.67 ± 0.34 than for the portable device at 0.55 ± 0.33 . For DVD, both performed similarly: 0.50 ± 0.33 for conventional versus 0.52 ± 0.32 for portable. Concordance was lower for TVD for both, reflecting reduced agreement with more extensive disease. Taken altogether in all patients with vessel disease, the portable ECG had a mean Jaccard concordance of 0.49 ± 0.33 compared to 0.52 ± 0.35 for the conventional ECG. Median and interquartile Jaccard values were consistent across modalities, suggesting stable agreement patterns between the two ECG systems and CAG findings. (Table 5)

Among 105 patients with coronary vessel disease, key confounding factors present in the patients were hypertension, diabetes, smoking, and their combination. The most prevalent confounding factor was smoking, present in 44 (41.9%) patients, followed by hypertension in 41 (39.0%) patients, and diabetes in 36 (34.3%) patients. No parameter demonstrated a statistical difference according to the number of coronary vessels involved, whether SVD, DVD, or TVD; therefore, the severity of vessel involvement was not related to the prevalence of risk factors. (Table 6).

Table 7 presents the multinomial logistic regression and reports the adjusted RRRs with 95% CIs for SVD/DVD/TVD of predictors age, sex, diabetes, hypertension, and smoking. In this multivariable analysis comparing DVD and TVD to SVD, none of the examined predictors were

Table 4
Diagnostic performance of portable and standard ECGs for detection of coronary artery involvement.

Artery / category	ECG type	Sensitivity (%) [95% CI]	Specificity (%) [95% CI]	PPV (%) [95% CI]	NPV (%) [95% CI]	Cohen's κ (95% CI)	PABAK	McNemar's value	Effect size (risk difference), 95% CI
Overall vessel involvement	Portable ECG	84.76% (76.67–90.40%)	75% (32.56–100%)	98.80% (96.72–100%)	15.70% (0–32.18%)	Weighted $\kappa = 0.03$ (–0.22–0.16)*	0.68	–	–
	Conventional ECG	78.10% (69.27–84.93%)	75% (32.56–100%)	98.70% (96.55–100%)	11.53% (0–23.82%)	Weighted $\kappa = 0.05$ (–0.12–0.22)*	0.56	–	–
LAD	Portable ECG	88.46% (79.50–93.81%)	29.03% (13.05–45.01%)	75.82% (67.03–84.62%)	50.00% (26.90–73.10%)	0.2 (0.004–0.39)	0.43	0.03	0.12 (0.02–0.22)
	Conventional ECG	82.05% (72.10–89.00%)	51.61% (34.02–69.20%)	81.01% (72.36–89.66%)	53.33% (35.48–71.18%)	0.34 (0.15–0.53)	0.47	1.00	0.01 (–0.09–0.11)
LCX	Portable ECG	32.07% (21.09–45.48%)	71.42% (59.60–83.26%)	51.51% (34.46–68.57%)	52.63% (41.40–63.86%)	0.03 (–0.14–0.21)	0.10	0.01	–0.18 (–0.31–(–0.05))
	Conventional ECG	28.30% (17.97–41.57%)	76.78% (65.73–87.84%)	53.57% (35.10–72.04%)	53.08% (42.22–63.95%)	0.05 (–0.11–0.22)	0.15	0.001	–0.23 (–0.36–(–0.10))
RCA	Portable ECG	45% (33.09–57.51%)	67.35% (54.22–80.48%)	62.79% (48.34–77.24%)	50% (37.94–62.06%)	0.12 (–0.06–0.30)	0.10	0.02	–0.16 (–0.29–(–0.04))
	Conventional ECG	51.67% (39.31–63.82%)	81.63% (70.79–92.47%)	77.5% (64.56–90.44%)	57.97% (46.32–69.96%)	0.32 (0.15–0.48)	0.30	0.002	–0.17 (–0.29–(–0.06))

* Represents weighted kappa across order category (SVD → DVD → TVD).

significantly associated with the extent of CAD. Age indicates that, in comparison to SVD, DVD or TVD are associated with a 3–4% increased risk with each extra year of age, with a statistically not significant correlation (P -value >0.05). Similarly, all parameters, such as diabetes, HTN, and smoking, showed wide CIs and high p -values, indicating no clear evidence of association.

Discussion

The present study was carried out to determine the diagnostic Agreement between the ECG findings from the Portable ECG device and the conventional ECG with the CAG findings in identifying vessel involvement in MI patients and to explore the association of coronary vessel disease with patient-specific risk factors such as diabetes, Hypertension, and smoking. The mean age of the study population was 58 ± 11.96 years, with a significant male predominance (88.07%). These demographics are comparable to findings reported by Maqbool Jafary et al. (52 ± 10 years) [18], the study by Boden et al. (62 ± 5 years) [19], and a study by Shaikh et al. (48.45 ± 13.79 years) [3]. In our study, chest pain was the predominant presenting complaint (80.73%), with shortness of breath (23.85%). In a study by Chowdhary GS et al., Chest pain was the most common symptom in 62.16% cases [20]. In the study by Haider KH et al., Chest pain typical of acute MI was the most common presenting symptom in 96% of patients [21].

Recent studies have shown the increasing involvement of computational models in the prediction of cardiovascular events using ECG signals, such as using machine learning techniques on treadmill exercise tests to predict obstructive CAD [22] and deep learning models for short-term mortality in acute pulmonary embolism [23]. We present here the complementary work that develops a real-world, practical validation of a portable ECG against invasive CAG. The measurements of PR, QRS, QT, and QTc using the device revealed minimal bias and consistent performance with conventional ECG measurements, further confirming its reliability. These findings highlight the potential of portable ECGs to bridge computational predictions and bedside application, particularly in resource-limited settings.

Our study demonstrated that in a variety of MI types, the culprit artery detected by a CAG may be substantially predicted from ECG data. This is consistent with Joseph et al., who stated that ECG in patients with STEMI is valuable and can reliably predict the culprit artery before angiography [24]. Our study assessed ECG abnormalities in relation to CAG findings, categorizing patients into SVD, DVD, and TVD. According to the findings of CAG, the patients with vessel involvement, the majority had SVD (38.09%), followed by DVD (33.33%) and TVD (28.57%). These findings are consistent with previous studies by Ezhumalai et al. [25] and Swan et al. [26], whereas Shaikh et al. [3] reported DVD as the most common presentation, followed by SVD and TVD. In the present study, the sensitivity, specificity, PPV, and NPV of portable ECG in identifying the coronary vessel involvement in patients with MI were 84.76%, 75%, 98.80%, and 15.70% while for the conventional ECG it was 79.10%, 75%, 98.70% and 11.53%, indicating the high capability of portable ECG to correctly identify patients with angiographically confirmed coronary vessel involvement. Agreement measures indicated substantial agreement of ECGs with CAG for PABAK, and weighted κ values showed slight agreement, reflecting limited exact agreement on vessel count. In research by Manue D et al. (2022), the diagnostic performance of ECG in detecting significant CAD and its anatomical localization compared to CAG was such that the overall sensitivity per patient was 59.5%, specificity was 59.1% and PPV was 71.0%, which is less in comparison to our study. [16]

In this study, for the LAD artery, the sensitivity of portable and conventional was 88.46% and 82.05%, the specificity was 29.03% and 51.61%, the PPV was 75.82% and 81.01% and the NPV was 50% and 53.33% respectively. Similarly, in a study by Manue D et al., the sensitivity of the ECG for LAD was 60%, specificity was 40%, PPV was 66.67%, and NPV was 33.33% which is less than our study except for

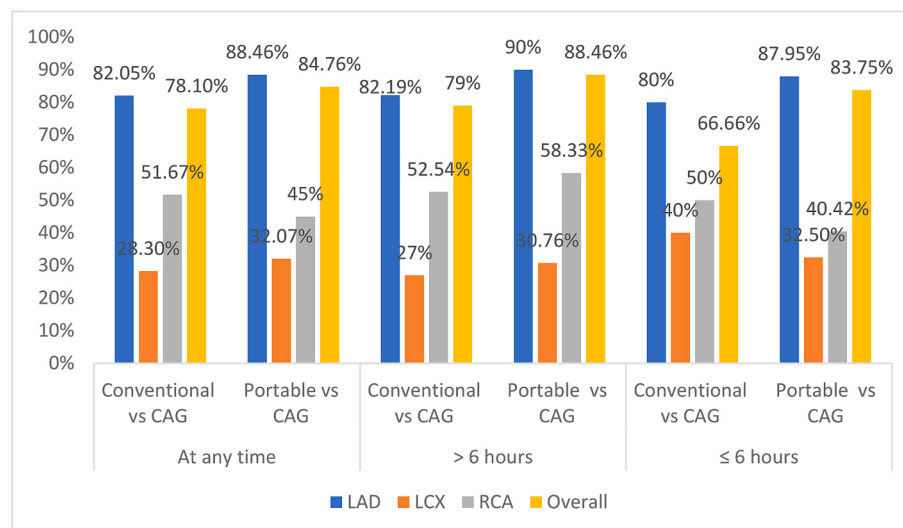


Fig. 4. Sensitivity of the portable and conventional ECG at different time intervals.

Table 5

Comparison of Jaccard concordance between ECG modalities and CAG by vessel disease type.

Vessel disease type	Number of patients (%)	Mean Jaccard concordance (portable ECG vs CAG) $\pm$ SD	95% CI (lower–upper)	Median (Jaccard IQR) portable	Mean Jaccard concordance (conventional ECG vs CAG) $\pm$ SD	95% CI (lower–upper)	Median (Jaccard IQR) conventional
SVD	40	0.55 $\pm$ 0.33	0.45–0.64	0.5 (0.33–1)	0.67 $\pm$ 0.34	0.56–0.77	0.5 (0.5–1)
DVD	35	0.52 $\pm$ 0.32	0.41–0.63	0.5 (0.33–0.66)	0.5 $\pm$ 0.33	0.39–0.61	0.5 (0.33–0.66)
TVD	30	0.44 $\pm$ 0.30	0.33–0.56	0.5 (0.33–0.66)	0.44 $\pm$ 0.33	0.32–0.56	0.33 (0.33–0.66)
Overall	109	0.49 $\pm$ 0.33	0.42–0.55	0.5 (0.33–0.66)	0.52 $\pm$ 0.35	0.46–0.59	0.5 (0.33–1)

Table 6

Comparison of risk factors across SVD, DVD, and TVD using χ^2 test.

Parameter		SVD (n = 40)	DVD (n = 35)	TVD (n = 30)	Total (N = 105)	p-value
Diabetes	yes	16	7	13	36	0.088
	No	24	28	17	69	
Hypertension (HTN)	yes	14	14	13	41	0.770
	No	26	21	17	64	
Smoking	yes	17	16	11	44	0.758
	No	23	19	19	61	
Diabetes + HTN	yes	9	5	5	19	0.635
	No	31	30	25	86	

Table 7

Multinomial logistic regression analysis of factors associated with SVD, DVD, and TVD, presenting adjusted RRRs with 95% CIs.

Predictor	Adjusted RRR (95% CI) — DVD vs SVD	p-value	Adjusted RRR (95% CI) — TVD vs SVD	p-value
Age (per year)	1.03 (0.99–1.07)	0.20	1.04 (0.99–1.08)	0.11
sex	3.42 (0.56–20.96)	0.18	2.79 (0.57–13.70)	0.21
Diabetes	2.59 (0.85–7.91)	0.09	0.86 (0.30–2.43)	0.77
Hypertension (HTN)	0.63 (0.23–1.73)	0.37	0.72 (0.26–2.02)	0.54
Smoking (males only)	1.07 (0.38–3.01)	0.89	1.25 (0.42–3.67)	0.69

Multinomial logistic regression; reference = SVD, n = 105).

specificity [16]. In another study by Arun N et al., the sensitivity of the ECG for LAD was 71.79%, specificity was 72.13%, PPV was 66.2% and NPV was 80%. [27]. Mahmoodzadeh S et al. reported sensitivity of 37.3%, specificity of 79.9%, PPV of 65.2% and NPV of 55.8% [7]. Parameters like sensitivity, PPV, and NPV for LAD in our study were

better than previous studies, indicating good ability to correctly identify cases with coronary vessel involvement and to rule out disease when absent. Agreement of ECGs with CAG was moderate for PABAK and slight to fair for Cohen's Kappa. McNemar's test for Portable ECG showed a statistically significant difference from CAG, indicating some disagreement, whereas conventional ECG showed no significant difference, indicating good concordance with the CAG. For the effect size, portable ECG was more effective than conventional ECG in detecting MI with a meaningful and statistically significant increase, while conventional ECG essentially shows no difference. However, the specificity was comparatively lower than that reported in previous studies. This could be possible due to temporal variation in ischemic changes, particularly in patients receiving ongoing therapy, as the portable ECG was done after the conventional ECG, and along with that, portable ECGs are primarily designed as a point-of-care device for community or pre-hospital use, rather than for in-hospital settings. Despite this, the overall diagnostic performance of the ECG remains clinically valuable, as maintaining high sensitivity is crucial in acute coronary syndrome detection.

In the current study, we reported the Jaccard index across all vessel disease types as a patient-level and multi-label concordance metric to quantify the overlap between arteries identified by ECG and those confirmed by CAG. There was moderate agreement between the findings obtained using ECG and the results from CAG for portable and conventional ECG modalities. This continuous metric enabled us to capture partial matches and yield a more granular assessment of diagnostic concordance compared with categorical methods, thus offering a framework that is reproducible in clinical practice for the evaluation of ECG–CAG agreement. In our study, no significant association was observed between risk factors (diabetes, hypertension, smoking) with the number of coronary vessels involved. While the previous study by Suri P et al. showed a significant association between Diabetes and the number of coronary vessels involved, and non-significant association for

hypertension and Smoking [28]. In another study by Hegde SS et al. reported a significant association for diabetes with the larger number of vessels involved (p -value 0.014) [29]. These findings are similar to our study except for diabetes, as our study showed no significant association; this could be due to the small sample size and uneven distribution of participants among study groups (SVD, DVD, or TVD).

Limitations

This study has several limitations. The small sample size, uneven distribution of risk factors across SVD, DVD, and TVD groups, and the low number of female participants limit generalizability. The time interval between conventional and portable ECG recordings was prolonged in some cases, and very few participants had a duration of less than six hours between conventional ECG and CAG, which may have affected accuracy. Moreover, differences in ECG accuracy may in part be related to the longer time gap between portable and conventional ECG acquisitions. However, further studies should be focused on patients who have a time gap of less than 15 min between both ECG recordings to minimize temporal variability and allow a better assessment of diagnostic agreement. While simultaneous or near-simultaneous ECG acquisition would be ideal. TIMI flow was assessed during CAG but was not included in this study, which limits the ability to distinguish acute from chronic lesions. Additionally, chronic or stable coronary stenoses may appear severe on CAG yet be unrelated to the acute event, highlighting that anatomical stenosis alone cannot reliably identify the IRA. Future studies incorporating TIMI flow, or functional assessments of myocardial viability could help better differentiate acute from chronic lesions and improve the accuracy of IRA identification, further strengthening the correlation between ECG-based MI localization and the underlying coronary pathology. Diagnostic performance was not evaluated in patients with conduction abnormalities, arrhythmias, chronic kidney disease, or structural heart disease. Future studies are needed to overcome these limitations and provide stronger evidence regarding the clinical applicability of portable ECG.

Clinical implications

Results of the current study indicate that Portable ECG may be a useful and accessible modality for the early detection and assessment of vessel involvement in MI, especially in resource-poor or rural settings where conventional ECG machines and CAG are not readily available. In view of the extent of concordance of Portable ECG reports with angiographic findings, Portable ECG can facilitate appropriate triage, and referral in primary care. Its portability and integration with smartphones also confer an advantage for point-of-care applications and home-based monitoring in high-risk populations.

Conclusion

This study shows a moderate diagnostic agreement between the portable ECG and CAG on the detection of vessel involvement among MI patients, with about approximately 50% of its participants showing complete concordance. Notably, this paper, unlike prior research that merely compares portable ECG with conventional ECG, has showcased diagnostic Agreement of portable ECG results against the CAG, which provides anatomic confirmation of MI. Results confirm the applicability of the portable ECG as an accessible, cost-effective point of care tool where access to immediate CAG could be compromised. The presence of multiple risk factors among SVD, DVD, and TVD groups points out the multifactorial aspect of CAD progression. In general, the present study provides new clinical evidence supporting the integration of portable ECGs into cardiovascular care and risk stratification, particularly in underserved populations.

CRedit authorship contribution statement

Chandra Mohan: Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Conceptualization. **Kunal Gururani:** Supervision, Formal analysis, Conceptualization. **Anurag Rawat:** Writing – review & editing, Supervision, Methodology. **Yogendra Singh:** Writing – review & editing, Project administration, Methodology, Conceptualization. **Nitin Chandola:** Writing – review & editing, Writing – original draft, Validation, Resources, Project administration. **Deeksha Agarwal:** Investigation, Formal analysis, Data curation. **Sengar Yashwardhan Pratap Singh:** Writing – original draft, Resources, Investigation. **Milan Prabhakar:** Writing – original draft, Resources, Investigation, Formal analysis.

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Declaration of competing interest

The authors declare no competing interests.

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Appendix A. Supplementary data

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Glossary

CAG: Coronary Angiography
 CAD: Coronary Artery Disease
 MI: Myocardial Infarction
 PCI: Percutaneous Coronary Intervention
 STEMI: ST-elevation myocardial infarction
 NSTEMI: non-ST-elevation myocardial infarction
 LAD: left anterior descending
 RCA: Right coronary artery
 LCx: left circumflex artery
 SVD: Single Vessel Disease
 DVD: Double Vessel Disease
 TVD: Triple Vessel Disease
 PABAK: Prevalence- and bias-adjusted κ
 PPV: Positive predictive value
 NPV: Negative predictive value