LETTER TO THE EDITOR

On the detection of acute coronary occlusion with the miniECG

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We would like to thank Ratcliffe *et al.*, for their letter in response to our manuscript 'Detection of acute coronary occlusion with a novel mobile electrocardiogram device: a pilot study'.[1] In their letter, they discuss the importance of triaging patients with cardiac chest pain, the use of mobile devices, and the necessity of correctly assessing acute coronary syndrome patients. They also bring out important questions regarding our study, and we believe that addressing these concerns is crucial. In this letter, we take the opportunity to respond to their points.

We were fortunate to receive a well-positioned critical letter by Ratcliffe *et al.* warning about the potential lack of diagnostic power of the miniECG in general and possibly even greater unreliability in women. For our study, we could not perform an analysis on sex differences due to the sample size and distribution of patients based on sex, especially for occlusion myocardial infarction patients, as 89% were male. Among the false-negative cases, there were patients with high body mass index (BMI) who did not present ST-segment deviations on miniECG recordings, whereas the 12-lead electrocardiogram (ECG) showed ST-segment elevations. We believe this could be due to anatomical characteristics of the patients, such as chest wall adipose tissue. The miniECG version, used at the time, was designed for evaluating the capabilities of the four-electrode arrangement without considering all anatomical conditions; in our preliminary testing, all subjects had low BMIs. Therefore, it is too early to conclude that using a miniECG device will widen the diagnostic gap between females and males. On the contrary, we believe that if a patient can make a recording during complaints, we will detect more ischaemia, especially in symptomatic angina with no obstructive coronary artery disease (ANOCA) patients with coronary spasms and microvascular disease. We believe that for future designs, it is important to consider all possible uses, as researchers have pointed out that the design of medical devices has been limited and has a design gap for all users.[2] This gap should motivate all to make new technologies more accessible and reliable.

As previously mentioned, there are several important areas of improvement based on the outcomes reported in our study. First, the quality of the recordings is now provided in real time and with visual feedback. In currently ongoing studies, we have observed considerable improvements of the quality, providing similar figures as reported for other devices with high-quality recordings > 90%.[3] Second is in terms of various populations to show effectiveness of the device. We aim to show the effectiveness of the device in larger, more balanced populations, to fully demonstrate the performance of the miniECG. Active involvement of patients and considerations based on populations should be included in future designs to provide high-quality reproducible results.[4]

The pathway for developing medical devices is paved by conscious design considering the type of patients, practical use, and clinical testing to demonstrate the performance and reliability in detecting cardiovascular diseases. Spatz *et al.*[5] have discussed challenges for the correct diagnosis using innovative devices. These include the use of digital health technologies, their adaptation to healthcare systems, and the implementation of devices in clinical practice. Steps we believe should be considered for the development of medical devices, and that are key for the correct implementation of technologies. The miniECG has been developed to evaluate if by measuring in the precordial area it is feasible to detect other cardiac disorders than arrhythmias. Our study was a first step towards the development and validation of the device which allows us to learn on the capabilities of the miniECG and the necessary improvements required in its design and the applications in future studies, with a focus on gender balance.

It is important to realize that a normal ECG is never a reason to discard the potential presence of ischaemia. The ECG is just the first tool to come to a diagnosis.

Funding

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

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Data availability

No new data were generated or analysed in support of this research.

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