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Title: Smartphone ECG for evaluation of STEMI: Results of the ST LEUIS Pilot Study

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Corresponding Author: Dr. Joseph Brent Muhlestein, MD

Corresponding Author's Institution: Intermountain Medical Center

First Author: Joseph B Muhlestein, MD

Order of Authors: Joseph B Muhlestein, MD; Viet Le, PA-C; David Albert, MD; Fidela L Moreno, MD; Jeffrey L Anderson, MD; Frank Yanowitz, MD; Robert B Vranian, MD; Gregory W Barsness, MD; Charles F Bethea, MD; Harry W Severance, MD; Barry Ramo, MD; John Pierce, MD; Alejandro Barbagelata, MD; Joseph Brent Muhlestein, MD

**Abstract: Background:** 12-lead ECG is a critical component of initial evaluation of cardiac ischemia, but has traditionally been limited to large, dedicated equipment in medical care environments. Smartphones provide a potential alternative platform for the extension of ECG to new care settings and to improve timeliness of care.

**Objective:** To gain experience with smartphone electrocardiography prior to designing a larger multicenter study evaluating standard 12-lead ECG compared to smartphone ECG.

**Methods:** 6 patients for whom the hospital STEMI protocol was activated were evaluated with traditional 12-lead ECG followed immediately by a smartphone ECG using right (VnR) and left (VnL) limb leads for precordial grounding. The AliveCor™ Heart Monitor was utilized for this study. All tracings were taken prior to catheterization or immediately after revascularization while still in the catheterization laboratory.

**Results:** The smartphone ECG had excellent correlation with the gold standard 12-lead ECG in all patients. Four out of six tracings were judged to meet STEMI criteria on both modalities as determined by three experienced cardiologists, and in the remaining two, consensus indicated a non-STEMI ECG diagnosis. No significant difference was noted between VnR and VnL.

**Conclusions:** Smartphone based electrocardiography is a promising, developing technology intended to increase availability and speed of electrocardiographic evaluation. This study confirmed the potential of a smartphone ECG for evaluation of acute ischemia and the feasibility of studying this technology further to define the diagnostic accuracy, limitations and appropriate use of this new technology.

October 31, 2014  
Galen S. Wagner, MD  
Editor-in-Chief  
Journal of Electrocardiology

Dear Dr. Wagner,

I am respectfully submitting a manuscript entitled: “*Smart Phone ECG for Evaluation of STEMI: Results of the ST LEUIS Pilot Study.*” I appreciate your consideration of it for publication in the Journal of Electrocardiology.

The contents of this paper constitute original research performed wholly by the named authors and at the named institutions. The authors have each approved its publication. This original research has not previously been published and is not currently submitted for publication elsewhere. Additionally, it is acknowledged that if accepted for publication, it will not be published elsewhere, including electronically, in the same form, in English or in any other language, without the written consent of the copyright-holder.

Joseph Boone Muhlestein MD<sup>a,b</sup>, Viet Le PA<sup>a</sup>, David Albert MD<sup>c</sup>, Fidela Ll. Moreno MD<sup>a</sup>, Jeffrey L. Anderson MD<sup>a,b</sup>, Frank Yanowitz MD<sup>a,b</sup>, Robert B. Vranian MD<sup>d</sup>, Gregory W. Barsness MD<sup>e</sup>, Charles F. Bethea MD<sup>f</sup>, Harry W Severance MD<sup>g</sup>, Barry Ramo MD<sup>h</sup>, John Pierce<sup>i</sup>, Alejandro Barbagelata MD<sup>j</sup>, Joseph Brent Muhlestein MD<sup>a,b</sup>

<sup>a</sup>Intermountain Heart Institute, Salt Lake City, Utah

<sup>b</sup>The University of Utah, Department of Internal Medicine, Salt Lake City, Utah

<sup>c</sup>AliveCor™ Corporation, San Francisco, CA

<sup>d</sup>Mary Washington Hospital, Fredericksburg, Virginia

<sup>e</sup>Mayo Clinic, Rochester, Minnesota

<sup>f</sup>Integrus Heart Hospital, Oklahoma City, Oklahoma

<sup>g</sup>Erlanger Institute for Clinical Research, UT College of Medicine, Chattanooga, Tennessee

<sup>h</sup>New Mexico Heart Institute, Albuquerque, New Mexico

<sup>i</sup>Duke University, Durham, North Carolina

<sup>j</sup>Buenos Aires, Argentina

Sincerely,

Joseph Boone Muhlestein, MD  
Intermountain Heart Institute  
Intermountain Medical Center  
5121 South Cottonwood Street  
Murray, UT, 84157  
Tel. (801) 507-4760  
Fax (801) 507-4789  
E-mail [josephmuhlestein@gmail.com](mailto:josephmuhlestein@gmail.com)

## Highlights

- Smartphone based ECG was compared to 12-lead ECG for 6 STEMI protocol activations.
- Excellent concordance between smartphone and 12-lead ECG was noted on all subjects.
- A single lead ground on either arm appeared to be adequate for acutely evaluating ischemia.

## **Smartphone ECG for evaluation of STEMI: Results of the ST LEUIS Pilot Study**

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Jeffrey L. Anderson MD<sup>a,b</sup>, Frank Yanowitz MD<sup>a,b</sup>, Robert B. Vranian MD<sup>d</sup>, Gregory W.  
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MD<sup>i</sup>, Alejandro Barbagelata MD<sup>j</sup>, Joseph Brent Muhlestein MD<sup>a,b</sup>

<sup>a</sup>Intermountain Heart Institute, Salt Lake City, Utah

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<sup>c</sup>AliveCor™ Corporation, San Francisco, CA

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<sup>f</sup>Integrus Heart Hospital, Oklahoma City, Oklahoma

<sup>g</sup>Erlanger Institute for Clinical Research, UT College of Medicine, Chattanooga, Tennessee

<sup>h</sup>New Mexico Heart Institute, Albuquerque, New Mexico

<sup>i</sup>Duke University, Durham, North Carolina

<sup>j</sup>University of Texas Medical Branch

Corresponding author:

Joseph Brent Muhlestein

[brent.muhlestein@imail.org](mailto:brent.muhlestein@imail.org)

Intermountain Heart Institute  
5121 South Cottonwood Street  
Salt Lake City, Utah 84107  
Telephone: 801-507-4760

## **Abstract**

**Background:** 12-lead ECG is a critical component of initial evaluation of cardiac ischemia, but has traditionally been limited to large, dedicated equipment in medical care environments.

Smartphones provide a potential alternative platform for the extension of ECG to new care settings and to improve timeliness of care.

**Objective:** To gain experience with smartphone electrocardiography prior to designing a larger multicenter study evaluating standard 12-lead ECG compared to smartphone ECG.

**Methods:** 6 patients for whom the hospital STEMI protocol was activated were evaluated with traditional 12-lead ECG followed immediately by a smartphone ECG using right (VnR) and left (VnL) limb leads for precordial grounding. The AliveCor™ Heart Monitor was utilized for this study. All tracings were taken prior to catheterization or immediately after revascularization while still in the catheterization laboratory.

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**Conclusions:** Smartphone based electrocardiography is a promising, developing technology intended to increase availability and speed of electrocardiographic evaluation. This study confirmed the potential of a smartphone ECG for evaluation of acute ischemia and the feasibility of studying this technology further to define the diagnostic accuracy, limitations and appropriate use of this new technology.

**Key words:** ECG, STEMI, Heart Attack, Myocardial infarction, smartphone, iPhone, ischemia

## Highlights

- Smartphone based ECG was compared to 12-lead ECG for 6 STEMI protocol activations.
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- A single lead ground on either arm appeared to be adequate for acutely evaluating ischemia.

## **Introduction**

Annually, one in six deaths is due to cardiovascular disease. The American Heart Association has reported that 405,309 Americans died from cardiovascular disease (CVD) in 2008, and that annually an estimated 785,000 Americans will experience a first time coronary event, 470,000 will suffer a recurrent event, and 195,000 will have a silent first myocardial infarction[1].

Urgent revascularization is indicated in patients with ST-Elevation Myocardial Infarction (STEMI) which is diagnosed largely on electrocardiographic criteria[2]. The majority of STEMI deaths occur within the first 1 to 2 hours[3]. Many barriers have been identified preventing early recognition of STEMI including lack of the patient's ability to identify that they are experiencing an MI, misattributing symptoms of STEMI to some other disease, fearing embarrassment of false alarm, not fitting a "stereotype" for heart attack, and lack of recognition by bystanders of a STEMI event[3,4].

Given that earlier treatment of STEMI reduces mortality and morbidity, it is important to increase the speed of diagnosing a STEMI event. As ECG is the method for diagnosing STEMI and is also the most simple and accessible diagnostic modality, it is possible that by extending the availability of reliable ECGs to a high-risk outpatient population, delays to early recognition and subsequent treatment could be reduced and more prompt lifesaving revascularization achieved.

Smartphones provide a possible platform for the extension of the ECG as they have become common across world, including poorer nations. A report on a 2012 survey by the Nielsen group of US mobile consumers estimates that over half of US mobile consumers use a smart device[5]. Smart devices do not have voice capability but are otherwise similar to

smartphones with comparable hardware and software. Differences exist among operating systems and hardware specifications, but a standard set of features including a touch screen, internet connectivity and the ability to run 3<sup>rd</sup> party applications have become ubiquitous.

With the development of smartphones, independent software developers have created applications or “apps” for multiple uses. One such app works in tandem with a phone case with embedded sensors and provides a single channel lead for accurate rate and rhythm assessment[6,7]. This device has been shown capable of distinguishing between normal sinus rhythm and atrial fibrillation when used by a trained medical professional. The device has been validated against 12-lead ECGs in a small number of patients for accurately identifying atrial fibrillation with sensitivities from 87% to 100%, specificities from 90% to 97%, and total accuracies from 94% to 97%. The ECG readings included independent blinded assessments by three different cardiologists as well as an automated algorithm analysis[8].

While this device has been shown to provide a single channel lead reading that is diagnostic for normal sinus rhythm and atrial fibrillation, it has not been validated in its ability to provide readings during an acute MI, including time sensitive STEMI events, for accurate assessment and diagnosis at point of care or even patient-applied application.

Following the success of single lead smartphone based rhythm evaluation, interest has developed in more comprehensive electrocardiographic evaluation using smartphones which can assess ischemic ST-T wave changes. A preliminary study was recently published using the original single lead device attached to typical 12-lead ECG leads and compared this to a standard 12-lead reading. A non-acute patient population was studied and the authors noted good concordance between the two modalities[9]. At present, a test device has been created with two wire leads, designed to be used with traditional ECG stickers and connect with a smart device via



Bluetooth. It differs from a 12-lead ECG in that the tracings are taken serially rather than simultaneously, it uses computer averaging to give a single representative tracing rather than raw voltage data, and it uses a single extremity lead for grounding of the precordial leads instead of an average. How these differences affect its ability to diagnosis STEMI and non-STEMI has not previously been determined.

## **Objectives**

The primary objective of this study was to assess the operational feasibility of using a smartphone to obtain “12-lead equivalent” ECG recordings in patients suspected to have acute MI, with particular focus on STEMI. Our intent was to use results from this pilot study to design a larger multi-center study, the objective of which is to determine if the smartphone ECG is an acceptable substitute for a standard ECG in the identification of STEMI.

Specific goals of this pilot study included: to obtain simultaneous standard 12-lead ECG and the smartphone “12-lead equivalent” ECG recordings on patients for whom the STEMI protocol was activated; to determine the operational feasibility of obtaining these simultaneous recordings; to make preliminary assessment of diagnostic accuracy; to make recommendations for the conduct of the planned multi-center study that will determine if the smartphone ECG is an acceptable replacement for a standard ECG in the identification of STEMI.

By validating the smartphone ECGs capacity to accurately assess the presence or absence of STEMI or non-STEMI compared to gold standard 12-lead ECG, we may increase the accessibility of electrocardiography and hasten the diagnosis and treatment of the life threatening events.

## **Materials and methods**

This study was designed as a single center, prospective, non-randomized, open study, with a single-patient clinical design (i.e., the patients serve as their own control). Target enrollment was 5 patients and 6 patients were eventually enrolled over 27 days. Inclusion criteria included age  $\geq 18$  years, ability of patient or legally-acceptable representative to provide written informed consent prior to study procedure, chest pain evaluated in the emergency department, and activation of the STEMI protocol based on clinical and preliminary ECG criteria. Exclusion criteria included inability to obtain legally-acceptable consent or any condition that the Principal Investigator felt would increase the risk to the patient or compromise the timing or quality of the trial. For inclusion, the smartphone ECG had to be obtained in the emergency department prior to revascularization or in the catheterization laboratory before or after revascularization, immediately following a comparison 12-lead ECG.

All smartphone ECGs were obtained by the research team directly after being trained by the device company. Upon activation of the STEMI protocol, the team was alerted and went to evaluate and consent the patient as quickly as possible. One out of the six patients had consent and recordings taken in the emergency department. All others were obtained in the catheterization laboratory following revascularization.

The smartphone ECG was obtained following repeat 12-lead ECG using the AliveCor<sup>TM</sup> Heart Monitor using an iPod Touch device with Wi-Fi connectivity (see figure 1). The iPod Touch is a smart device running the iOS operating system, similar to the iPhone smartphone. For this study, “smartphone ECG” and “smart device ECG” were felt to be synonymous. The Heart Monitor was held near the iPod Touch to allow for a wireless Bluetooth connection. Electrodes attached to the AliveCor<sup>TM</sup> Heart Monitor were connected to ECG stickers sequentially with a

15 second recording obtained on each lead configuration. The tracings were wirelessly uploaded to the AliveCor™ servers where they were processed with sequential averaging of QRS complexes and obtained by accessing their website and downloading the processed waveforms.

Two configurations were obtained for the precordial leads, VnL and VnR. VnL was obtained using the left arm for grounding and VnR with the right arm acting as ground. These were evaluated independently by the ECG reviewers alongside the gold standard 12-lead ECG.

The ECG reviewers comprised three experienced cardiologists who were provided no clinical context beyond the inclusion criteria of the study and tasked to evaluate the ECGs based on waveform alone. Conflicting reads were discussed among the reading panel and a consensus majority was achieved in each case to provide the final read of STEMI or not STEMI.

## Results

The study enrolled six patients for whom the STEMI protocol was activated. All 6 were white males with ages of 52, 56, 60, 62, 64, and 85 years old. Expedited transfer to the catheterization laboratory led to only one ECG being obtained in the emergency department and all others being performed in the laboratory immediately post revascularization. All tracings obtained were felt to be of adequate technical quality for interpretation. Example tracings are shown in figures 2 through 4.

The reading panel found perfect correlation between the different modalities with regard to STEMI criteria. Four ECGs were judged to meet STEMI criteria and two did not in both the 12-lead and smartphone ECG tracings. Three of the four STEMI reads were inferior and one was anterior. The other two reads were suggestive of myocardial ischemia but did not meet STEMI criteria on either modality. See Table 1 for full details of reads. All reads had a three out of three majority after deliberation among the reading panel.

VnR and VnL were read separately for each patient. In all cases they were felt to provide similar diagnostic information with only minor, diagnostically irrelevant differences. In two patients VnR was felt to be slightly closer to the 12-lead than VnL, and in one VnL was felt to be slightly closer (see table 1). No differences noted were sufficient to change whether or not the ECG met STEMI criteria.

## **Discussion**

This study importantly demonstrates that the smartphone ECG is capable of identifying an ST-segment myocardial infarction using a technology platform that is now readily available. The significance of this lies in its ability to extend electrocardiographic evaluation into new use case scenarios, including personalized use by the owner or point-of-care, out-of-hospital first medical contact. These and other important scenarios include settings where a standard 12-lead ECG is not immediately available. Settings of particular need include rural areas with no nearby medical facilities, developing nations and regions, and travel scenarios such as cruise ships and tour buses. It would be unfeasible to provide standard 12-lead ECG devices in such settings, but smartphone penetration has already become commonplace and has the potential to provide a foundation for the greater spread of electrocardiography.

Additionally, hospitals and clinics where ECGs may already be available might have increased penetration with this technology allowing for prompt electrocardiographic evaluation without the expense of additional dedicated ECG machines and staff.

There are limitations to this study. It was a small, male only population at a single center. It did not extensively evaluate other, non-STEMI clinical settings. All but one patient had tracings performed following revascularization. It used only trained individuals to perform the recordings and used prototype hardware. The device was somewhat cumbersome with long leads attached and EKG stickers were required.

However, the quality of tracings obtained (as noted above), and the 100% correspondence between 12-lead and smartphone ECG readings are promising and encouraging. The discrepancies noted were subtle and not diagnostically impactful. Reading cardiologists noted that concordance was always at least “good” and typically “excellent.” Possible explanations for

minor differences include the small time delay required to perform the smartphone ECG, the averaging technique used in processing, and using a single grounding lead for the precordial measurements. Improvements in future prototypes to allow for more rapid measurement as well as a larger study population will help further minimize the sources of these minor differences.

As the study could not interfere with the revascularization process and the catheterization laboratory efficiency in treating these STEMI patients, all but one of the tracings were obtained in the lab post revascularization. Since the evolution of ECG findings is rapid after reperfusion, this may have limited the number of cases with truly acute STEMI findings. More often an evolving/resolving pattern was noted. However, concordance was not affected since a comparison ECG was taken just prior to the smartphone ECG.

The amount of training to adequately perform smartphone ECGs is still unclear. This study used research associates who had been trained by the device company to perform all recordings. A previous study with a related product found receptionists were uncomfortable performing a single lead recording, whereas nursing staff were much more comfortable[10]. With the added complexity of obtaining a more complicated 12-lead tracing, the ability for this technology to be utilized by non-medical personnel requires further study.

Looking to more widespread adoption, there are several technological questions that should be addressed. The current implementation uses a remote server for processing which requires an active internet connection. Local processing on the smartphone would allow a tracing to be obtained without an active internet connection. A 15 second read on each lead was required with the current implementation. Local processing could also allow for a lead to be attached only long enough for an accurate tracing, with the device providing a signal when an adequate read is obtained and indicate when the leads can be advanced to the next position.

Additionally, no automated reading is available within the present system. Whether it would be beneficial to have an automated read, with the inherent potential for error but potentially a much quicker response, or rely solely on remote expert readings, was not addressed in this study. The current technological iteration relies on traditional ECG stickers and leads with clips. A device not requiring stickers and leads also may facilitate more general adoption.

With these limitations of our current study in mind, we are currently planning a multi-center study to further evaluate the concordance of smartphone ECG compared to 12-lead ECG. The intention is to evaluate 100 patients for whom the STEMI protocol is activated and 200 additional patients who present to the emergency department with a chief complaint of chest pain. The intent will be to verify the findings of the pilot study on a larger, more heterogeneous population, to extend the study to patients for whom the STEMI protocol was not activated, and to assess overall diagnostic accuracy in a more general chest pain population.

Several modifications to the pilot protocol will be considered. Given the difficulty in obtaining research tracings prior to revascularization, we may look to include clinical staff such as ECG technicians or emergency department nurses or aides to acquire some of the tracings. Additionally, given the excellent concordance between VnR and VnL and the added time and effort required to obtain the separate tracings, we will likely proceed with VnR serving as the sole smartphone precordial measurement.



## **Conclusions**

The AliveCor™ Heart Monitor, a smart device based ECG system was found to generate “12-lead equivalent” ECGs that demonstrated excellent concordance with a standard 12-lead ECG for the detection of STEMI as well as non-STEMI ischemic changes. These pilot results suggest that a low cost, convenient alternative to existing ECG technology using now common smartphones and smart devices may extend the availability of ECG beyond its current reach and facilitate the early detection of STEMI, including personalized use by the owner or by point-of-care, out-of-hospital first medical contact. The promise of smart device diagnosis of acute coronary syndromes deserves further evaluation in larger, multi-center studies.

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**Disclosures:** David Albert is the founder and current chief medical officer of AliveCor, Inc. No other authors have conflicts of interest to disclose.

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## **Figures**

Figure 1: AliveCor™ Heart Monitor with 5th generation iPod Touch used for this pilot study.

Figure 2: 12-lead ECG obtained just prior to smartphone ECG during a STEMI activation. This 12-lead ECG was read as concordant with the smartphone ECGs. This was read as an inferolateral STEMI.

Figure 3: VnR, Smartphone ECG using the right arm for grounding. This was also read as an inferolateral STEMI.

Figure 4: VnL, Smartphone ECG using the left arm for grounding. This was also read as an inferolateral STEMI.

**Table 1**

Age	Race	Gender	Time	12-lead read	Correlation of 12-lead with smartphone ECG	VnR vs VnL (compared to 12-lead)
52	White	Male	0846	Evolving anterior MI	Good	R>L
56	White	Male	0931	Inferolateral MI	Excellent	R=L
60	White	Male	1410	Evolving inferior MI	Excellent	R>L
62	White	Male	2029	Diffuse non-specific ST changes, not MI	Good	R<L
64	White	Male	1628	Marked precordial ST depression suggesting posterior ischemia, not MI	Good	R=L
85	White	Male	1902	Evolving inferior-posterior MI	Excellent	R<L

Table 1: Characteristics of the six enrolled patients and description of reads.

Figure 1  
[Click here to download high resolution image](#)



Figure 1

Figure 2  
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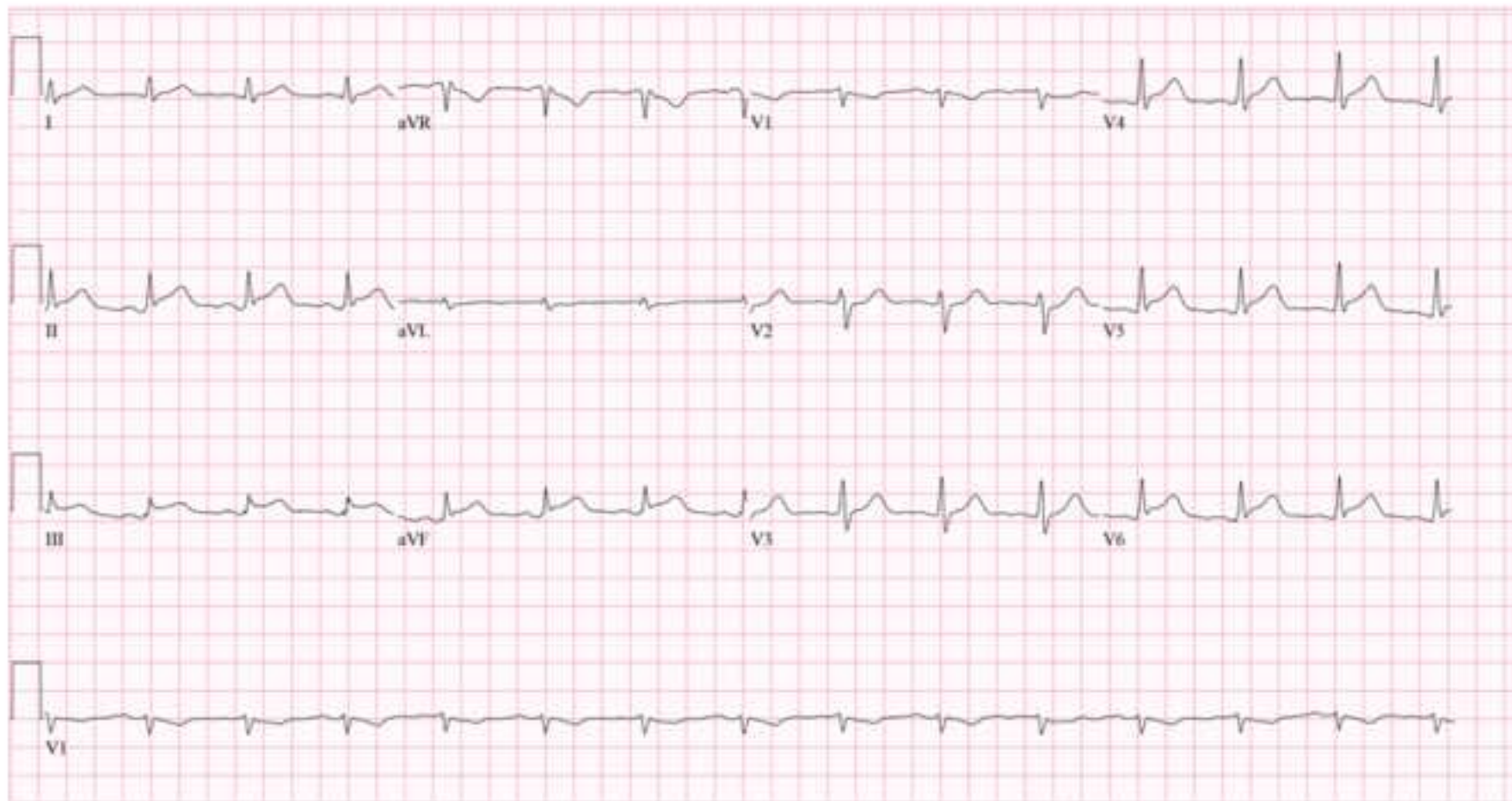


Figure 2

Figure 3  
[Click here to download high resolution image](#)

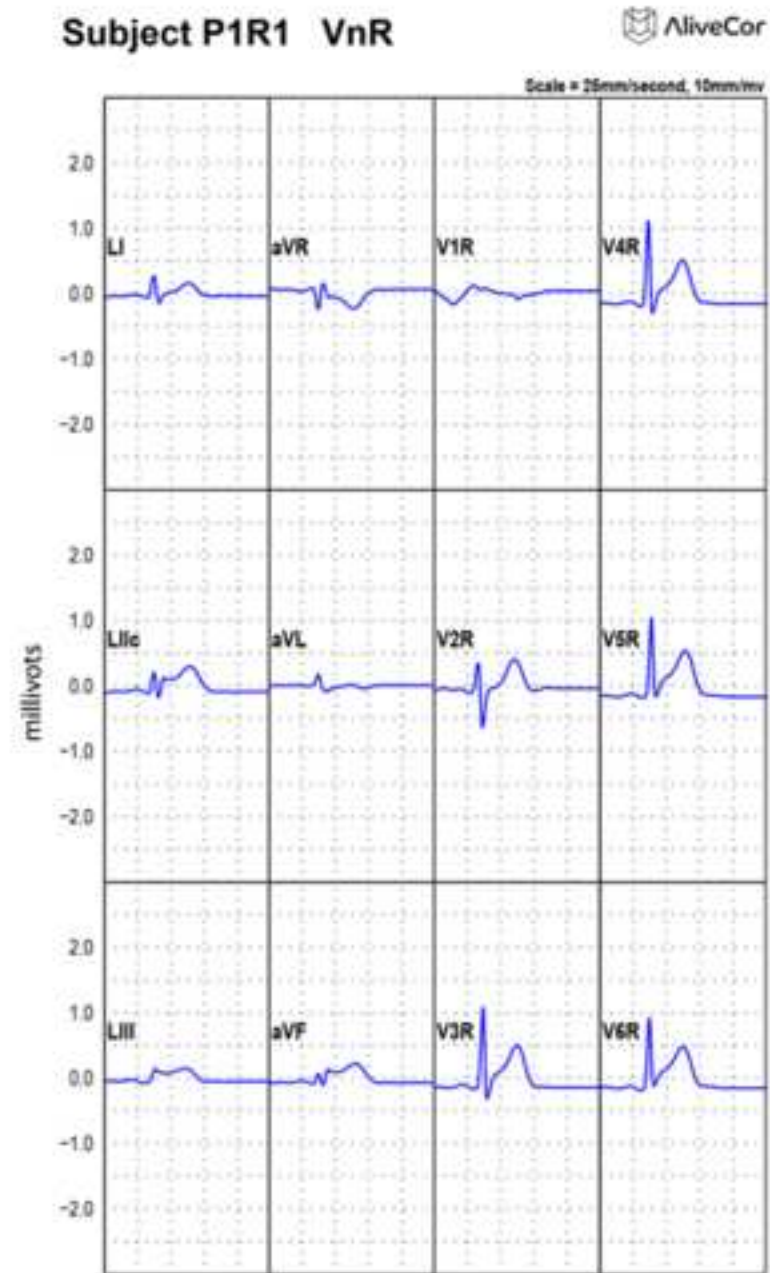


Figure 3

Figure 4  
[Click here to download high resolution image](#)

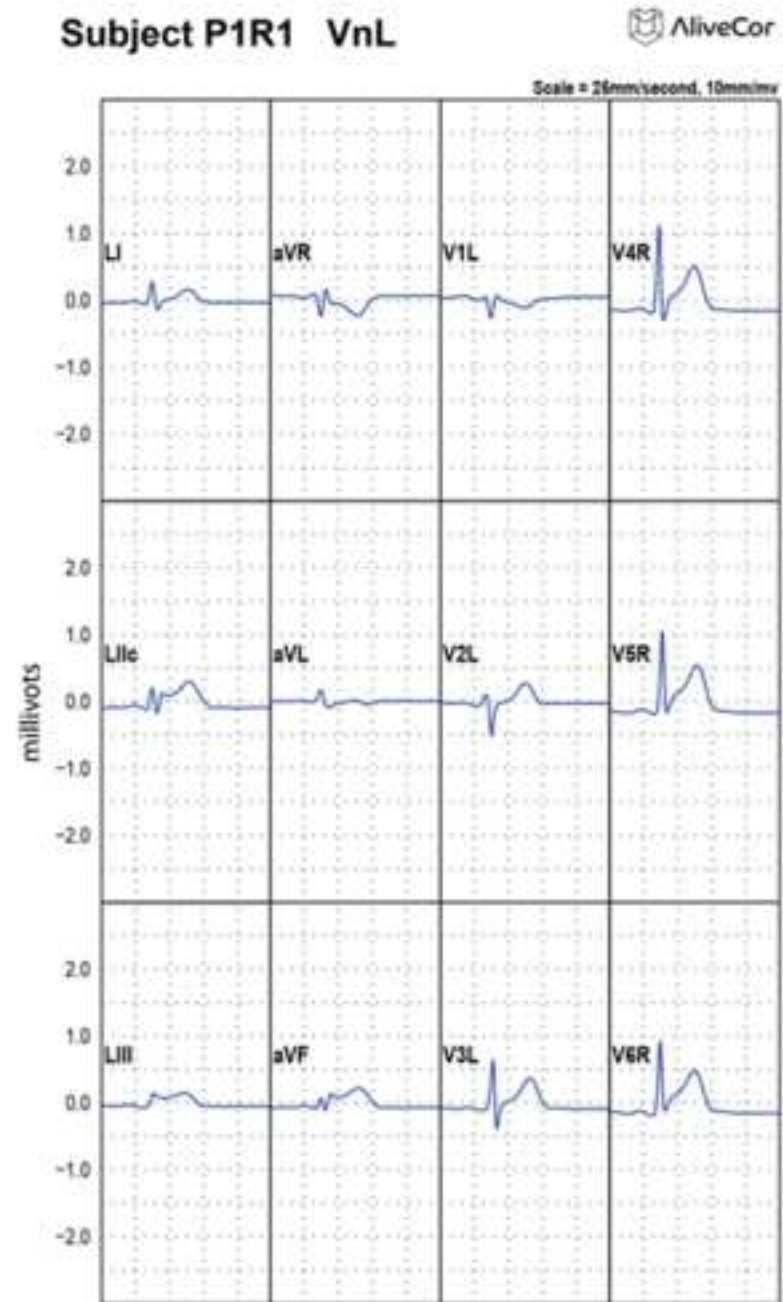


Figure 4