

DIAGNOSTIC ACCURACY OF A NOVEL 3-LEAD ECG SYSTEM COMPARED TO STANDARD 12-LEAD ECG FOR DETECTION OF ACUTE ISCHEMIA

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Background

- Prehospital delays remain a major challenge in ACS treatment. A novel portable device, designed to be always with patients, including when they experience symptoms, may help address this issue.
- This compact, cable-free device, about the size of a credit card – manufactured by HeartBeam, Inc. – records 3-lead ECG signals in three dimensions, capturing a comprehensive view of the heart's electrical activity with the potential to enable early ischemia detection.

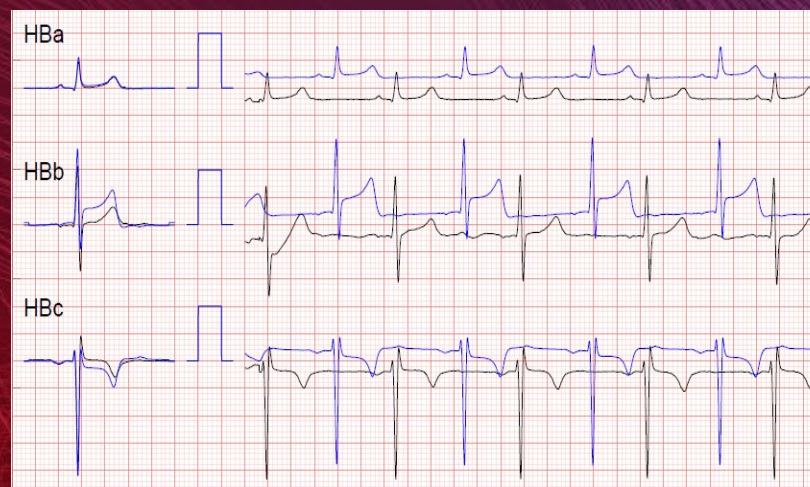
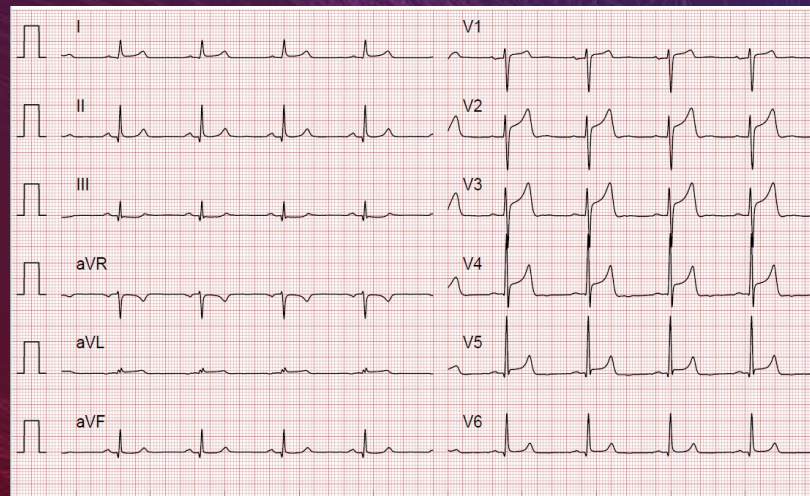


Objective

- This study evaluated the diagnostic accuracy of the 3-dimensional 3-lead ECG compared to simultaneously recorded standard 12-lead ECG for the detection of acute ischemia.

Methods

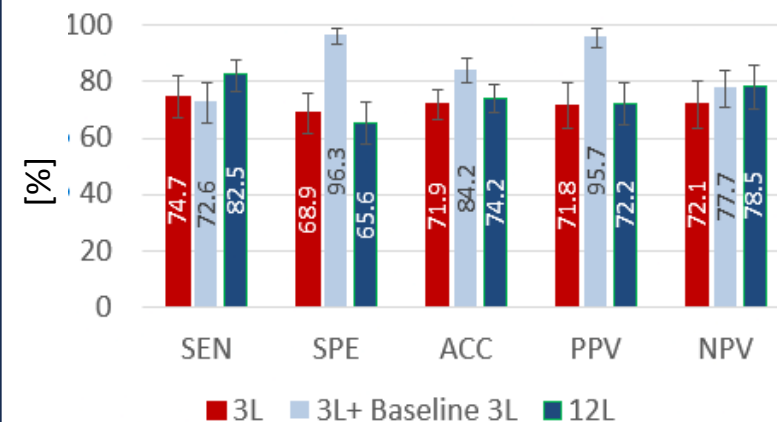
- 66 patients with angiographically confirmed coronary artery disease undergoing PCI were enrolled.
- Transient coronary artery occlusion (~ 90s) via balloon catheter was used as a controlled model for myocardial ischemia.
- Standard 12-lead ECG was augmented with four additional electrodes to replicate the HeartBeam 3-lead ECG, enabling simultaneous 12-lead and 3-lead ECG recordings.
- 120 balloon occlusion and 66 pre-occlusion recordings were obtained.
- Three cardiologists provided independent binary judgment (Yes/No) on the presence of acute ischemia for each 12- and 3-lead recording.



Example of STEMI recording: Top - Standard 12-Lead ECG; Bottom - HeartBeam 3D 3-Lead ECG (blue) with asymptomatic baseline overlay (black)
ST elevation seen in anterior leads of 12-L ECG and on HeartBeam lead 'b'

Results

- 3-lead ECG demonstrated sensitivity and specificity of approx. 75% and 69%, respectively, compared to 83% and 66% for the 12-lead ECG. When the 3-lead ECG was overlaid with an asymptomatic baseline, sensitivity was 73% and specificity increased to 96%.



Ischemia detection with HeartBeam 3D 3-lead configuration, 3D 3-lead with overlaid asymptomatic baseline, and standard 12-lead ECG

Conclusion

- The 3-lead ECG configuration demonstrated comparable performance to the standard 12-lead ECG for detecting acute ischemia.
- With baseline overlay, the 3-lead system exceeded the single 12-lead ECG in diagnostic accuracy, particularly improving specificity.
- These findings support the potential of HeartBeam's portable, patient-centric 3D 3-lead ECG device as a valuable tool for reducing prehospital symptom-to-door time for acute ischemia patients.