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## The first handheld device for autonomic self-detection of symptomatic acute coronary artery occlusion: feasibility, performance and implications for time-efficient self-triage of outpatients with CAD

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**Funding Acknowledgement:** Ghent University, Industrial Research Fund (IOF reference: F2015/IOF-advanced/084).

**Background:** Time delay between onset of symptoms and seeking medical attention is a major determinant of mortality and morbidity in patients with acute coronary artery occlusion (ACAO). Response time might be reduced by reliable self-detection of ACAO. Currently no self-applicable device can accurately detect ACAO. We have recently shown that an automatic algorithm based upon a three lead system (RELF method) accurately detects ACAO.

**Purpose:** In this multicenter observational study we tested the operational feasibility, sensitivity and specificity of our RELF method, built into a mobile handheld device, for detection of ACAO.

**Methods:** Patients with planned elective percutaneous coronary intervention (PCI), who were able to use a smartphone, were asked to perform random ambulatory self-recordings for at least one week. A similar self-recording was made before angioplasty and at 60 s of balloon occlusion.

**Results:** The operational feasibility of ambulatory self-recordings in enrolled patients with CAD was 59/64 (92.1%, 95% CI: 83.0–96.6). Of all self-recordings 91.1% (n=4567) were automatically classified as successful within one minute. The mean false positive rate during daily life condi-

tions was 4.19% (95% CI: 3.29–5.10). Amongst 65 balloon occlusions, 63 index-tests at 60 s of occlusion were available. The sensitivity for the target conditions “ACAO”, “ACAO with ECG changes” and “ACAO with ECG changes and ST segment elevation myocardial infarction (STEMI) criteria” was respectively 55/63 (0.87; 95% CI: 0.77–0.93), 54/57 (0.95; 95% CI: 0.86–0.98) and 35/35 (1.00). The figure depicts all (n=3936) ST difference vector (STDVn) measurements obtained during ambulatory postural changes, exercise and coronary artery occlusion with and without ECG changes and/or STEMI criteria. Receiver Operator Curve (ROC) for ACAO at different cut-off values of the magnitude of STDVn was 0.973 (95% CI: 0.956–0.990).

**Conclusions:** Self-recording with our RELF device is feasible for the majority of patients with CAD. The sensitivity and specificity for automatic detection of the earliest phase of acute coronary artery occlusion support the concept of our RELF device for patient empowerment to reduce delay and increase survival without overloading emergency services. This is the first clinical study that confirms the proof-of-concept of self-detection of acute coronary artery occlusion in outpatients with CAD.

