

# Detection of acute coronary occlusion with a novel mobile electrocardiogram device: a pilot study

Alejandra Zepeda-Echavarria <sup>1</sup>, Rutger R. van de Leur <sup>2</sup>, Melle Vessies <sup>2</sup>,  
Nynke M. de Vries<sup>2</sup>, Meike van Sleuwen <sup>2</sup>, Rutger J. Hassink <sup>2</sup>,  
Thierry X. Wildbergh <sup>3</sup>, JL van Doorn<sup>3</sup>, Rien van der Zee<sup>4</sup>,  
Pieter A. Doevendans <sup>2,5,6</sup>, Joris E.N. Jaspers <sup>1</sup>, and René van Es <sup>2,\*</sup>

<sup>1</sup>Department of Medical Technology and Clinical Physics, University Medical Center Utrecht, Utrecht University, Utrecht, The Netherlands; <sup>2</sup>Department of Cardiology, University Medical Center Utrecht, Utrecht University, Internal ref E03.511, Heidelberglaan 100, 3584 CX Utrecht, The Netherlands; <sup>3</sup>Department of Cardiology, Meander Medical Center Amersfoort, Amersfoort, The Netherlands; <sup>4</sup>Stichting Cardiovasculaire Biologie, Delft, The Netherlands; <sup>5</sup>Netherlands Heart Institute, Utrecht, The Netherlands; and <sup>6</sup>Central Military Hospital, Utrecht, The Netherlands

Received 6 September 2023; revised 10 January 2024; accepted 15 January 2024; online publish-ahead-of-print 17 January 2024

## Aims

Many portable electrocardiogram (ECG) devices have been developed to monitor patients at home, but the majority of these devices are single lead and only intended for rhythm disorders. We developed the miniECG, a smartphone-sized portable device with four dry electrodes capable of recording a high-quality multi-lead ECG by placing the device on the chest. The aim of our study was to investigate the ability of the miniECG to detect occlusive myocardial infarction (OMI) in patients with chest pain.

## Methods and results

Patients presenting with acute chest pain at the emergency department of the University Medical Center Utrecht or Meander Medical Center, between May 2021 and February 2022, were included in the study. The clinical 12-lead ECG and the miniECG before coronary intervention were recorded. The recordings were evaluated by cardiologists and compared the outcome of the coronary angiography, if performed. A total of 369 patients were measured with the miniECG, 46 of whom had OMI. The miniECG detected OMI with a sensitivity and specificity of 65 and 92%, compared with 83 and 90% for the 12-lead ECG. Sensitivity of the miniECG was similar for different culprit vessels.

## Conclusion

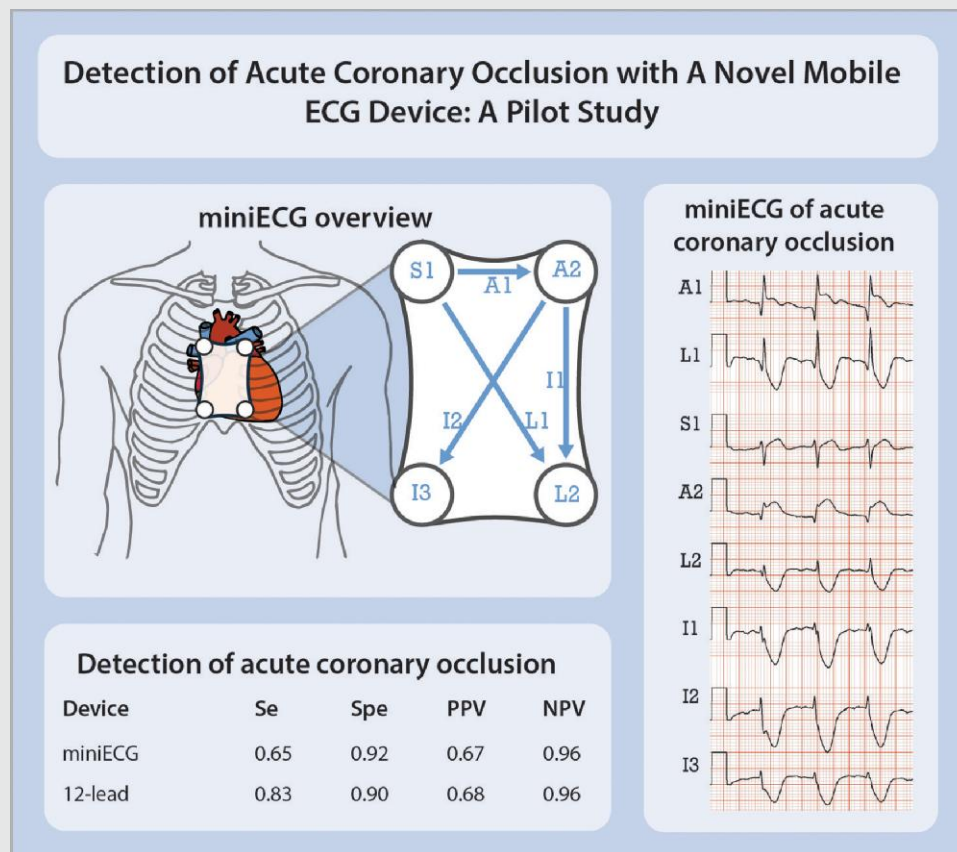
The miniECG can record a multi-lead ECG and rule-in ST-segment deviation in patients with occluded or near-occluded coronary arteries from different culprit vessels without many false alarms. Further research is required to add automated analysis to the recordings and to show feasibility to use the miniECG by patients at home.

\* Corresponding author. Tel: +0031 88 757 3453, Email: [r.vanes-2@umcutrecht.nl](mailto:r.vanes-2@umcutrecht.nl)

© The Author(s) 2024. Published by Oxford University Press on behalf of the European Society of Cardiology.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (<https://creativecommons.org/licenses/by-nc/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact [journals.permissions@oup.com](mailto:journals.permissions@oup.com)

## Graphical Abstract

**Keywords**

Occlusive myocardial infarction • STEMI • Wearable • ECG • Cardiac ischaemia

**Introduction**

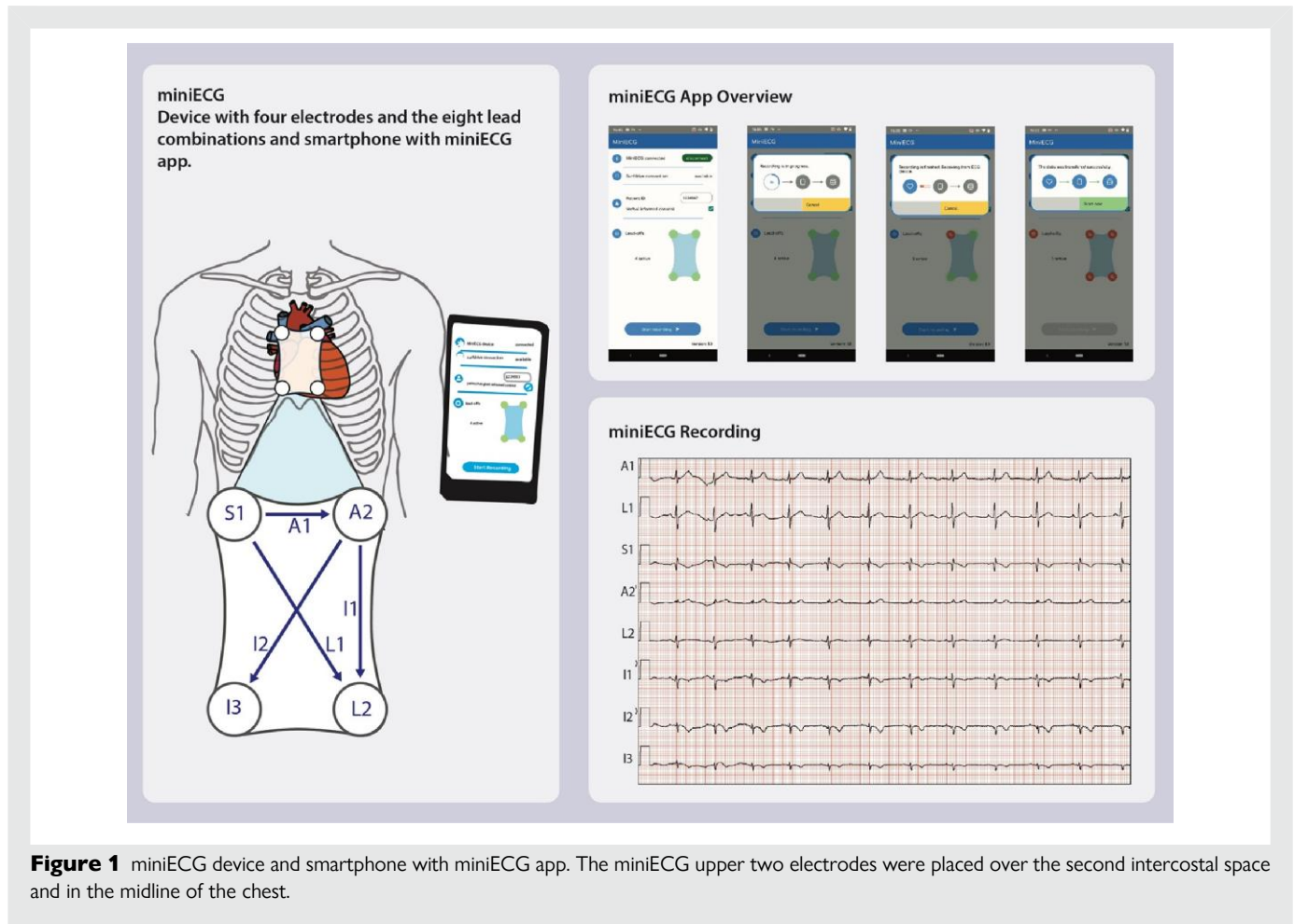
Acute coronary syndrome (ACS) is one of the leading causes of death, accounting for 8.95 million annual deaths globally in 2020.<sup>1</sup> Mortality and other adverse outcomes are more frequent when patients with ACS are not detected early.<sup>2</sup> Many improvement strategies have therefore been implemented to decrease door-to-balloon time, such as enhancing prehospital management and having stand-by teams.<sup>3,4</sup> While these strategies have greatly reduced door-to-balloon time, the symptom-to-door time has not been reduced. Recent studies have shown that symptom-to-door times are most important to further optimize and improve patient outcomes in a modern healthcare system.<sup>5</sup> Even more important, studies have shown that over 16% of males and 30% of females with myocardial infarction (MI) do not present to the emergency services at all.<sup>6</sup>

The first tool for diagnosis of ACS, and especially ST-segment elevation myocardial infarction, is the electrocardiogram (ECG).<sup>7</sup> Recent research has highlighted that in patients with non-ST-segment elevation myocardial infarction, total or near total coronary occlusion can be observed.<sup>2</sup> Recently, a new classification was proposed, making the distinction between acute coronary occlusive myocardial infarction (OMI) and non-occlusive myocardial infarction (NOMI). To use this classification besides the ECG, other

indicators such as troponin levels and TIMI flow can be included for diagnosis.<sup>8</sup>

To improve the symptom-to-door time, an ECG should be recorded rapidly. Especially in situations when an ECG is not readily available, for example at home, including when there are atypical symptoms, there is an opportunity to use wearables and portable ECG devices. However, current ECG devices for home use are primarily intended for the detection of rhythm disorders, such as atrial fibrillation.<sup>9–11</sup> There has been initial research on the capabilities of home ECG devices to diagnose ACS patients. Studies performed using other wearables reported limitations, as not all MI-associated ST-segment deviations were visible. This is likely due to the limited number of leads and position of the device during measurement.<sup>12,13</sup> In contrast, in a multi-centre observational study, ST-segment elevations were visible on patients measured during planned elective percutaneous coronary intervention (PCI) with a three-lead detection system placed in the precordial area.<sup>14,15</sup>

We developed a mobile handheld device called the miniECG that can simultaneously record a multi-lead ECG using four dry precordial electrodes. In a previous study, we investigated the ability of the miniECG to capture ischaemic changes on a porcine coronary occlusion model where we could see ST-segment deviations.<sup>16</sup> In the present study, we evaluate the capabilities of the miniECG to detect OMI in a real-world population of patients presenting with chest pain.



**Figure 1** miniECG device and smartphone with miniECG app. The miniECG upper two electrodes were placed over the second intercostal space and in the midline of the chest.

## Methods

### Study design and participants

In this consecutive prospective multi-centre study, we included patients presenting at the emergency department (ED) with chest pain between May 2021 and February 2022 at the Utrecht Medical Center, Utrecht, The Netherlands (UMCU), or the Meander Medical Center, Amersfoort, Netherlands (MMC). Patients included had to be 18 years or older and capable to provide informed consent. Patients that could not be measured due to anatomical restrictions (recent sternotomy or physical restrictions not allowing full contact with the miniECG) received ventricular pacing, or patients with ventricular assist devices were excluded from the study. Patients were also excluded when coronary angiography (CAG) outcome and/or preprocedural 12-lead ECG were not available, as it was not possible to confirm ST-elevation myocardial infarction (STEMI) and OMI diagnosis.

### Study device

At the University Medical Center Utrecht, we developed a mobile, smartphone-sized device capable to record ECGs using four precordial electrodes, the miniECG (Figure 1). The device is characterized by having four stainless steel electrodes that record eight ECG leads, four of them are bipolar leads (A1, L1, I1, and I2) and four unipolar channels (S1, A2, L2, and I3). Based on the ST-segment changes and the locations of the infarctions, we named the leads of the miniECG as follows: leads A1 and A2 for the anterior side; I1, I2, and I3 for the inferior side; L1 and L2 for the lateral side; and finally S1 for the superior side.

Electrocardiogram recordings were performed by placing the device over the sternal midline of patients; the two upper electrodes were placed

by the second intercostal spaces (Figure 1). For the study, ECG recordings were made for 10 s at 250 Hz. Signals were post-processed using a band-pass filter at 0.67–100 Hz and a 50 Hz notch filter before analysis.

### Electrocardiogram acquisition

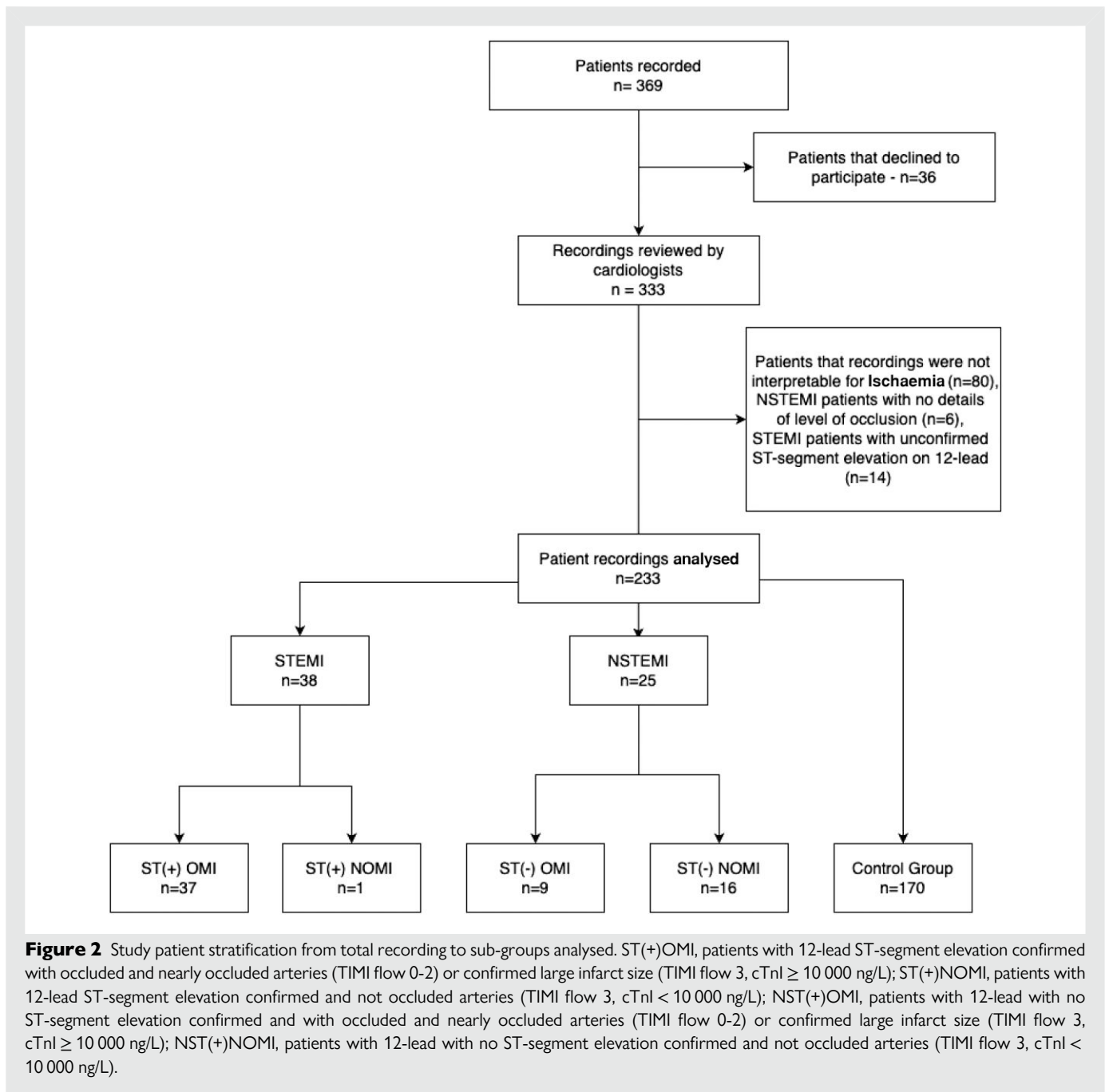
Patients were included upon arrival at the ED, and a 12-lead ECG was recorded, and then subsequently, they were measured with the miniECG. In the case ST-segment elevation was identified in the ambulance, patients were immediately directed to the catheterization laboratory for CAG procedure and if indicated PCI, and a miniECG recording was performed prior to the intervention. For these patients, the ambulance ECG was used as a reference.

### Electrocardiogram evaluation

The miniECG recordings were evaluated by two cardiologists independently and blinded for the clinical outcome of the patients. The cardiologists first evaluated whether the miniECG was of adequate quality for interpretation of ST-segment deviations. Next, the presence of >1 mm ST-segment elevations and depressions (ST-segment deviations) was scored. In case of disagreement in the presence of ST-segment deviations, the miniECGs were re-evaluated by a third cardiologist. For the 12-lead ECGs, the interpretation of the attending cardiologist was used to determine whether a STEMI was suspected.

### Outcomes

Firstly, we compared the interpretation of the miniECG (e.g. ST-segment deviations or not) to the clinical diagnosis based on the 12-lead ECG and troponin levels and divided the cohort in three groups: STEMI,



non-ST-elevation myocardial infarction (NSTEMI), and controls. These results were compared with the 12-lead ECG evaluations of the attending cardiologists during clinical practice (e.g. STEMI or no STEMI), the outcomes of the CAG (TIMI flow), and infarct size (troponin levels 24 h). Troponin level assays at the UMCU utilized Siemens Diagnostics hs-cTnI assay with upper limit normal (ULN)  $< 45.2$  ng/L, while the troponin level assays at the MMC utilized Abbot Architect hs-cTnI with male ULN  $< 0.03$   $\mu\text{g/L}$  and with women ULN  $< 0.02$   $\mu\text{g/L}$ .

Next, we compared the miniECG and 12-lead ECG interpretation to the presence of OMI. Patients with occluded or nearly occluded arteries and TIMI flow 0-2 were classified as OMI, patients with TIMI flow 3 but with high troponin levels (cTnI  $\geq 10\,000$  ng/L) were also included in this category as the troponin levels indicate a large size infarct, and patients with TIMI flow 3 with elevated troponin levels  $< 10\,000$  ng/L were classified as NOMI. Patients without elevated troponin levels remained in the control

group. Finally, this results in five groups: ST(+)OMI, ST(-)OMI, ST(+)NOMI, ST(-)NOMI, and controls.

### Statistical analysis

Data are presented as mean  $\pm$  SD or as number with percentages, as appropriate. Continuous variables were compared using analysis of variance (ANOVA). For the categorical data such as the location of infarction, we used the  $\chi^2$  test. The  $P$ -value of  $< 0.05$  was considered statistically significant.

## Results

Between 26 April 2021 and 24 February 2022, 369 patients with complaints of chest pain were identified by the ambulance services and ED

**Table 1** Baseline characteristics of patients included in the study

	ST(+) <b>OMI</b> [N (%)]	ST(+) <b>NOMI</b> [N (%)]	ST(-) <b>OMI</b> [N (%)]	ST(-) <b>NOMI</b> [N (%)]	Control [N (%)]
PATIENTS	37	1	9	16	170
SEX, MALE, N (%)	33 (89.1)	1 (100)	8 (89)	10 (62.5)	104 (61)
MEAN AGE	62.9 ± 11.3	54	64 ± 13.0	70.5 ± 10.3	63.1 ± 13.3
Body Mass Index (BMI)	27.7 ± 4.8	—	26.3 ± 10.8	24.9 ± 7.1	24.9 ± 10.1
MEAN TIME BETWEEN 12-LEAD ECG AND MINIECG	26 min ± 20 min	—	32 min ± 31 min	1 h 15 min ± 1 h 27 min	30 min ± 46 min
TROPONIN LEVELS	87 583 ± 106 652	5315	36 536 ± 69 617	1678 ± 2574	
HISTORY OF CARDIOVASCULAR DISEASE	14 (38)	0 (0)	3 (33.3)	10 (62.5)	113 (66)
CAG	3 (8.8)	0 (0)	0 (0)	1 (6.25)	40 (23)
PCI	8 (21)	0 (0)	1 (11.1)	4 (25)	53 (31)
CABG	0 (0)	0 (0)	0 (0)	0 (0)	14 (8)
Other	0 (0)	0 (0)	0 (0)	0 (0)	5 (2.9)
COMORBIDITIES					
Hypertension	10(28)	1 (100)	5 (55.5)	10 (62.5)	91 (53.5)
Hypercholesterolaemia	16 (43)	0 (0)	4 (44.4)	9 (56.25)	85 (50)
Diabetes	4 (11)	0 (0)	1 (11.1)	2 (12.5)	33 (19.4)
History of smoking	14 (37)	1 (100)	2 (22.2)	0 (0)	52 (30.5)

ST(+)**OMI**, patients with 12-lead ST-segment elevation confirmed with occluded and nearly occluded arteries (TIMI flow 0-2) or confirmed large infarct size (TIMI flow 3, cTnl ≥ 10 000 ng/L); ST(+)**NOMI**, patients with 12-lead ST-segment elevation confirmed and not occluded arteries (TIMI flow 3, cTnl < 10 000 ng/L); NST(+)**OMI**, patients with 12-lead with no ST-segment elevation confirmed and with occluded and nearly occluded arteries (TIMI flow 0-2) or confirmed large infarct size (TIMI flow 3, cTnl ≥ 10 000 ng/L); NST(+)**NOMI**, patients with 12-lead with no ST-segment elevation confirmed and not occluded arteries (TIMI flow 3, cTnl < 10 000 ng/L).

**Table 2** ST-segment deviations observed on miniECG recordings over patient groups

ST-segment deviations	N	12-lead ECG	miniECG	P-value
OMI	46	38 (82.6%)	30 (65.2%)	0.0575
OMI culprit vessel				0.9407
LAD	21	17 (80.9%)	13 (61.9%)	0.512
RCA	14	12 (85.7%)	8 (57.1%)	0.094
RCX	9	7 (77.7%)	7 (77.7%)	1.0
LM	2	2 (100%)	2 (100%)	1.0
NOMI	17	6 (35.2%)	2 (11.7%)	0.105
Control	170	12 (7%)	13 (7.6%)	0.835

to participate in the study. Thirty-six (9.7%) patients declined to participate in the study, 100 (27.1%) recordings were excluded from analysis, as they were considered low quality for interpreting ischaemia (80, 21.4%), no CAG was performed (6, 1.9%), or no 12-lead ECG was available for comparison (14, 3.8%). Of the miniECG recordings that were excluded due to quality issues, 19% presented with a STEMI, 5% with a NSTEMI, and 76% were controls. In total, 233 (63%) miniECG recordings were annotated by the cardiologists for cardiac ischaemia (Figure 2). Baseline characteristics are summarized in Table 1.

When considering only the 12-lead ECG and troponin levels, a total of 38 (16%) patients presented with STEMI, while 25 (10.7%) patients had a NSTEMI. In the patients identified as STEMI, the miniECG showed

ST-segment deviations in 30 patients (79%), while in the patients with NSTEMI, 2 patients (8%) showed ST-segment deviations. Forty-six patients had OMI and 17 NOMI. Thirty (65.2%) OMI and 2 (11%) NOMI patients had ST-segment deviations on their miniECG, and 38 (83%) and 6 (35%) had ST-segment elevation on their 12-lead ECG, respectively. One hundred and seventy (73%) patients were not considered OMI or NOMI, and in this group, there were 13 (7.6%) patients that showed ST-segment deviations on their miniECG recordings and 12 (7.0%) showed ST-segment elevations on the 12-lead ECGs (Table 2).

Sensitivity, specificity, positive predictive value, and negative predictive value for detecting STEMI by the miniECG were 79% (95% confidence interval (CI) 63–90), 92% (95% CI 88–96), 67% (95% CI 54–77), and 96% (95% CI 92–98), respectively. For the detection of OMI, these measures were 65% (95% CI 50–79), 92% (95% CI 87–95), 67% (95% CI 54–77), and 91% (95% CI 81–90) for the miniECG, compared with 83% (95% CI 69–92), 90% (95% CI 85–94), 68% (95% CI 54–77), and 96% (95% CI 92–97) for the 12-lead ECG, respectively. When taking only OMI patients with ST-segment elevation into account, the miniECG measures are 81% (95% CI 65–92), 92% (95% CI 88–96), 67% (95% CI 55–77), and 96% (95% CI 93–98), respectively.

Culprit lesions were reported in left anterior descending artery (16/37), right coronary artery (12/37), ramus circumflexus (7/37), and left main coronary artery (2/37; Table 3). The locations of ischaemia as detected by the 12-lead ECG were anterior (10/37), antero-lateral and lateral (7/37), inferior (8/37), posterior and infero-postero-lateral (IPL, 11/37), and pan-ischaemia (1/37). For the anterior MI, miniECG ST-segment elevations were observed in leads A1 (7/10) and A2 (5/5), while ST-segment depressions were observed in leads I2 (8/10) and I3 (8/10). For IPL and posterior MI's, miniECG recordings showed ST-segment elevations in leads I1 (7/11), I2 (8/11), and I3 (8/11) and ST-segment depressions in the anterior lead A2 (6/11; see Figure 4).

**Table 3** Infarction characteristics on ST(+)OMI patients based on miniECG ST-segment deviation on confirmed ST-segment elevation patients medical centre

ST deviation visible on miniECG?	Confirmed ST-OMI patients			P-value
	N	Yes	No	
N (%)	37	30 (82%)	7 (18%)	
MALES, N (%)	30 (85%)	27 (90%)	6 (85.7%)	
MEAN BMI (SD)		27.1 ± 4.1	29.6 ± 6.7	0.244
AGE, YEARS (SD)		63.8 ± 11.5	59.4 ± 10.9	0.367
MEAN TIME BETWEEN 12-LEAD ECG AND MINIECG, MIN (SD)		26 min (21)	28 min (15)	0.829
CULPRIT LESION				0.29
LAD	16	13 (81.25%)	3 (18.7%)	
RCA	12	8 (66.6%)	4 (33.3%)	
RCX	7	7 (100%)	0 (0%)	
LEFT MAIN	2	2 (100%)	0 (0%)	
LOCATION				0.72
ANTERIOR	10	8 (80%)	2 (20%)	
ANTERO-LATERAL/LATERAL	7	6 (85.7%)	1 (14.2%)	
INFERIOR	8	6 (75%)	2 (25%)	
IPL/POSTERIOR	11	9 (81.8%)	2 (18.2%)	
PAN-ISCHAEMIA	1	1 (100%)	0 (0%)	

ST(+)OMI, patients with 12-lead ST-segment elevation confirmed and with occluded and nearly occluded arteries (TIMI flow 0-2) or confirmed large infarct size (TIMI flow 3, cTnI ≥ 10 000 ng/L).

Figure 3 shows examples of the ST-segment deviations on the miniECG recordings in comparison to the 12-lead ECG.

In 7 out of 37 patients with ST-segment elevation on the 12-lead ECG and OMI, no ST-segment deviations were detected with the miniECG. For these patients, the MI locations were anterior (2), antero-lateral (1), inferior (2), IPL (1), and posterior (1). For two of these patients, other characteristics on the miniECG were noted such as inverted T-waves (2/2), high R-peak amplitudes (>1.5 mV, 1/2), and high-amplitude T-waves (1/2). For two patients, the reported body mass indexes (BMI) were higher than 30 kg/m<sup>2</sup>. Finally for the other three patients, their BMIs were higher than 25 kg/m<sup>2</sup>. In comparison, for OMI patients, the mean BMI was 27.1 kg/m<sup>2</sup>, while for false negative patients, it was 29.6 kg/m<sup>2</sup> (Table 3).

## Discussion

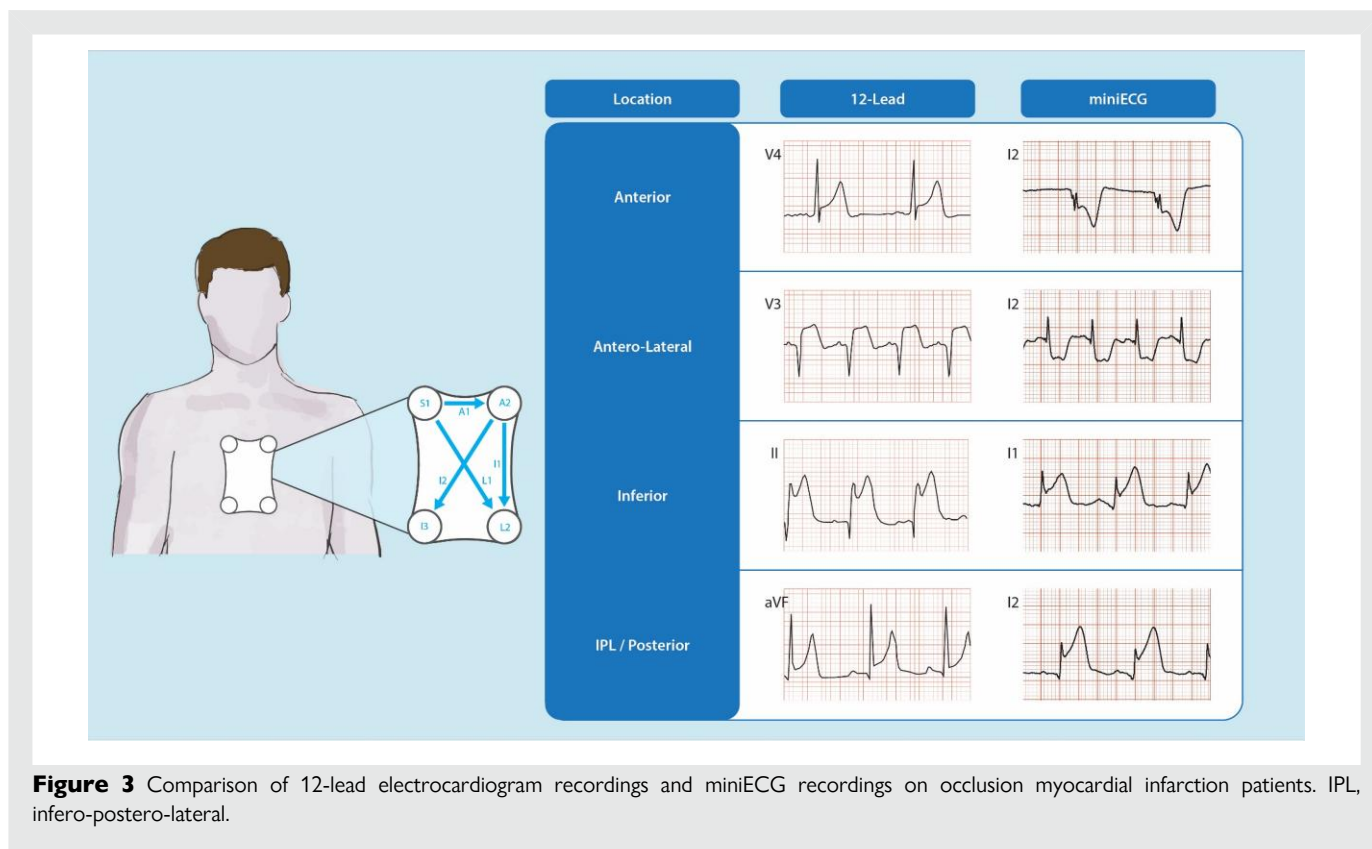
In this study, we evaluated the performance of a novel precordial ECG device (the miniECG) to detect ST-segment deviations due to ACS in patients presenting to the ED with chest pain. The miniECG is able to detect ST deviations in 65% of patients with OMI and has a low rate of false positives with a specificity of 92%. While an OMI can never be ruled out with the ECG alone, this indicates that the miniECG can be used to rule in which patients need rapid workup and transport to a PCI centre, without having many false alarms. This could be of great importance to reduce time to treatment when a 12-lead ECG is not readily available or for patients with atypical complaints. Contrary to other single-lead ECG wearables, the device was able to detect ST deviations for all different culprit vessels. With this study, we have taken the initial steps to understand the capabilities of the miniECG as a tool to improve rapid diagnosis of acute coronary occlusion.

Two important opportunities of the miniECG are, first, to reduce symptom-to-balloon interval in patients with OMI and, second, to pick up ST deviations in patients with intermitted or atypical symptoms. Previous studies have shown that the symptom-to-door time

in patients with a STEMI is one of the most important predictors of outcome.<sup>5</sup> When the miniECG is available to patients at home or at institutions and departments where currently no 12-lead ECG is available, this could speed up recognition of OMI. With a sensitivity of 65% and specificity of 92% for OMI, the miniECG can be used to rule in, but never to rule out, just like the 12-lead ECG (with a sensitivity of 83% for OMI). Secondly, patients with atypical and intermittent symptoms could use the miniECG to detect ischaemia that warrants rapid referral. Studies have shown that 15–30% of patients with acute MI do not recognize these symptoms and never contact emergency services or only after the window for early PCI (<12 h).<sup>6</sup> Case reports already showed the value of an Apple Watch to detect ST deviations in patients with intermittent angina pectoris or atypical symptoms.<sup>17,18</sup>

One of the major challenges for using the miniECG at home could be the number of false positives (5.5%). While this proportion is low, it could be higher than the prevalence of OMI in this population, depending on the selection criteria for performing a miniECG. It could lead to more unnecessary referrals and even coronary angiographies. Further studies should be performed to better understand the miniECG patterns of OMI and other abnormalities with ST-segment deviations (such as early repolarization, pericarditis, or left bundle branch abnormality) to reduce the number of false positives.

Other single-lead ECG wearables, such as the Apple Watch, were not useful for detection of ischaemic ST-segment deviations from different coronary artery culprits as their single-lead design leads to a sensitivity of only 34%.<sup>12</sup> Workarounds have been proposed, where the Apple Watch is placed on all standard 12-lead ECG positions, but these are too time consuming and complicated for real-world use.<sup>19</sup> Other multi-lead ECG wearables were not validated for the detection of cardiac ischaemia.<sup>20</sup> Another study using a continuous ECG recording device with electrodes on the right shoulder, left shoulder, left iliac crest, and sternum showed the feasibility to detect OMI from all culprit vessels in the outpatient setting.<sup>14</sup> Our study adds that a



**Figure 3** Comparison of 12-lead electrocardiogram recordings and miniECG recordings on occlusion myocardial infarction patients. IPL, infero-postero-lateral.

simple event recorder device with fixed electrodes like the miniECG could also be very useful to detect OMI from all different culprit vessels. The design of the miniECG could allow patients to perform recordings at the first indication of symptoms.

An additional advantage over single-lead devices is that the miniECG can already indicate the culprit vessel, as there were markedly different ECG signatures for the different locations of ischaemia. As shown in Figure 4, anterior MI shows ST-segment elevation in the A leads with reciprocal depression in the I leads. Inferior MI shows elevation in the I leads, while in antero-lateral and infero-lateral MI, the L leads are also involved.

Importantly, the miniECG showed lower sensitivity (67%) for detection of OMI as compared to the 12-lead ECG (82%). For the locations observed in study, this could not be due to the measurement location of the device, as sensitivity was similar for culprit vessels (Table 3).

For the RCA, the 12-lead ECG performed better than the miniECG (Table 3). This shortcoming could be related to the position of electrodes as the miniECG measures locally in the chest area, while for the 12-lead ECG, the distance between the electrodes is larger, covering a larger area than the miniECG. Also, the 12-lead ECG measures the heart activity in all planes in comparison to the miniECG, which measures on the frontal plane. Further research should be performed to understand the importance of the miniECG placement and how to compensate this shortcoming. The use of the miniECG could evolve to similar approaches such as the Apple Watch where the watch has been placed over the chest area and showed improved performance.<sup>12,21</sup>

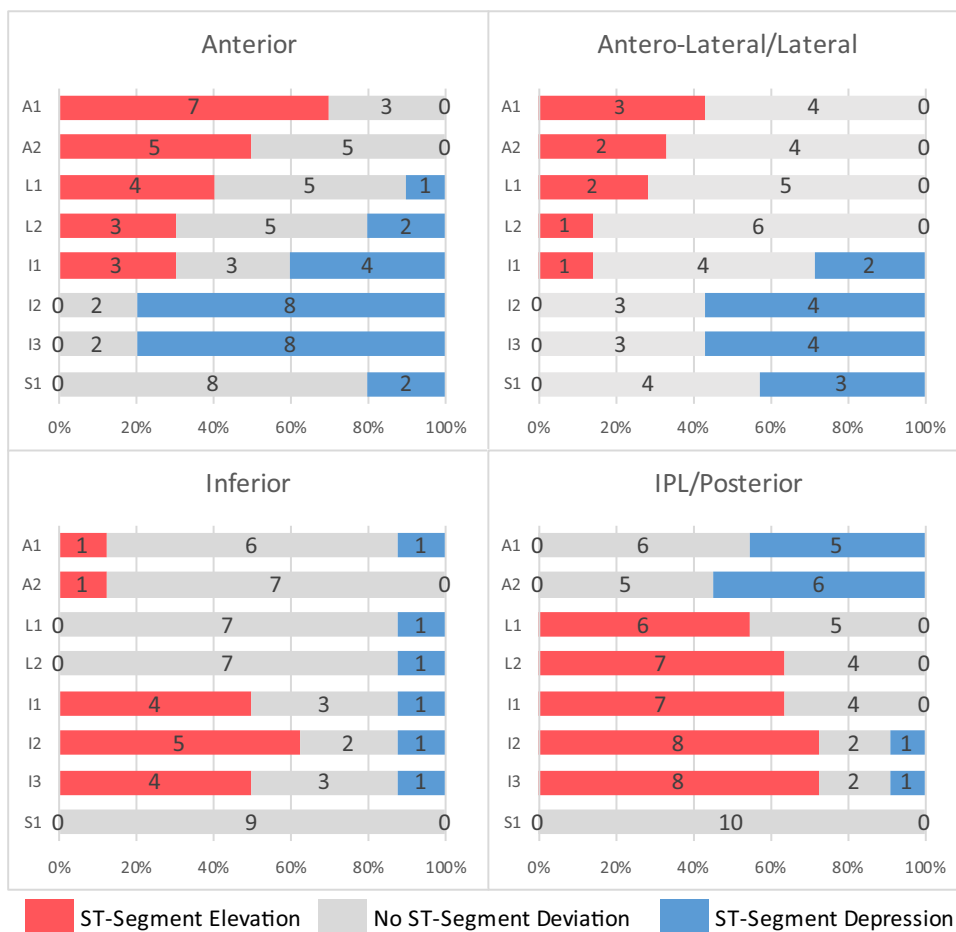
Inspection of the OMI cases without ST-segment elevations on the miniECG but with ST-segment elevation on the 12-lead ECG indicated a higher proportion of females and patients with a high BMI, although differences were not statistically significant. This points to anatomical limitations of the miniECG, as the device is located further away

from the heart in these patients, which leads to smaller QRS vectors that make ST deviations harder to recognize. This is in line with earlier studies that showed microvoltages were associated with excessive chest wall adipose tissue.<sup>22,23</sup>

One of the limitations of our study was that technicians and nurses using the miniECG did not have visual feedback of the recording and as a consequence could not see quality of the recordings. For 79/333 of the recordings, cardiologists concluded that these ECGs were not of sufficient quality to interpret for ischaemia. We believe the quality of these ECGs was affected by the fact that for this prototype version of the miniECG and the app, no live recordings were shown. For wearable devices (smartwatches) with similar recording approach, Mannhart *et al.*<sup>24</sup> reported that a similar ratio of inconclusive tracings was recorded with these devices. On a new version of the miniECG, we have re-designed the app in such a way that it shows two of the channels recorded, allowing real-time visual feedback on the quality of the recordings and showing if motion artefacts and baseline wander would be visible in the final recording. This new version of the app is currently in use and evaluated in a new study where we observed a considerable decline of low-quality recordings. Another reason for the low quality of the recordings was due to the acute environment where measurements were taken (ED and catheterization laboratory), as attending patients was a priority. Measurements were not shown at the time of recording, and quality was not checked promptly.

Another limitation of this study was that for 14 patients, we were not able to confirm ST-segment elevations were present on their ECGs upon arrival at the hospital, as no 12-lead ECG recordings were available. Therefore, we were not able to compare the miniECG recordings with the 12-lead ECG. To fully determine the capabilities of the miniECG to detect OMI on any location, we believe it will be necessary to measure more patients, as our total sample size of OMI patients was 46.

As new mobile ECG devices are becoming available for home use, there is an area of opportunity for timely detection of cardiac disorders.



**Figure 4** miniECG leads where ST deviations were observed on patients with confirmed ST elevation on 12-lead electrocardiogram and with occluded or nearly occluded coronary arteries. IPL, infero-postero-lateral.

In the case of patients with occluded and nearly occluded coronary arteries, the early detection of occlusion would allow to triage them upon arrival to ED or catheterization laboratory. To allow the early detection of occlusion and to trigger interventions adequately, the next technological step is the inclusion of artificial intelligence that could help to triage acute cases reducing time to treatment.<sup>25</sup> When such technology is available, the miniECG should be validated in the home setting. Moreover, further research is required to demonstrate non-inferiority of the miniECG to the standard 12-lead ECG in the detection of other common cardiac (ab)normalities.

## Conclusions

In conclusion, the miniECG can record multi-lead ECG and rule in OMI from a variety of culprits. Further studies should focus on adding automated analysis of the recordings and validation of the results with patients at home.

## Supplementary material

Supplementary material is available at *European Heart Journal – Digital Health*.

## Acknowledgements

We kindly acknowledge all the clinical staff that supported the study at the UMC Utrecht and Meander Medical Center.

## Funding

This research was funded by the Netherlands Organisation for Health Research and Development (ZonMw) with grant number 104021004 and the Dutch Heart Foundation with grant number 2019B011.

**Conflict of interest:** P.A.D. and R.v.d.Z. own stock in HeartEye B.V., a company also active in the field of handheld ECG devices. R.R.v.d.L. and R.v.E. own stock in Cordys Analytics, a spin-off of the UMC doing ECG-AI analysis. The other authors have no conflicts of interest to declare.

## Data availability

The data that support the findings of this study are available on reasonable request to the corresponding author.

## References

1. Tsao CW, Aday AW, Almarazooq ZI, Alonso A, Beaton AZ, Bittencourt MS, et al. Heart disease and stroke statistics—2022 update: a report from the American Heart Association. *Circulation* 2022;145:E153–E639.



2. Khan AR, Golwala H, Tripathi A, Bin Abdulhak AA, Bavishi C, Riaz H, et al. Impact of total occlusion of culprit artery in acute non-ST elevation myocardial infarction: a systematic review and meta-analysis. *Eur Heart J* 2017;**38**:3082–3089.
3. Namdar P, Yekefallah L, Jalalian F, Barikani A, Razaghpour A. Improving door-to-balloon time for patients with acute ST-elevation myocardial infarction: a controlled clinical trial. *Curr Probl Cardiol* 2021;**46**:100674.
4. Karkabi B, Meir G, Zafirir B, Jaffe R, Adawi S, Lavi I, et al. Door-to-balloon time and mortality in patients with ST-elevation myocardial infarction undergoing primary angioplasty. *Eur Heart J Qual Care Clin Outcomes* 2021;**7**:422–426.
5. Redfors B, Mohebi R, Giustino G, Chen S, Selker HP, Thiele H, et al. Time delay, infarct size, and microvascular obstruction after primary percutaneous coronary intervention for ST-segment-elevation myocardial infarction. *Circ Cardiovasc Interv* 2021;**14**:E009879.
6. van der Ende MY, Juarez-Orozco LE, Waardenburg I, Lipsic E, Schurer RAJ, van der Werf HW, et al. Sex-based differences in unrecognized myocardial infarction. *J Am Heart Assoc* 2020;**9**:e015519.
7. Ibanez B, James S, Agewall S, Antunes MJ, Bucciarelli-Ducci C, Bueno H, et al. 2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: the Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC). *Eur Heart J* 2018;**39**:119–177.
8. Pendell Meyers H, Bracey A, Lee D, Lichtenheld A, Li WJ, Singer DD, et al. Accuracy of OMI ECG findings versus STEMI criteria for diagnosis of acute coronary occlusion myocardial infarction. *IJC Heart and Vasculature* 2021;**33**:100767.
9. Bansal A, Joshi R. Portable out-of-hospital electrocardiography: a review of current technologies. *J Arrhythm* 2018;**34**:129–138.
10. Wasserlauf J, You C, Patel R, Valys A, Albert D, Passman R, et al. Smartwatch performance for the detection and quantification of atrial fibrillation. *Circ Arrhythm Electrophysiol* 2019;**12**:e006834.
11. Perez MV, Mahaffey KW, Hedlin H, Rumsfeld JS, Garcia A, Ferris T, et al. Large-scale assessment of a smartwatch to identify atrial fibrillation. *N Engl J Med* 2019;**381**:1909–1917.
12. Caillol T, Strik M, Ramirez FD, Abu-Alrub S, Marchand H, Buliard S, et al. Accuracy of a smartwatch-derived ECG for diagnosing bradyarrhythmias, tachyarrhythmias, and cardiac ischemia. *Circ Arrhythm Electrophysiol* 2021;**14**:102–104.
13. Nigolian A, Dayal N, Nigolian H, Stettler C, Burri H. Diagnostic accuracy of multi-lead ECGs obtained using a pocket-sized bipolar handheld event recorder. *J Electrocardiol* 2018;**51**:278–281.
14. Van Heuverswyn F, De Buyzere M, Coeman M, De Pooter J, Drieghe B, Duytschaever M, et al. Feasibility and performance of a device for automatic self-detection of symptomatic acute coronary artery occlusion in outpatients with coronary artery disease: a multicentre observational study. *Lancet Digit Health* 2019;**1**:e90–e99.
15. El Haddad M, Vervloet D, Taeymans Y, De Buyzere M, Bové T, Stroobandt R, et al. Diagnostic accuracy of a novel method for detection of acute transmural myocardial ischemia based upon a self-applicable 3-lead configuration. *J Electrocardiol* 2016;**49**:192–201.
16. de Vries NM, Zepeda-Echavarría A, van de Leur RR, Loen V, Vos MA, Boonstra MJ, et al. Detection of ischemic ST-segment changes using a novel handheld ECG device in a porcine model. *JACC: Advances* 2023;**2**:100410.
17. Stark K, Czermak T, Massberg S, Orban M. Watch out for ST-elevation myocardial infarction: a case report of ST-elevation in single-lead electrocardiogram tracing of a smartwatch. *Eur Heart J Case Rep* 2020;**4**:1–4.
18. Drexler M, Elsner C, Gabelmann V, Gori T, Münzel T. Apple Watch detecting coronary ischaemia during chest pain episodes or an apple a day may keep myocardial infarction away. *Eur Heart J* 2020;**41**:2224–2224.
19. Spaccarotella CAM, Polimeni A, Migliarino S, Principe E, Curcio A, Mongiardo A, et al. Multichannel electrocardiograms obtained by a smartwatch for the diagnosis of ST-segment changes. *JAMA Cardiol* 2020;**5**:1176–1180.
20. Zepeda-Echavarría A, van de Leur RR, van Sleuwen M, Hassink RJ, Wildbergh TX, Doevendans PA, et al. Electrocardiogram devices for home use: technological and clinical scoping review. *JMIR Cardio* 2023;**7**:e44003.
21. Avila CO. Novel use of Apple Watch 4 to obtain 3-lead electrocardiogram and detect cardiac ischemia. *Perm J* 2019;**23**:99102.
22. Kurisu S, Ikenaga H, Watanabe N, Higaki T, Shimonaga T, Ishibashi K, et al. Electrocardiographic characteristics in the underweight and obese in accordance with the World Health Organization classification. *IJC Metab Endocr* 2015;**9**:61–65.
23. Fraley MA, Birchem JA, Senkottaiyan N, Alpert MA. Obesity and the electrocardiogram. *Obes Rev* 2005;**6**:275–281.
24. Mannhart D, Lischer M, Knecht S, du Fay de Lavallaz J, Strebel I, Serban T, et al. Clinical validation of 5 direct-to-consumer wearable smart devices to detect atrial fibrillation. *JACC Clin Electrophysiol* 2023;**9**:232–242.
25. van de Leur RR, Blom LJ, Gavves E, Hof IE, van der Heijden JF, Clappers NC, et al. Automatic triage of 12-lead ECGs using deep convolutional neural networks. *J Am Heart Assoc* 2020;**9**:e015138.