



Scientific Background

Version 5.0

Introduction: CardioSecur's one-of-a-kind ECG Technology

The 12-lead electrocardiogram (ECG) is the worldwide gold standard for the detection of myocardial ischemia. 12 leads are usually derived from 10 electrodes. The EASI lead system is an alternative to the conventional method, resorting to vector electrocardiography and allowing a three-dimensional view of the heart. EASI was described by Dower et al. in the 1980's and uses only 5 electrodes (4 recording + 1 grounding) to derive the standard 12 leads⁵⁻⁸. The agreement between an EASI derived 12-lead ECG and a standard 12-lead ECG has been shown in many reviewed studies⁹⁻²⁶.

CardioSecur's technology is based upon the EASI standard, additionally removing the grounding electrode to allow for the registration of a derived 12-lead ECG using only 4 electrodes. The agreement of the modified CardioSecur setting has been clinically proven^{1,2}.

Historic Background

Over the past century various lead systems have been developed from which electrocardiograms are transcribed. Conventional 12-lead ECG systems with 10 electrodes are based on methods from Einthoven, Goldberger, and Wilson developed between 1903 – 1934.

360° Lead System of Today

CardioSecur is a vector-derived 12/22-lead ECG based upon the EASI standard. Frank established the basis of this lead system in the 1960s, which Dower further developed into the standard that is used today. CardioSecur has further developed the EASI standard so that it only requires four electrodes. The positioning of the four electrodes creates a tetrahedron, which captures the heart's activity from all angles and computes 22 leads (all conventional 12 leads I, II, III, aVR, aVL, aVF, V1-6, plus V7-V9 and VR3-VR9). By recording additional leads, CardioSecur's ECG is one step ahead as it complies with the guidelines of the European Society of Cardiology (ESC) to also record posterior leads when myocardial infarction is suspected.^{27,28} The guidelines also recommend 12-lead ECG technology for a conclusive A-Fib diagnosis.³⁶ CardioSecur is the only ECG system that enables physicians to be 100% compliant with the ESC guidelines. The value of including additional leads has been shown in many studies,³²⁻³⁹ and includes the potential to reduce unnecessary "rule-out MI" admissions³⁰.

Personalized Analysis

CardioSecur offers in its patient-oriented products (e.g. CardioSecur Active) the highest possible sensitivity for detecting any heart rhythm changes and myocardial ischemia by comparing the user's ECG with a previously recorded reference ECG (also recommended by the ESC). When first using e.g. the CardioSecur Active system, the user records a reference ECG—all subsequent measurements are compared to this reading. This personalized comparison allows for detection of any ECG changes, even when preexisting ECG abnormalities are present (e.g. left bundle branch block, ST deviation, prior MI changes). For example, guidelines for diagnosis of ST segment elevation acute myocardial infarction

require the presence of at least 1 mm (0.1 mV) J-point elevation in at least 2 anatomically contiguous leads (with the exception of V2-V3 where the criteria are an elevation of >0.2 mV for men > 40, >0.25 mV for men < 40, and >0.15 mV for women).²⁹ If ECG changes fit these criteria, the patient receives an in-app feedback from CardioSecur that immediate medical attention is recommended. The intra-individual ECG comparison also offers the opportunity to detect ECG changes that have pseudo-normalized, in particular those of the ST segment and the T-waves. The serial use of CardioSecur also allows for detection of “silent” myocardial ischemia in patients without symptoms.

Effect of different ECG Models on Diagnostic Power

The EASI lead system meets all diagnostic capabilities of a conventional 12-lead ECG and due to more leads with only 4 electrodes allows professionals to work beyond the gold standard. The inevitably different electrode placements on the body result in minor characteristic differences between the two systems, mainly regarding absolute amplitude or axis. However, these differences do not bear any medical significance for the diagnosis of an ECG. This has been frequently proven in third-party as well as internal clinical studies comparing both lead systems.^{18, 25}

Benefits of CardioSecur vs. the Gold Standard

CardioSecur adds value in the management of patients with cardiac disease as revealing timely ECG changes decreases the likelihood of undesirable cardiac events and early detection allows for successful treatment.³ CardioSecur shows >99% agreement in presence or absence of ischemia compared to the conventional 12 leads standard ECG.¹ CardioSecur demonstrates 100% concordance with respect to the localization of myocardial ischemia compared to a standard ECG¹.

The benefits of CardioSecur include the use of 22-leads, which allow professionals to adhere to the guidelines of the European Society of Cardiology (ESC) and the American Heart Association (AHA) demanding evaluation of the right, left and posterior walls. When an infarction is suspected and the 12-lead ECG is inconclusive, the ESC recommends recording additional leads (V7-V9, VR3 VR4).^{33, 34} CardioSecur is the only ECG that implements this guideline into practice in one synchronous ECG reading, without need to reposition electrodes. Furthermore, the CardioSecur system also offers the following benefits:

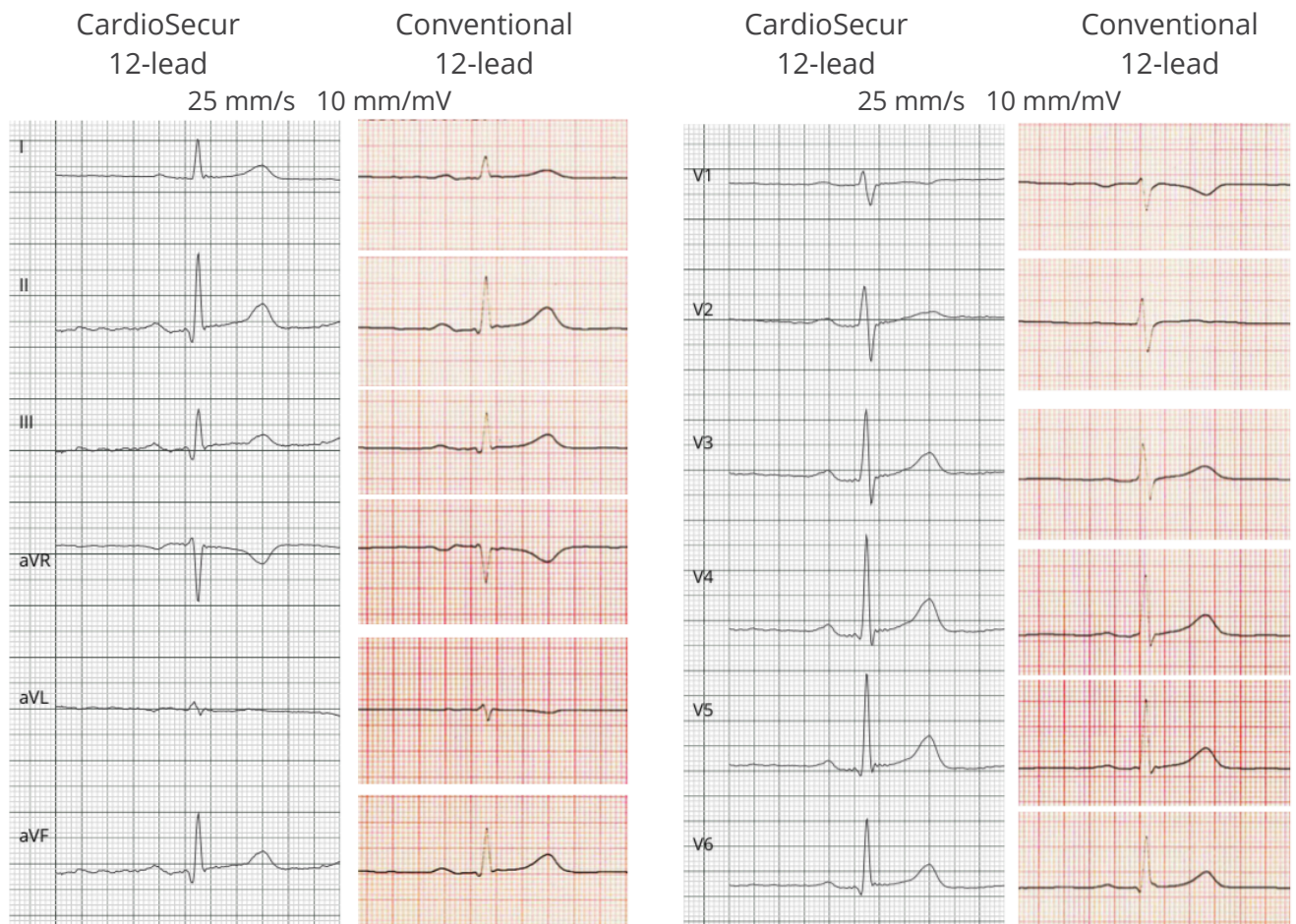
- CardioSecur only requires 4 electrodes which create less muscle artefacts, have higher signal stability with change in body position, save time attaching the electrodes and require no reattachment of electrodes or moving of the patient when additional leads need to be examined.
- The 4 electrode positions with CardioSecur are on very marked spots on the human thorax mitigating significantly the risk of lead misplacement across the various anatomies of patients.
- Using posterior leads in patients presenting with symptoms suspicious for heart attack reveals more patients with posterior myocardial infarction who benefit from early reperfusion treatment.⁴⁴
- Isolated ST changes in leads V7-V9 and VR3-VR9 for the first time identifies patients

with acute posterior wall myocardial infarction. Early identification of these patients is important for adequate triage and treatment of patients with ischemic chest pain without ST changes on a standard 12-lead ECG.³⁹

- The use of a 22-lead ECG has the potential to substantially reduce unnecessary “rule-out MI” admissions.³⁷ CardioSecur enables accurate diagnosis and localization of:
 - Acute STEMI
 - NSTEMI
 - Old infarctions
 - Angioplasty-induced ischemia
 - Arrhythmias
 - Cardiac interval measurement
 - Intraventricular conduction disturbances (i.e. bundle branch blocks)
 - Wolff Parkinson White Syndrome

Characteristic differences between CardioSecur and a conventional 12-lead ECG

1. R-waves: with CardioSecur, there is a slight difference in amplitude with **no diagnostic impact**. R-wave progression is not affected.
2. T-waves: with CardioSecur, there is a slight difference in amplitude but **no morphological impact**. This has no diagnostic effect.



3. Q-waves: with CardioSecur, these are commonly **slightly deeper**, but not wider, in the leads of the inferior wall. This has **no diagnostic impact**.
4. Obese patients: with CardioSecur, there is a minor difference on the axis. This has **no impact on ischemia diagnosis**.

CardioSecur and Brugada Syndrome

CardioSecur does not compute the higher placed chest leads capable of detecting Brugada syndrome.

References

The abstracts for each reference are given in the section “Abstracts” below.

Internal Research

1. Bonaventura, Klaus, Wellnhofer E, and Fleck E. Comparison of Standard and Derived 12-lead Electrocardiograms Registered by a Simplified 3-lead Setting with Four Electrodes for Diagnosis of Coronary Angioplasty-induced Myocardial Ischemia. *European Cardiology*, vol. 8, issue 3, 2012, p. 179.
2. Triebel, David, et al. Comparative study of the CardioSecur pro ECG system with the EASI Philips M2601B. Personal MedSystems Frankfurt, Central Hospital of the Hungarian Defence Forces Budapest. Abstract presented at eCardiology Congress 2016: Berlin.
3. van Langenhove, Glenn and Bruno Schwagten. The Revealing timely ECG changes Decreases the likelihood of Undesireable Cardiac Events-Trial (REDUCE-Trial). Poster presented at ESC Congress 2014: Barcelona.
4. Kenedi, Peter, et al. Effect of Body Position on a Mobile, Vector-Derived, 12-Lead Electrocardiogram. *EC Cardiology*, vol. 5, issue 8, 2018, pp. 589-595.
5. Hanna Kern, Jan Stiepak, Erik Popp, Sebastian Spaich, Thomas Zelniker, Evangelos Giannitsis, Hugo Katus, Michael Preusch, University of Heidelberg, Germany, First real-world experience with CardioSecur in the preclinical setting – When time does matter, Resuscitation 2017, ERC Symposium on Guidelines: Abstract Presentations.

About the EASI Technology

6. Dower, GE. The ECGD: a derivation of the ECG from VCG leads. *Journal of Electrocardiology*, vol. 17, issue 2, 1984, pp. 189-91.
7. Dower, GE, et al. On deriving the electrocardiogram from vectorcardiographic leads. *Clinical Cardiology*, vol. 3, issue 2, 1980, pp. 87-95.
8. Dower, GE, et al. Deriving the 12-lead electrocardiogram from four (EASI) electrodes. *Journal of Electrocardiology*, vol. 21, supplement, pp. 182-7.
9. Tomasic, I and Trobec, R. Electrocardiographic systems with reduced numbers of leads–synthesis of the 12-lead ECG. *IEEE Rev Biomed Eng*, vol. 7, 2014, pp. 126-42.
10. Wehr, G, et al. A vector-based, 5-electrode, 12-lead monitoring ECG (EASI) is equivalent to conventional 12-lead ECG for diagnosis of acute coronary syndromes. *Journal of Electrocardiology*, vol. 39, issue 1, 2006, pp. 22-8.
11. Sejersten, M, et al. Detection of acute ischemia from the EASI-derived 12-lead electrocardiogram and from the 12-lead electrocardiogram acquired in clinical practice. *Journal of Electrocardiology*, vol. 40, issue 2, 2007, pp. 120-6.
12. Lancia, L, et al. Continuous ECG Monitoring in Patients with ACS or Heart Failure: EASI versus Gold Standard. *Clinical Nursing Research*, Published Apr 16, 2017.
13. Chantad, D, et al. Derived 12-lead electrocardiogram in the assessment of ST-segment deviation and cardiac rhythm. *Journal of Electrocardiology*, vol. 39, issue 1, 2006, pp. 7-12.

14. Horacek, BM, et al. Diagnostic accuracy of derived compared to standard 12-lead electrocardiograms. *Journal of Electrocardiology*, vol. 33, supplement, 2000, pp. 155-60.
15. Drew, Barbara J, et al. Comparison of a vectorcardiographically derived 12-lead electrocardiogram with the conventional electrocardiogram during wide QRS complex tachycardia, and its potential application for continuous bedside monitoring. *American Journal of Cardiology*, vol. 69, issue 6, 1992, pp. 612-8.
16. Feldman, C L, et al. Comparison of the standard ECG with the EASIcardiogram for ischemia detection during exercise monitoring. *Computers in Cardiology*, 1997, pp. 343-345.
17. Lancia, L, et al. A Comparison between EASI System 12-lead ECGs and standard 12-lead ECGs for improved clinical nursing practice. *J Clin Nurs*, vol. 17, issue 3, 2008, pp. 370-7.
18. Drew, Barbara J, et al. Accuracy of the EASI 12-lead electrocardiogram compares to the standard 12-lead electrocardiogram for diagnosing multiple cardiac abnormalities. *Journal of Electrocardiology*, vol. 32, 1999, pp. 38-47.
19. Drew, Barbara J, et al. Comparison of standard and derived 12-lead electrocardiograms for diagnosis of coronary angioplasty-induced myocardial ischemia. *American Journal of Cardiology*, vol. 79, issue 5, 1997, pp. 639-44.
20. Rautaharju, PM, et al. Comparability of 12-lead ECGs derived from EASI leads with standard 12-lead ECGs in the classification of acute myocardial ischemia and old myocardial infarction. *Journal of Electrocardiology*, vol. 35, supplement, 2002, pp. 35-9.
21. Adams, MG and Drew, BJ. Body position effects on the ECG: implication for ischemia monitoring. *Journal of Electrocardiology*, vol. 30, issue 4, 1997, pp. 285-91.
22. Drew, Barbara J, et al. Value of a derived 12-lead ECG for detecting transient myocardial ischemia. *Journal of Electrocardiology*, vol. 28, supplement, 1995, p. 211.
23. Drew, Barbara J and Ide, B. Diagnosing ischemia from the bedside monitor. *Prognostic Cardiovascular Nursing*, vol. 11, issue 1, 1996, pp. 45-6.
24. Drew, Barbara J, et al. Derived 12-lead ECG. Comparison with the standard ECG during myocardial ischemia and its potential application for continuous ST-segment monitoring. *Journal of Electrocardiology*, vol. 27, supplement, 1994, pp. 249-55.
25. Pahlm O, et al. Comparison of waveforms in conventional 12-lead ECGs and those derived from EASI leads in children. *Journal of Electrocardiology*, vol. 36, issue 1, 2003, pp. 25-31.
26. Welinder A, et al. Diagnostic conclusions from the EASI-derived 12-lead electrocardiogram as compared with the standard 12-lead electrocardiogram in children. *American Heart Journal*, vol. 151, issue 5, 2006, pp. 1059-64.
27. Drew, Barbara J, et al. Practice standards for electrographic monitoring in hospital settings. *Circulation*, vol. 110, 2004, pp. 2721-2746.
28. Denes P. The importance of derived 12-lead electrocardiography in the interpretation of arrhythmias detected by Holter recording. *Am Heart J*, vol. 124, issue 4, 1992, pp. 905-11.
29. Martinez J P, et al. Assessment of QT-measurement accuracy using the 12-lead electrocardiogram derived from EASI leads. *Journal of Electrocardiology*, vol. 40, 2007, pp. 172-5.

30. Horacek B M, et al. Optimal electrocardiographic leads for detecting acute myocardial ischemia. *Journal of Electrocardiology*, vol. 34, 2001, pp. 97-111.
31. Welinder A E, et al. EASI-Derived vs. standard 12-lead electrocardiogram for Selvester QRS score estimations of chronic myocardial infarct size, using cardiac magnetic resonance imaging as gold standard. *Journal of Electrocardiology*, vol. 42, issue 2, 2009, pp. 145-51.
32. Nelwan S P, et al. Simultaneous comparison of 3 derived 12-lead electrocardiograms with standard electrocardiogram at rest and during percutaneous coronary occlusion. *Journal of Electrocardiology*, vol. 41, issue 3, 2008, pp. 230-7.

ESC Guidelines

33. Ibanez, Borja, 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), *European Heart Journal*, vol. 39, issue 2, 2017, pp. 119-177.
34. Roffi Marco, et al. 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: Task Force for the Management of Acute Coronary Syndromes in Patients Presenting without Persistent ST-Segment Elevation of the European Society of Cardiology (ESC), *European Heart Journal*, vol. 37, issue 3, 2016, pp. 267-315.
35. Thygesen, Kristian, et al. Third universal definition of myocardial infarction. *European Heart Journal*, vol. 33, 2012, pp. 2551-2567.
36. Paulus Kirchhof, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS: The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC), developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC, endorsed by the European Stroke Organisation (ESO), *European Heart Journal* (2016) 37, 2893-2962

The Value of Additional ECG Leads

37. Justis, DL and Hession, WT. Accuracy of 22-lead ECG Analysis for diagnosis of acute myocardial infarction and coronary artery disease in the emergency department: a comparison with 12-lead ECG. *Ann Emerg Med*, vol. 21, issue 1, 1992, pp. 1-9.
38. Liu, X, et al. Right precordial leads V4R and V5R in ECG detection of acute ST elevation MI Associated with Proximal Right Coronary Artery Occlusion. *Computers in Cardiology*, vol. 32, 1995, pp. 651-654.
39. Matezky S, Freinmark D, Feinberg MS, et al. Acute myocardial infarction with isolated ST-segment elevation in posterior chest leads V7-9: „hidden“ ST-segment elevations revealing acute posterior infarction. *J Am Coll Cardiol*, vol. 34, issue 3, 1999, pp. 748-53.
40. Khaw, K, et al. Improved detection of posterior myocardial wall ischemia with the 15-lead electrocardiogram. *American Heart Journal*, vol. 138, 5 pt 1, 1999, pp. 934-40.
41. Michaelides, AP, et al. Improved detection of Coronary Artery Disease by Exercise Electrocardiography with the Use of Right Precordial Leads. *New England Journal of Medicine*, vol. 340, 1999, pp. 340-345.

42. Agarwal JB, et al. Importance of posterior chest leads in patients with suspected myocardial infarction, but nondiagnostic, routine 12-lead electrocardiogram. *American Journal of Cardiology*, vol. 83, issue 3, 1999, pp. 323-6.
43. Zalenski RJ, et al. Value of posterior and right ventricular leads in comparison to the standard 12-lead electrocardiogram in evaluation of ST-segment elevation in suspected acute myocardial infarction. *American Journal of Cardiology*, vol. 79, issue 12, 1997, pp. 1579-85.
44. Van Borselen OF, Verheugt FWA, Meursing BTJ, and Ophuis AJM. Posterior Myocardial Infarction: the dark side of the moon. *Neth Heart Journal*, 2007 Jan;15(1):16-21.

Abstracts

1. Comparison of Standard and Derived 12-lead Electrocardiograms Registered by a Simplified 3-Lead Setting with Four Electrodes for Diagnosis of Coronary Angioplasty-induced Myocardial Ischaemia.

European Cardiology, vol. 8, issue 3, 2012, p. 179.

Klaus Bonaventura¹, Ernst Wellnhofer² and Eckart Fleck²

1. Department of Cardiology, Angiology, Heart, Thorax and Vascular Centre, Klinikum Ernst von Bergmann and University Outpatient Clinic Potsdam, Sports, Medicine and Sports Orthopaedics, University of Potsdam, Potsdam, Germany; 2. Department of Cardiology, German Heart Institute Berlin, Berlin, Germany

Background: Electrocardiograms (ECGs) derived by the transformation of three bipolar quasi-orthogonal leads have, according to EASI, been introduced for many years for use in emergency situations and for the monitoring of patients during the acute phase of myocardial infarction (MI). Theoretically, a further reduction and simplification of the classic EASI setting of five electrodes may even improve acceptance of the derived 12-lead ECG in these critical situations, especially in the telemedical use and for monitoring of cardiovascular patients. The objective of the present study was to evaluate the comparability of the 12-lead ECG derived by a system that reduces the classic EASI setting from five to four electrodes with the standard 12-lead ECG in the detection of acute MI induced during percutaneous transluminal coronary angioplasty (PCI).

Methods: To determine whether a 12-lead ECG derived from a reduced EASI setting using only 4 electrodes would demonstrate typical ST-segment changes of ischemia during PCI (percutaneous coronary intervention) 24 patients with overall 148 episodes of balloon-induced myocardial ischemia were monitored with continuous 12-lead ST-segment monitoring during PCI. A derived 12-lead ECG was registered by the 4-electrode system. 2 blinded cardiologists not involved in the intervention compared both ECGs for each patient.

Results: Of the 148 episodes of balloon inflation recorded with the derived ECG, 104 (70.3 %) were associated with typical and significant ischemic ST-segment changes during balloon inflation. The amplitudes of these ST deviations were similar to those observed during transient myocardial ischemia observed in clinical settings (median peak ST deviation, 234 microV). There was agreement regarding presence or absence of ischemia in 147 of 148 episodes, with both derived and standard electrocardiographic methods (>99 % agreement). With use of the standard ECG as the 'gold standard' for ischemia diagnosis, there were no false negatives (0 %) and only one false-positive (0.7 %) with the derived ECG. There was no significant difference between the two techniques by linearity tests ($p > 0.1$). Bland-Altman analysis showed no significant bias. Moreover, both methods demonstrated 100% concordance with respect to localization of myocardial ischemia (anterior, inferior and lateral).

Conclusions: The new 4-electrode set 12-lead ECG is as an alternative to the standard 12-lead ECG with 10 electrodes in emergency situations and for cardiovascular monitoring.

DOI: 10.15420/ecr.2012.8.3.179

2. Comparative Study of the CardioSecur Pro ECG system with the EASI Philips M2601B.

Abstract presented: eCardiology Congress, 2016: Berlin

David Triebl, Peter Kenedi, Istvan Predas, Adam Szekely, Markus Skribek, Markus Riemenschneider

Personal MedSystems GmbH Frankfurt, Central Hospital of the Hungarian Defence Forces Budapest

Aim of the Study: A comparative study was conducted to validate the ECG measurements of CardioSecur. CardioSecur is a tablet-based ECG system using 4 electrodes to derive a 22-channel ECG (standard 12-leads + V7-V9 and VR1-VR9). The technology of CardioSecur is based on the calculation of 12 leads from 4 electrodes which are comparable to the standard 12 lead ECG.

Methods: To assess both the technical and the medical comparability of the systems, the setup was divided into two procedures, the first test covering the medical diagnostic accuracy of the two systems, the second test covering the technical comparability of the ECG signal, generated with the reduced lead system. In the first test, ECG measurements were taken from 41 individuals with both systems. A clinical diagnosis was made on both ECGs and the orientation of the P, R, S, and T waves were evaluated and compared. To assess the technical waveform of the two systems, ECGs were simulated with an ECG simulator to ensure identical electrical input on both systems. These ECGs were simulated at frequencies between 30 and 180bpm. Additionally, pathological ECG patterns were simulated and recorded with the systems. These waveforms were compared with respect to morphology and height of the electrical signal in the standard 12 leads of both systems.

Results: The clinical diagnosis for 41 measured patients was identical in the ECGs measured with both CardioSecur and Philips M2601B. This ensures equal clinical sensitivity and specificity in both devices. The additional 10 leads of CardioSecur were not part of the study as the Philips device does not offer this option. The second test, covering a technical analysis including waveforms and peak heights, revealed differences in the heights of the R and S wave. CardioSecur showed an absolute peak 10% higher than the Philips device. This can be explained by the use of different filter settings in the devices. The Philips M2601B clearly states that the recorded ECG may not be used for ST-segment evaluation. CardioSecur uses a filter setting compliant with the regulatory standards to allow for ST-segment evaluation. Consequently, a difference in absolute peak height can also appear. Morphologically, all patient ECGs showed identical orientation of the measured parameters. The simulated ECGs showed identical morphology for all measured settings.

Conclusion: This study has shown that the clinical information in the CardioSecur device is identical to the information of ECGs of the Philips M2601B device. A closer examination of the raw signal in peak heights arises from the different filter systems. Morphologically, the orientation of all recorded ECGs and R-wave progression were identical in all measured ECGs. Therefore, the diagnostic capabilities of the CardioSecur device can be seen as wholly comparable to those of the Philips ECG. The possible benefits of an additional 10 leads in the CardioSecur device will be the subject of future studies.

3. The Revealing Timely ECG Change Decreases the Likelihood of Undesirable Cardiac Events-Trial (REDUCE-Trial).

Presented: European Society of Cardiology Conference, 2014: Barcelona

van Langenhove¹, Schwagten B¹.

1. ZNA Middelheim, Antwerpen, Belgium.

Background: ECG technology is extremely useful in the diagnosis of a wide variety of cardiac diseases. Plenty of arrhythmic and ischemic conditions however are hard to diagnose and therefore treat because they don't appear during the physician's consultation. For cases with persistent or recurrent problems single-lead event recorders, holters or implantable devices have been developed to diagnose the underlying disease or symptoms. However due to their susceptibility to artefacts, the fact that they don't provide 12-lead ECG information data and a necessary invasive procedure, they may not lead to satisfying results in all patients (1).

Purpose: To investigate whether the mobile 12-lead ECG CardioSecur™ (Personal MedSystems GmbH) is offering additional value in the management of patients with cardiac preconditions. CardioSecur™ is a mobile 12-lead ECG device based on the validated EASI-ECG-technology and allows for a 12-lead ECG using four electrodes only. Once the patient has recorded a reference ECG on the device he can perform control-readings. An algorithm that is based on clinical guidelines will detect ECG changes between those two ECGs and give the patient a recommendation to act. For example, in the case of minor ECG changes that patient will receive a yellow-warning and the information to make an appointment with his doctor. If major ECG changes occur, the patient will receive a red warning telling him to contact his physician immediately. If no ECG changes are detected, and also if minor changes are detected, the patient is informed that he should see a physician if symptoms pertain for longer than 20 minutes. ECG data can be transmitted to a database that can be accessed by the physician or medical institution.

Methods: This is a monocentric, single-armed non-randomized trial. Patients were asked to undertake measurements with the device once weekly and every time they were experiencing symptoms over a maximum period of three months. Subsequently patients were followed up for nine months. At inclusion and after follow-up patients were underwent a comprehensive diagnostic assessment consisting of a standard 12-lead ECG, echocardiogram and exercise-ECG.

Inclusion criteria: 18 - 80 years of age plus CABG, PCI, AMI in the last 12 months, angina pectoris treated pharmacologically, significant rhythm disturbance for which they received either a pharmacological or electrophysiological intervention, or recurrent palpitations of unknown origin in the past. Ability to handle device, regular access to the internet, signed the informed consent form. The following outcomes were assessed: Is the device able to detect ECG-changes and give the patient a correct recommendation and clinical relevance. The local ethic's committee at the ZNA Middelheim approved the study, that was conducted in line with the guidelines for GCP and the declaration of Helsinki.

Results: In total 51 patients were recruited between 11/2011 and 03/2012. Patient

characteristics and main symptoms are shown in table 1.

Patient Characteristics		
	n (total = 51)	%
Female Patients	28	55%
Age (Mean)	59 years (+/- 10)	
Symptoms		
Angina Pectoris	7	13,7%
Palpitations	21	41,2%
Atypical Chestpain	17	33,3%
Tachycardia of unclear origin	6	11,8%

Table 1: Patient characteristics and symptoms.

Patients recorded in total 1.237 ECG-readings with 2,2% of the measurements being symptom-induced and the rest being undertaken during weekly measurements. In five patients (9,8%) the CardioSecur™ device showed its clinical relevance: It diagnosed a new or so far undiagnosed condition and led to a successful treatment. A full overview of the results of the readings, number of critical results, diagnosis and interventions performed is given in table 2.

Patient Reference ID	Result	n of Readings	Diagnosis	Intervention
1	red	5	90% stenosis	Coro. Angiogramm followed by PCI
2	red	4	Paroxysmal AF	PVI
3	yellow	46	Monofocal ventricular premature beats, with bi- and trigemina	Focal ablation
4	yellow	18	AV nodal re-entry tachycardia	Ablation
5	yellow	7	Paroxysmal AF	PVI

Table 2: Results of clinical value

Out of those five patients, one patient (ID 1) was suffering from a severe ischemia. Four patients had arrhythmias with two suffering from atrial fibrillation (ID 2 & 5), one from monofocal ventricular premature beats (ID 3), with bi- and trigemina and one from AV nodal re-entry tachycardia (ID 4). During the study period, no events were reported that the device should have been able to detect. Patients reported a high ease of use and 80% would recommend the device to a friend or family member.

Conclusions: We showed that CardioSecur™ system is an important tool for diagnosing cardiovascular disease and adds value in the management of patients with cardiac diseases such as rhythm disturbances and ischemic episodes. Further research is needed to validate this first study in larger patient cohorts and assess the long-term effects of this 12-lead mobile ECG.

References: (1) Barrett P et al. Comparison of 24-hour Holter Monitoring with 14-day Novel Adhesive Patch Electrocardiographic Monitoring. Am J Med. 2014 Jan;127(1):95.e11-7. (2) Drew B et al. (3) Drew et al. (4). Bonaventura.

4. Effect of Body Position on a Mobile, Vector-Derived, 12-Lead Electrocardiogram

EC Cardiology, vol. 5, issue 8, 2018, p. 589-595.

Péter Kenedi¹, István Préda^{2,3}, Jessica Thuer¹, Ádám Székely², Marucs Skribek^{2,3}, David Triebel¹, Athar Abu Helou¹, Markus Riemenschneider¹

1. Personal MedSystems GmbH, Frankfurt, Germany 2. Department of Cardiology, Central Hospital of the Hungarian Defence Forces, Budapest, Hungary 3. Department of Cardiology and Cardiovascular Surgery, Semmelweis University, Budapest, Hungary

Background: The electrocardiogram (ECG) is a critical component of cardiovascular diagnosis. ECGs are standardly recorded in the supine position; however, due to time and space constraints as well as patient limitations, they are often performed in other positions (sitting, standing). Several studies have examined the effect of body position on electrocardiograms using various methods, body positions, and parameters, with varied results reported. This study's aim was to further evaluate the effect of body position on a mobile, vector-derived, 12-lead ECG, to determine if body position should be considered when performing an ECG.

Methods: Electrocardiograms from 39 patients were examined in the lying, sitting, and standing positions. Heart rate, PQ interval, QRS duration, QTc interval, P-, QRS-, and T-vectors, and R and S amplitudes were statistically evaluated using correlation coefficient and one-factorial Analysis of Variance (ANOVA). Changes of the Q waves, ST segments, and T waves were qualitatively evaluated.

Results: No changes of statistical or clinical significance were detected. No notable differences were seen in regard to intervals. For the vectors, a -9 degree change in the P axis with sitting, a -4 degree change in the QRS axis when standing, and a 3.8 degree increase in the T vector with change of position were seen. Negligible changes were seen in the wave amplitudes. 5/39 patients (13%) demonstrated T wave changes with change in position.

Conclusions: The results suggest that a vector-derived, 12-lead electrocardiogram can be used in different body positions without impacting key ECG parameters.

DOI:

5. First real-world experience with CardioSecur® in the preclinical setting – When time does matter.

Resuscitation 2017, ERC Symposium on Guidelines: Abstract Presentations

Hanna Kern*, Jan Stiepak, Erik Popp, Sebastian Spaich, Thomas Zelniker, Evangelos Giannitsis, Hugo Katus, Michael Preusch, University of Heidelberg

Background: The CardioSecur® (CS) (Personal MedSystems GmbH) is a novel electrocardiogram (ECG) device consisting of only 4 electrodes, but providing 22 leads. Whereas the conventional 12-lead ECG (cECG) derived from 10 electrodes is currently used as the gold standard, additional leads might provide more information, e.g. posterior myocardial infarction (MI).

This study reveals first real-world experience of CS in the pre-clinical setting.

Materials and methods: The CS system was implemented on two emergency ambulances from May to November 2016 in Heidelberg. All patients with suspected acute coronary syndrome (ACS) had an ECG recorded using both systems, cECG and CS, and were admitted to the chest pain unit in the University Hospital of Heidelberg. Definitive diagnosis, cardiac catheterization results and laboratory tests were obtained from the patients' records.

Results: In total, 64 patients (mean 67.8 ± 14.9 years) with ACS were included. Thereof, 16 patients suffered from ST-elevation MI (STEMI), 15 patients from non-STEMI and 33 patients from unstable angina.

CS had the same sensitivity compared to cECG. In patients with STEMI, infarct area was misspecified in 3 (18.8%) patients using CS and in 5 (31.3%) subjects using cECG. Interestingly, our data showed that no additional leads were recorded by any emergency physician (EP), although strict posterior MI is often masked using the cECG, and leads V7–V9 are required for accurate diagnosis. In total, 18/21 (85.7%) EPs reported to prefer implementation of CS compared to cECG in the preclinical setting.

Conclusion: Major advantages of CS lie in quick and correct positioning of the electrodes, and quicker employment in the acute situation. Moreover, producing more leads and, therefore, omitting the cumbersome additional affix of electrodes, CS might reveal more frequently strict posterior MI. This data support the effectiveness of CS in the preclinical setting.

6. The ECGD: a derivation of the ECG from VCG leads.

Journal of Electrocardiology, vol. 17, issue 2, 1984, pp. 189-91.

Dower GE

No abstract available

PMID: 6736842

7. On deriving the electrocardiogram from vectorcardiographic leads

Clinical Cardiology, vol. 3, issue 2, 1980, pp. 87.95.

Dower GE, Machado HB, Osborne JA

Abstract

The issue of whether a traditional or scientifically based system for applying electrodes to the body for routine electrocardiography may be resolved by deriving the 12-lead ECG from the Frank XYZ signals. The result, the ECGD, is sufficiently close to the ECG for serial comparisons to be valid. Reducing data acquisition to the XYZ signals alone has several technical advantages. These have been realized with the introduction of a computer system employing the ECGD at a large general hospital. Plotting the lead vectors of the ECGD on Aitoff's projection of the sphere brings out important relationships between the leads, one to another, and to the spatial directions of the QRS and T vectors. Reversing the polarity of a VR enhances the sequential relationship between the limb leads; this is taken advantage of in an educational display generated by the computer.

PMID: 6993081

8. Deriving the 12-lead electrocardiogram from four (EASI) electrodes.

Journal of Electrocardiology, vol. 21, supplement, pp. 182-7.

Dower GE, Yakush A, Nazzari SB, Jutzy RV, Ruiz CE

Abstract

Computerized interpretation of the electrocardiogram has now advanced to computerization of the electrocardiograph, resulting in greatly increased versatility, including the capacity for adapting to a variety of lead systems rather than being tethered to the old Einthoven-Wilson-Goldberger (EWG) system. Many varieties of display beyond the 12-lead ECG are also available in software. To date, these new and interesting capabilities have scarcely been exploited. The EASI lead system uses the E, A, and I electrode positions of the Frank lead system, plus an electrode, S, positioned over the upper end of the sternum and, if necessary, ground (anywhere convenient). Its outputs form quasi-xyz signals, x'y'z', that can be approximately transformed into xyz signals by means of a matrix derived from the EASI lead vectors. The result forms a good basis for deriving the 12-lead ECG, using previously published coefficients for the Frank lead system. The match with the conventional ECG can then be improved by statistical means. The results are surprisingly good, and certainly of clinical value. Recent widespread interest in silent ischemia and its detection through Holter monitoring suggests an immediate application which has been rendered practical by the recent introduction of three-channel recorders. The EASI electrode positions give technically satisfactory Holter recordings. Very compact three-channel, multiplexed, radio telemetry equipment is now commercially available and provides another application for the EASI 12-lead ECG. (ABSTRACT TRUNCATED AT 250 WORDS)

PMID: 3216172

9. Electrocardiographic systems with reduced numbers of leads–synthesis of the 12-lead ECG.

IEEE Rev Biomed Eng, vol. 7, 2014, pp. 126-42.

Tomasic I, Trobec R

Abstract

Systems with reduced numbers of leads that can synthesize the 12-lead electrocardiogram (ECG) with an insignificant or a small loss of diagnostic information have been proposed. The advantage over standard 12-lead ECG systems is the smaller number of measurement sites (i.e., electrodes) and, consequently, fewer wires. In this paper, we review all the important systems with reduced numbers of leads together with the methodology for synthesizing the leads. The fundamental theoretical background necessary to understand the most important concepts related to the synthesis is included. The presented theoretical and experimental justifications for the synthesis show that it is not necessary to measure a large number of leads directly, because the standard 12-lead ECG and arbitrary additional leads can be synthesized. Various approaches to evaluating the synthesized 12-lead ECG are defined and explained, and a number of systems that synthesize 12-lead ECG are presented as they were introduced in the literature. We cover the developments and improvements from the 1940s to the present day. The systems are classified on the basis of the synthesis method used, the approach to the evaluation of the synthesized ECG (depending on the measurement sites used), and on the number and types of leads employed. Based on a detailed assessment of state-of-the-art systems, open problems and challenges are highlighted, while further developments of electrocardiographic systems are envisaged.

PMID: 23708809

10. A vector-based, 5-electrode, 12-lead monitoring ECG (EASI) is equivalent to conventional 12-lead ECG for diagnosis of acute coronary syndromes.

Journal of Electrocardiology, vol. 39, issue 1, 2006, pp. 22-8.

Wehr G, Peters RJ, Khalife K, Banning AP, Kuehlkamp V, Rickards AF, Sechtem U

Aims: The conventional 12-lead electrocardiogram (cECG) derived from 10 electrodes using a cardiograph is the gold standard for diagnosing myocardial ischemia. This study tested the hypothesis that a new 5-electrode 12-lead vector-based ECG (EASI; Philips Medical Systems, formerly Hewlett Packard Co, Boeblingen, Germany) patient monitoring system is equivalent to cECG in diagnosing acute coronary syndromes (ACSs).

Methods: Electrocardiograms (EASI and cECG) were obtained in 203 patients with chest pain on admission and 4 to 8 hours later. Both types of ECGs were graded as ST-elevation myocardial infarction if at least 1 of the 2 consecutive recordings showed ST elevation more than 0.2 mV, as ACS if one or both showed ST elevation less than 0.2 mV, T-wave inversion, or ST depression. Otherwise, the ECG was graded negative.

Results: Final diagnosis was identical in 177 patients (87%; 95% confidence interval (CI), 82%-91%; kappa=0.81; SE=0.035). ST-elevation myocardial infarction was correctly identified or excluded by EASI with a specificity of 94% (95% CI, 89%-97%) and a sensitivity of 93% (95% CI, 86%-97%; using cECG as the gold standard). Of 118 patients with enzyme elevations, an almost identical number (72 (61% by EASI) and 73 (62% by cECG) had ST elevations. Both techniques were equivalent in predicting subsequent enzyme elevation (identical, 108/143; 75% of ACS and ST-elevation myocardial infarction ECGs by ESI and cECG). Thus, both ECG methods had exactly the same specificity of 59% (95% CI, 48%-69%) and sensitivity of 91% (95% CI, 85%-96%) for detecting myocardial injury.

Conclusion: EASI is equivalent to cECG for the diagnosis of myocardial ischemia.

PMID: 16387045

11. The relative accuracies of ECG precordial lead waveforms derived from EASI leads and those acquired from paramedic applied standard leads.

Journal of Electrocardiology, vol. 40, issue 2, 2007, pp. 120-6.

Sejersten M, Pahlm O, Pettersson J, Clemmensen PM, Rautaharju F, Zhou S, Maynard C, Feldman CL, Wagner GS

Abstract

Accurate precordial electrode placement can be difficult in emergency situations leading either to loss of time or diminished accuracy. A possible solution is the quasi-orthogonal EASI lead system, with only five electrodes and easily defined landmarks to provide a derived 12-lead electrocardiogram (ECG). The purpose of this study was to test the hypothesis that precordial waveforms in EASI-derived ECGs have no greater deviation from those in gold standard ECGs, than do the precordial waveforms in paramedic acquired standard ECGs. Twenty paramedics applied the standard precordial electrodes employing the routine procedure. A certified ECG technician applied the 6 standard precordial electrodes in their correct gold standard positions, and the EASI electrodes. 12-lead ECGs were obtained from the paramedics' standard leads, and derived from the EASI leads, for comparison with the gold standard ECG. In each precordial lead recording, 6 computer-measured QRS-T waveform parameters were considered. Differences between deltaEASI-gold standard versus deltaparamedic-gold standard were calculated for every waveform in every lead resulting in 720 comparisons. EASI and paramedic results were "equally accurate" in 47%, the paramedic was more accurate in 31%, and EASI was more accurate in the remaining 22%. The differences from gold standard recording of precordial waveforms in ECGs derived from the EASI leads and those acquired via paramedic-applied standard electrodes are similar. The results suggest that the EASI lead system may provide an alternative to the standard ECG precordial leads to facilitate data acquisition and possibly save valuable time in emergency situations.

PMID: 12942479

12. Continuous ECG Monitoring in Patients with ACS or Heart Failure: EASI versus Gold Standard.

Clinical Nursing Research, published April 16, 2017.

Lancia L, Toccaceli A, Petrucci C, Romano S, Penco M

Abstract

The purpose of the study was to compare the EASI system with the standard 12-lead surface electrocardiogram (ECG) for the accuracy in detecting the main electrocardiographic parameters (J point, PR, QT, and QRS) commonly monitored in patients with acute coronary syndromes or heart failure. In this observational comparative study, 253 patients who were consecutively admitted to the coronary care unit with acute coronary syndrome or heart failure were evaluated. In all patients, two complete 12-lead ECGs were acquired simultaneously. A total of 6,072 electrocardiographic leads were compared (3,036 standard and 3,036 EASI). No significant differences were found between the investigated parameters of the two measurement methods, either in patients with acute coronary syndrome or in those with heart failure. This study confirmed the accuracy of the EASI system in monitoring the main ECG parameters in patients admitted to the coronary care unit with acute coronary syndrome or heart failure.

PMID: 28412843

13. Derived 12-lead electrocardiogram in the assessment of ST-segment deviation and cardiac rhythm.

Journal of Electrocardiology, vol. 39, issue 1, 2006, pp. 7-12.

Chantad D, Krittayaphong R, Komoltri C

Background: There are little data on the validation of 12-lead electrocardiogram (ECG) derived by the EASI lead system used for continuous monitoring in critical care settings.

Objective: The objectives of this study were to determine the accuracy of 12-lead ECG derived by the EASI lead system in the detection of ST-segment deviation and cardiac rhythm compared with the standard 12-lead ECG.

Methods: All patients admitted to the coronary care unit were studied. Kappa statistics was used to calculate the agreement between both ECG systems in the determination of cardiac rhythm and premature ventricular complex morphology. ST-segment analysis was performed in patients with acute coronary syndromes. Pearson correlation was used to correlate the ST-segment deviation between both techniques. The sensitivity and specificity of the determination of significant ST-segment deviation by the EASI lead system were calculated.

Results: There were a total of 282 patients enrolled in this study. There was a complete agreement in the interpretation of cardiac rhythm between the 2 methods (kappa = 1). Analysis of ST-segment deviation of 12-lead ECG also showed a significant correlation (correlation coefficient varied from 0.62 in lead I to 0.823 in lead aVF with a P value of <.001 in all leads) between the 2 methods with very high sensitivity and specificity in the detection of significant ST-segment elevation and depression.

Conclusion: The 12-lead ECG derived by the EASI lead system is an accurate and reliable information for the assessment of ST-segment deviation and cardiac rhythm in critically ill patients.

PMID: 16387043

14. Diagnostic accuracy of derived versus standard 12-lead electrocardiograms.

Journal of Electrocardiology, vol. 33, supplement, 2000, pp. 155-60.

Horáček BM, Warren JW, Stóvíček P, Feldman CL

Abstract

To compare the diagnostic yield of electrocardiograms (ECGs) recorded by 12 standard leads with that of 12-lead ECGs derived from 3 bipolar EASI leads, we analyzed pertinent ECG data for 290 normal subjects and 497 patients who had had a prior myocardial infarction (MI); the latter group comprised 36 patients with a non-Q MI, 282 patients with a Q-wave MI, and 179 patients with a history of ventricular tachycardia (VT). We first estimated statistically an optimal set of coefficients for deriving the 12 standard leads from EASI leads and assessed this transformation in terms of goodness of fit. To gauge the diagnostic information content of the recorded vs. derived 12-lead ECGs, we performed successively two-group diagnostic classification--based on the Cardiac Infarction Injury Score (CIIS)--separating each of the patient subgroups from the normal group; the classification was repeated for 200 sets of patients selected randomly (with replacement), and the results were plotted as mean receiver operating characteristics. We found that derived 12-lead ECGs correlated well with the recorded ones, and reproduced faithfully the diagnostic features needed for the CIIS. When the CIIS was determined from features of the recorded standard 12 leads, its mean diagnostic performance (assessed in terms of area under the receiver operating characteristics curve) was 0.9004 for detecting non-Q MIs, 0.9546 for Q-wave MIs, and 0.9919 for MIs complicated by a history of VT. When, instead, features of derived 12 leads were used to determine the CIIS, diagnostic performance remained virtually unchanged (at 0.8905, 0.9531, and 0.9906, respectively). We conclude that, in our population, EASI-derived 12-lead ECGs contain nearly the same diagnostic information as standard 12-lead ECGs.

PMID: 11265716

15. Comparison of a vectorcardiographically derived 12-lead electrocardiogram with the conventional electrocardiogram during wide QRS complex tachycardia, and its potential application for continuous bedside monitoring.

American Journal of Cardiology, vol. 69, issue 6, 1992, pp. 612-8.

Drew BJ, Scheinman MM, Evans GT Jr.

Abstract

Previous investigators published conflicting reports comparing a vectorcardiographically derived electrocardiogram (ECGD) with the conventional 12-lead one (ECG). Prior comparisons were obtained in adults during sinus rhythm, but never in patients with wide QRS complex tachycardia. The ECGD was evaluated during baseline rhythms in patients with varying cardiac diagnoses, and the diagnostic accuracy of the 2 methods was compared during 64 episodes of wide QRS complex tachycardia in 49 patients during cardiac electrophysiologic study. All leads of the 12-lead ECGD closely resembled the conventional ECG in baseline and tachycardia tracings, except leads V3 and V4. QRS voltages were less in the ECGD, resulting in an inability to detect left ventricular hypertrophy in one third of patients with that diagnosis. There was excellent agreement between the ECGD and ECG in diagnosing prior myocardial infarction (92%), ventricular preexcitation patterns (100%), bundle branch and fascicular blocks (100%), and axis deviation. The ECGD was equally as valuable as the ECG in the diagnosis of wide QRS complex tachycardia. There was perfect agreement between the 2 lead systems in application of the morphologic criteria differentiating supraventricular tachycardia with aberration from ventricular tachycardia in leads V1, V2 and V6, and for criteria requiring axis determination and measurement of RS intervals in the precordial leads. The ECGD tracings contained less muscle artifact during body movements (e.g., after direct-current defibrillation). In conclusion, the ECGD's close correlation with the ECG, and its technical superiority and simple 5 torso-positioned electrode configuration make it worth pursuing as an option for continuous bedside monitoring.

PMID: 1536110

16. Comparison of the standard ECG with the EASIcardiogram for ischemia detection during exercise monitoring.

Computers in Cardiology, 1997, pp. 343-345.

Feldman CL, MacCallum G, Hartley LH

Abstract

The methodology for constructing the 12 lead ECG from Dower's EASI lead system-5 electrodes, all located at easy landmarks over bony areas of the thorax-has been recently updated with newly optimized coefficients. To test the ability of the updated EASIcardiogram to detect ischemia, 54 patients undergoing symptom limited, Bruce protocol exercise testing were studied with simultaneous standard 10 electrodes and EASI 5 electrode lead systems. Concordance between the two systems was 83%. In 34 patients with recent coronary angiograms sensitivity and specificity of the EASIcardiogram for detection of coronary disease were at least as good as that of the standard ECG. It is concluded that ST segment depression detected by the EASIcardiogram is very similar to that which is detected by the standard ECG and that the EASIcardiogram appears to have sensitivity and specificity at least equal to that of the standard ECG for detection of myocardial ischemia.

DOI: 10.1109/CIC.1997.647903

17. A Comparison between EASI System 12-lead ECGs and standard 12-lead ECGs for improved clinical nursing practice.

Journal of Clinical Nursing, vol. 17, issue 3, 2008, pp. 370-7.

Lancia L, Pisegna Cerone M, Vittorini P, Romano S, Penco M

Aims and Objectives: This study was carried out to verify the accuracy of 12-Lead ECG, obtained through a continuous ECG monitoring system with five cables positioned in EASI mode, to identify basic ECG alterations.

Background: This study concerns continuous ECG monitoring systems in Coronary Care Units. Continuous ECG monitoring is an important device for nursing surveillance and is useful in decreasing adverse events.

Design and Meethod: Thirteen patients admitted consecutively to the Coronary Care Unit for Acute Myocardial Infarction underwent daily and simultaneous recording of a12-lead ECG using both procedures: EASI ECG and STANDARD ECG. A sample of 1,164 ECG leads acquired in EASI mode was compared with a sample of as many ECG leads acquired using the standard procedure with a traditional cardiograph.

Results and Conclusions: In the Coronary Care Unit, Continous ECG monitoring with five cables positioned in EASI mode is a valid alternative to the standard 12-lead ECG for cardiac rhythm abnormalities detection and for acute myocardial ischemia and old myocardial infarction assessment. Therefore, the EASI system might be advantageous for long-term patient monitoring.

Relevance to clinical practice: The EASI system represents a valid device for the nursing surveillance of patients who need continuous ECG monitoring, improves clinical nursing practice in Coronary Care Units, supports the reduction of adverse events such as cardiac arrest and reduces the hospital costs.

PMID: 18205693

18. Accuracy of the EASI 12-lead electrocardiogram compared to the standard 12-lead electrocardiogram for diagnosing multiple cardiac abnormalities.

Journal of Electrocardiology, vol. 32, 1999, pp. 38-47.

Drew BJ, Pelter MM, Wung SF, Adams MG, Taylor C, Evans GT Jr, Foster E

Abstract

This study was performed to compare a derived 12-lead electrocardiogram (ECG) using a simple 5-electrode lead configuration (EASI 12-lead) with the standard ECG for multiple cardiac diagnoses. Accurate diagnosis of arrhythmias and ischemia often require analysis of multiple (ideally, 12) ECG leads; however, continuous 12-lead monitoring is impractical in hospital settings. EASI and standard ECGs were compared in 540 patients, 426 of whom also had continuous 12-lead ST segment monitoring with both lead methods. Independent standards relative to a correct diagnosis were used whenever possible, for example, echocardiographic data for chamber enlargement-hypertrophy, and troponin levels for acute infarction. Percent agreement between the 2 methods were: cardiac rhythm, 100%; chamber enlargement-hypertrophy, 84%-99%; right and left bundle branch block, 95% and 97%, respectively; left anterior and posterior fascicular block, 97% and 99%, respectively; prior anterior and inferior infarction, 95% and 92%, respectively. There was very little variation between the 2 lead methods in cardiac interval measurements; however, there was more variation in P, QRS, and T-wave axes. Of the 426 patients with ST monitoring, 138 patients had a total of 238 ST events (26, acute infarction; 62, angioplasty-induced ischemia; 150, spontaneous transient ischemia). There was 100% agreement between the 2 methods for acute infarction, 95% agreement for angioplasty-induced ischemia, and 89% agreement for transient ischemia. EASI and standard 12-lead ECGs are comparable for multiple cardiac diagnoses; however, serial ECG changes (eg, T-wave changes) should be assessed using one consistent 12-lead method.

PMID: 10688301

19. Comparison of standard and derived 12-lead electrocardiograms for diagnosis of coronary angioplasty-induced myocardial ischemia.

American Journal of Cardiology, vol. 79, issue 5, 1997, pp. 639-44.

Drew BJ, Adams MG, Pelter MM, Wung SF, Caldwell MA

Abstract

To determine whether a derived 12-lead electrocardiogram (ECG) would demonstrate typical ST-segment changes of ischemia during percutaneous transluminal coronary angioplasty (PTCA), 207 patients were monitored with continuous 12-lead ST-segment monitoring during angioplasty. Additionally, to compare the derived and standard ECGs during known periods of ischemia with PTCA balloon inflation, 151 patients were recorded with both electrocardiographic methods during the procedure. Of the 207 patients recorded with the derived ECG, 171 (83%) had typical ischemic ST-segment changes during PTCA balloon inflation. The amplitudes of these ST deviations were similar to those observed during transient myocardial ischemia observed in clinical settings (median peak ST deviation, 225 microV). There was agreement regarding presence or absence of ischemia in 150 of the 151 patients recorded with both derived and standard electrocardiographic methods (> 99% agreement). With use of the standard ECG as the "gold standard" for ischemia diagnosis, there were no false-positive results and only 1 false-negative result with the derived ECG. Furthermore, there was nearly perfect agreement between the two 12-lead methods in terms of anterior versus inferior wall patterns of ischemia. Future studies are required to determine whether continuous monitoring with a derived ECG would improve diagnosis and lead to better patient outcomes.

PMID: 9068524

20. Comparability of 12-lead ECGs derived from EASI leads with standard 12-lead ECGs in the classification of acute myocardial ischemia and old myocardial infarction.

Journal of Electrocardiology, vol. 35, supplement, 2002, pp. 35-9. .

Rautaharju PM, Zhous SH, Hancock EW, Horàcek BM, Feild DQ, Lindauer JM, Wagner GS, Pahlm O, Feldman CL

Abstract

We compared 12-lead electrocardiograms (ECGs) derived with an improved transformation matrix from EASI leads and standard 12-lead ECGs in the detection of acute myocardial ischemia and old infarction (MI). For the ischemia test, we used ECGs of 40 patients recorded prior to and at peak inflation during percutaneous transluminal coronary angioplasty, and for old MI we used test ECGs of 382 non-MI subjects and of 472 patients with prior MI documented by enzyme findings. Two experienced ECG readers served as separate, independent standards for lead-set comparisons, and the Philips ECG analysis program also classified the ECGs. The results showed no significant differences between the two lead sets in the detection of acute inflation-induced ischemia or of old MI according to coding by the electrocardiographers or the computer program. No significant differences were found between the electrocardiographers and the lead sets for acute ischemia. Classification differences between the electrocardiographers were larger than those between the lead sets for acute and old MI and were significant for the latter ($P < .001$). A more detailed comparison of the lead sets suggested a possible need for modified old-MI criteria and optimization of ST classification thresholds for acute ischemic injury, specific for the EASI 12-lead ECG. We conclude that the EASI-derived 12-lead ECG deserves serious consideration as an alternative to the standard 12-lead ECG in emergency situations and for monitoring in acute-care setting.

PMID: 12539097

21. Body position effects on the ECG: implication for ischemia monitoring.

Journal of Electrocardiology, vol. 30, issue 4, 1997, pp. 285-91.

Adams MG, Drew BJ

Abstract

Rotation of the heart in relation to surface electrocardiographic (ECG) electrodes when a patient turns to one side has been reported to cause ST-segment shifts, triggering false alarms with continuous ST-segment monitoring. We prospectively analyzed ST-segment and QRS complex changes in both standard and derived ECGs in 40 subjects (18 with heart disease and 22 healthy) in supine, right- and left-lying positions. Of the 40 subjects, 6 (4 cardiac, 2 healthy) developed positional ST deviations of 1 mm or more on the standard ECG. In the derived method, five of the same six subjects showed ST-segment deviation of which most occurred in the left-lying position. Positional ST changes were most frequent for males and for cardiac patients (33%). Changes in QRS complex morphology were common on the standard (28 of 40, 70%) and less frequent on the derived ECGs (17 of 40, 43%), occurring in both healthy and cardiac subjects. QRS axis changes occurred only on the standard ECG. It was concluded that (1) right and left side-lying positions frequently induce clinically significant ECG changes; (2) positional ST-segment deviation is less frequent than previously reported and is most likely to occur in males with cardiac disease; and (3) the derived method is less prone to positional QRS changes than the standard ECG.

PMID: 9375904

22. Value of a derived 12-lead ECG for detecting transient myocardial ischemia.

Journal of Electrocardiology, vol. 28, supplement, 1995, p. 211.

Drew BJ, Adams MG, Wung SF, Dower GE

Detection of transient myocardial ischemia (TMI) is an important objective for the treatment of ischemic heart disease in patients admitted to the cardiac care unit. The purpose of this study was to evaluate ST-segment monitoring of a derived 12-lead electrocardiogram (ECG) and compare it with routinely monitored V1 and II leads for detecting TMI.

Three hypotheses were tested, and it was found that the derived 12-lead ECG is superior to routine monitoring for (1) detecting TMI during coronary angioplasty balloon occlusion, (2) detecting abrupt coronary artery reocclusion following angioplasty, and (3) predicting in-hospital complications.

Patients were monitored simultaneously with both routine and experimental methods. The sample population consisted of 150 patients, of whom 77 underwent coronary angioplasty. Seventy-five of the 77 angioplasty patients (97%) exhibited ischemic ST-segment changes on the derived ECG compared to only 54 (70%) with the routine method. Five patients had abrupt coronary artery reocclusion following angioplasty and exhibited ST deviations with the derived 12-lead ECG, whereas only two patients exhibited ST changes with routine monitoring. Thirty-one patients had evidence of one or more ischemic events during continuous derived 12-lead ST monitoring in the cardiac care unit, while the remaining 119 had none. The group with ischemic events was no different from the group without ischemic events at the time of admission in terms of ejection fraction or the Norris Coronary Prognostic Index, which combines age, history of ischemia, heart size, and signs of congestive heart failure. Fifty-two percent of the group with ischemic events had complications compared to only 18% of the group without ischemic events. Hospital length of stay was longer for the group with ischemic events.

In conclusion, it was found that (1) continuous monitoring of the derived 12-lead ECG is superior to routine monitoring of leads V1 and II for detecting TMI and (2) ST monitoring of the derived 12-lead ECG may identify a high-risk subgroup and provide prognostic information unavailable from the usual clinical tests.

23. Diagnosing ischemia from the bedside monitor.

Prognostic Cardiovascular Nursing, vol. 11, issue 1, 1996, pp. 45-6.

Drew BJ, Ide B

No abstract available

24. Derived 12-lead ECG. Comparison with the standard ECG during myocardial ischemia and its potential application for continuous ST-segment monitoring.

Journal of Electrocardiology, 1vol. 27, supplement, 1994, pp. 249-55.

Drew BJ, Koops RR, Adams MG, Dower GE

Abstract: Many recent studies 1-1° have demonstrated the importance of continuous 12-lead ST-segment monitoring of patients with unstable coronary syndromes. For patients with acute myocardial infarction, ST monitoring is useful to predict patency of the infarct-related artery after thrombolytic therapy and to detect the serious complication of abrupt closure of the artery.^{1 5} Data from large clinical trials indicate that in-hospital reocclusion occurs in 12-38% of those with initial successful recanalization of the infarct artery. t~~~6 For patients who undergo transcatheter revascularization (eg, percutaneous transluminal coronary angioplasty [PTCA], atherectomy, laser, stem), ST-segment monitoring is useful for detecting sudden coronary artery closure caused by dissection, vasospasm, or thrombus at the intervention site. Data from the National Heart, Lung, and Blood Institute's PTCA Registry~7show that in-hospital coronary artery reocclusion after angioplasty occurs in nearly 7% of patients, and of these, 40% require emergent bypass surgery compared with only 3% of patients without this complication. Moreover, the risk of mortality, both in- hospital and during the 1-year follow-up period, is elevated after post-PTCA reocclusion. ~7

Krucoff and colleagues⁷ have shown that the 12-lead ST-segment pattern recorded before thrombolytic therapy or during PTCA balloon inflation provides a patient-specific, coronary site-specific ischemic pattern or "finger- print" that is reproduced if abrupt reocclusion of the culprit artery occurs after initial successful revascularization. Be- cause coronary artery reocclusion can be totally clinically

silent, continuous ST-segment monitoring is more sensitive than patients' symptoms for rapidly identifying patients presenting with complications in whom more aggressive therapy may be warranted. As the number of patients undergoing nonsurgical revascularization continues to grow, continuous 12-lead ST-segment monitoring will, no doubt, become a routine procedure in the cardiac care unit.

Although 12-lead ST-segment monitoring is valuable for patients with unstable coronary syndromes, it is currently highly impractical for patients in the cardiac care unit. For example, most current bedside cardiac monitors do not provide 12-lead ST analysis capability, so that double monitoring is required. One monitor comprises the routine five- electrode configuration of bedside monitoring for arrhythmias; the other monitor comprises the standard 10-electrode configuration for 12-lead ST-segment monitoring. Such a complicated hook-up is impractical for the following reasons: (1) the patient's mobility is severely curtailed; (2) the problems of muscle artifact are multiplied especially when the patient moves extremities (eg, when brushing teeth, eating, or getting up to the commode or bedside chair); (3) the 15 electrodes are difficult to maintain, and if one loses skin contact, multiple leads are affected, including occasional loss of the entire cardiac signal triggering alarms on the monitor; (4) in a diaphoretic patient, maintaining 15 adhesive-type skin electrodes requires repetitive replacement of electrodes, which is costly and time-consuming; (5) the left

precordial electrodes are difficult to

maintain in female patients with pendulous breasts or in men with hairy chests; (6) the multiple electrodes cause skin irritation and break-down, which is especially a problem when electrodes are placed adjacent to healing wounds such as the sternotomy incision in postcardiac surgery patients; and (7) the multiple electrodes and their lead wires interfere with portable chest x-rays, cardiac auscultation, procedures such as chest tube insertion, and resuscitative measures such as defibrillation.

With these problems in mind, we have been testing and perfecting a method to derive all 12 electrocardiogram (ECG) leads without the cumbersome electrode configuration required for the standard ECG. For such a method to eliminate the need to double-monitor patients in the cardiac care unit, it must be accurate for arrhythmia analysis and sensitive for recording ischemic patterns. In our first study, IS we demonstrated that a simple five-electrode configuration developed by Dower and associates⁹ was as valuable as the standard 12-lead ECG for diagnosing prior myocardial infarction, ventricular preexcitation patterns, bundle branch and fascicular blocks, and axis deviation and for distinguishing ventricular tachycardia from supra-ventricular tachycardia with aberrant conduction. Dower's ECG was derived from three modified vectorcardiographic signals and was called the ECGD.^{2°}

The purpose of the present study was to compare the ECGD with the standard 12-lead ECG in patients experiencing myocardial ischemia during PTCA.

25. Comparison of waveforms in conventional 12-lead ECGs and those derived from EASI leads in children.

Journal of Electrocardiology, vol. 36, issue 1, 2003, pp. 25-31.

Pahlm O, Pettersson J, Thulin A, Feldman CL, Field DQ, Wagner GS

Abstract

To investigate the possibility of simplifying electrocardiogram (ECG) recording in children, we compared waveforms in conventional 12-lead ECGs to those derived from EASI leads in 221 children of various ages. The conventional 12-lead ECGs and the ECGs using EASI electrode positions were collected simultaneously. We developed and determined the value of age-specific transformation coefficients for use in deriving 12-lead ECGs from the signals recorded at the EASI sites. We compared the results of using age-specific coefficients to the results of using adult coefficients and studied the "goodness-of-fit" between the conventional and the derived 12-lead ECGs. The age-specific coefficients performed slightly better than the adult coefficients, and good agreement was usually attained between the conventional 12-lead ECG and the EASI-derived 12-lead ECG. Our conclusion is that EASI leads in children have the same high levels of "goodness-of-fit" to replicate conventional 12-lead ECG waveforms, as reported earlier in adults.

PMID: 12607193

26. Diagnostic conclusions from the EASI-derived 12-lead electrocardiogram as compared with the standard 12-lead electrocardiogram in children.

American Heart Journal, vol. 151, issue 5, 2006, pp. 1059-64.

Welinder A, Field DQ, Liebman J, Maynard C, Wagner GS, Wettrell G, Pahlm O

Background: Fewer electrodes on more easily located places would facilitate electrocardiogram (ECG) recording. To investigate the possibility of simplifying ECG recording in children, we compared the diagnostic conclusions when interpreting standard versus EASI-derived 12-lead ECGs. Our hypothesis was that the variation of the interpretation of standard versus EASI-derived 12-lead ECGs was not greater than the intrareader variation of the interpretation of standard **ECGs**.

Methods: The study included 221 children. The 2 lead systems were recorded simultaneously. Two experienced pediatric cardiologists interpreted the ECGs. First, the reader interpreted a set of 221 ECGs with randomly allocated standard and EASI-derived 12-lead ECGs. Next, the reader interpreted the complementary ECG set without having access to the first set. Finally, the reader reinterpreted the standard ECGs from 98 children.

Results: The variation of the interpretation of standard versus EASI-derived 12-lead ECGs was only slightly larger than the intrareader variation of the interpretation of standard ECGs.

Conclusions: For most of the electrocardiographic diagnoses, the conclusions from EASI-derived 12-lead ECGs were similar to those from standard ECGs. These findings support the suggestion that the EASI lead system is a potential alternative to the standard ECG in children

PMID: 16644336

27. Practice standards for electrocardiographic monitoring in hospital settings: an American Heart Association scientific statement from the Councils on Cardiovascular Nursing, Clinical Cardiology, and Cardiovascular Disease in the Young: endorsed by the International Society of Computerized Electrocardiology and the American Association of Critical-Care Nurses.

Circulation, vol. 110, 2004, pp. 2721-2746.

Drew BJ, Califf RM, Funk M, Kaufman ES, Krucoff MW, Laks MM, Macfarlane PW, Sommargren C, Swiryn S, Van Hare GF

Abstract

The goals of electrocardiographic (ECG) monitoring in hospital settings have expanded from simple heart rate and basic rhythm determination to the diagnosis of complex arrhythmias, myocardial ischemia, and prolonged QT interval. Whereas computerized arrhythmia analysis is automatic in cardiac monitoring systems, computerized ST-segment ischemia analysis is available only in newer-generation monitors, and computerized QT-interval monitoring is currently unavailable. Even in hospitals with ST-monitoring capability, ischemia monitoring is vastly underutilized by healthcare professionals. Moreover, because no computerized analysis is available for QT monitoring, healthcare professionals must determine when it is appropriate to manually measure QT intervals (eg, when a patient is started on a potentially proarrhythmic drug). The purpose of the present review is to provide 'best practices' for hospital ECG monitoring. Randomized clinical trials in this area are almost nonexistent; therefore, expert opinions are based upon clinical experience and related research in the field of electrocardiography. This consensus document encompasses all areas of hospital cardiac monitoring in both children and adults. The emphasis is on information clinicians need to know to monitor patients safely and effectively. Recommendations are made with regard to indications, timeframes, and strategies to improve the diagnostic accuracy of cardiac arrhythmia, ischemia, and QT-interval monitoring. Currently available ECG lead systems are described, and recommendations related to staffing, training, and methods to improve quality are provided.

PMID: 15505110

28. The importance of derived 12-lead electrocardiography in the interpretation of arrhythmias detected by Holter recording.

Am Heart J, vol. 124, issue 4, 1992, pp. 905-11.

Denes P.

Abstract

Holter monitoring has been used extensively for the detection, diagnosis, and evaluation of therapy for cardiac arrhythmias. The availability of three-channel monitors allows for the recording of vectorcardiographic leads X, Y, and Z. One method, which was recently described by Dower et al., (*J Electrocardiol* 1988;21:5182-7), uses modified vectorcardiographic leads and allows for the acquisition of a derived 12-lead ECG of selected rhythm strips during the recording. In the present study, we evaluated the usefulness of the derived 12-lead ECG in the detection of P-wave and ST-segment shifts, assessment of QRST changes, and distinction between ventricular ectopic and aberrant supraventricular complexes. Our preliminary findings indicate that careful analysis of the derived 12-lead ECG provides additional information for a more accurate diagnosis of arrhythmias that are detected by the Holter monitor. The clinical importance and cost-effectiveness of the derived 12-lead ECG needs further evaluation.

PMID: 1382387

29. Assessment of QT-measurement accuracy using the 12-lead electrocardiogram derived from EASI leads.

Journal of Electrocardiology, vol. 40 2007, pp. 172-5.

Martinez JP, Laguna P, Olmos S, Pahlm O, Petterson J, Sörnmo L

Abstract

The purpose of the present study is to assess QT-interval measurements from the EASI 12-lead electrocardiogram (ECG) as compared with the standard 12-lead ECG. The QT interval was automatically determined in simultaneously recorded standard and EASI 12-lead ECGs, using a validated wavelet-based delineator. The agreement between the 2 sets of measurements was quantified both on a lead-by-lead basis and a multilead basis with global definitions of QRS onset and T-wave end. The results show that the agreement between QT-interval measurements from the 2 lead systems is acceptable, with negligible mean differences and with correlation coefficients ranging from 0.91 to 0.98 depending on the lead studied. Although the SD shows a clear dependence on the selected lead (ranging from 9.2 to 26.4 milliseconds), differences are within the accepted tolerances for automatic delineation. In a few patients, large differences were found, mainly because of changes in morphology present in both lead systems. QT intervals measured by the multilead approach were considerably more stable than single-lead measurements and resulted in a much better agreement between the 2 lead systems (correlation coefficient, 0.98; QT difference, 1.1 F 9.8 milliseconds). Thus, the EASI 12-lead ECG may be used for reliable QT monitoring when the multilead delineation approach is adopted.

DOI: 10.1016/j.electrocard.2006.08.089

30. Optimal electrocardiographic leads for detecting acute myocardial ischemia.

Journal of Electrocardiology, vol. 34, 2001, pp. 91-111.

Horacek BM, Warren JW, Penney CJ, MacLeod RS, Title LM, Gardner MJ, Feldman CL.

Abstract

This study identifies the most sensitive electrocardiographic leads for monitoring ST-segment changes caused by acute coronary ischemia. The data set consisted of 120-lead electrocardiograms (ECGs) digitally recorded during balloon-inflation angioplasty in 3 groups of patients with single-vessel disease (left anterior descending [LAD], 32; right coronary artery [RCA], 36; left circumflex [LCx], 23). The ST deviation was measured in all recorded leads during baseline and ischemic states, and its difference between these 2 states (DeltaST) was calculated at 352 sites and plotted as DeltaST maps. The patients in each group were divided, by means of DeltaST criteria, into subgroups of "responders" and "nonresponders." Mean DeltaSTs for each group/subgroup were calculated and standardized by the corresponding standard deviation (SD); these values were plotted as mean DeltaST and t maps. Sites where extrema of DeltaST occurred most frequently were sought in bootstrap trials, performed in each group/subgroup. The results suggest that the optimal sites for the ischemia-sensitive leads are: V(3) (+) and just below V(8) (-) for LAD-related ischemia; the left iliac crest (+) and above V(3) at the third intercostal space (-) for RCA-related ischemia; and just below V(8) (+) and above V(2) at the third intercostal space (-) for LCx-related ischemia. Three "optimal" bipolar leads using these sites registered, in the responders from the LAD, RCA, and LCx groups, mean DeltaST (+/-SD) of 232 +/- 59, 245 +/- 96 and 158 +/- 91 microV, respectively; the corresponding t values were 15.14, 9.90, and 6.75. In the 12-lead ECG, only lead V(3) approached optimal DeltaST and t values for the LAD responders (187 +/- 61 microV; t = 11.75) and lead III for the RCA responders (191 +/- 76 microV; t = 9.73), but even these values were significantly suboptimal (P = 0.0011 and P = 0.0120, respectively). We found that the "optimal" bipolar leads can be derived, to an excellent approximation, from the 12 standard leads or from 3 EASI leads (with 3 electrodes at Frank's transverse level and 1 on the manubrium), by using precalculated regression coefficients. By means of bootstrap trials, we estimated the mean sensitivity (SE) and the mean positive predictive value (PPV) with which 3 "optimal" vessel-specific leads could identify ischemia related to the LAD, RCA, and LCx arteries, in the test set, as (SE/PPV) 94.7/92.8%, 78.7/80.9%, and 81.5/80.9%. A similar diagnostic performance can be achieved by vessel-specific leads derived from the 12-lead ECG (93.0/93.4%, 76.6/82.0%, and 82.7/77.1%) and, interestingly, from the EASI lead system (97.8/88.4%, 78.0/80.2%, and 76.8/83.2%). Thus, although the "optimal" bipolar leads for detecting ischemia related to each of the 3 coronary arteries were found to require sampling outside the 12-lead ECG, these leads can be derived from the full set of 12 standard leads or--for clinical monitoring applications--from the EASI lead system by using fewer electrodes at convenient locations.

PMID: 11781943

31. EASI-Derived vs. standard 12-lead electrocardiogram for Selvester QRS score estimations of chronic myocardial infarct size, using cardiac magnetic resonance imaging as gold standard.

Journal of Electrocardiology, vol. 42, issue 2, 2009, pp. 145-51.

Welinder AE, Wagner GS, Horáček BM, Martin TN, Maynard C, Pahlm O

Abstract

Background: The size of myocardial infarction (MI) is of significance for the prognosis. Selvester scores might be valuable for this estimation.

Objective: To compare the differences in Selvester scores for chronic MI provided from standard and EASI-derived 12-lead electrocardiograms (ECGs) and to compare these scores to the MI size measured by delayed-enhancement magnetic resonance imaging (DE-MRI).

Methods: Thirty-seven patients were studied. In connection with their DE-MRI scan follow-up after chest pain, body surface potential mapping was performed. Standard and EASI 12-lead ECGs were constructed from the maps. Two investigators manually performed the measurements required for scoring with the Selvester system using a quad-plot format of the ECGs. One of the investigators repeated this once for the standard leads.

Results: The differences between the 2 ECG estimations of MRI-measured MI size were not statistically significant. Neither the association nor the agreement between MRI and EASI-lead measurements or between MRI and standard-lead measurements were very strong.

Conclusions: The differences between ECG and MRI measurements of MI size indicate that both methods may need improvement.

PMID: 19100565

32. Simultaneous comparison of 3 derived 12-lead electrocardiograms with standard electrocardiogram at rest and during percutaneous coronary occlusion.

Journal of Electrocardiology, vol. 41, issue 3, 2008, pp. 230-7.

Nelwan SP, Kors JA, Crater SW, Meij SH, van Dam TB, Sijmoons ML, Mrucoff MW

Abstract

Aim: The aim of the study was to simultaneously test the EASI lead system and two other derived ECG methods against the standard 12-lead ECG during percutaneous coronary intervention (PCI).

Methods: During 44 percutaneous coronary interventions, a simultaneously recorded 12-lead and EASI ECG were marked at the start of the PCI (baseline) and at known ischemia caused by balloon inflation (peak). ST deviations were measured 60 ms after the J point at baseline and peak in all leads and were summated (SUMST) to assess overall changes. For regional changes, the lead with the highest ST deviation (PEAKST) was marked. For each patient, derived 12-lead ECGs were computed from the EASI leads and a lead subset using patient-specific coefficients (PS) and coefficients based on a patient population (GEN). Absolute differences were computed between each derived and routine ECG for SUMST and PEAKST.

Results: SUMST was at baseline 567 microV (range: 150-1707) and increased at peak to 871 microV (range: 350-2101). SUMST difference at peak was for EASI: 163 microV (CI: 90-236, $P < .001$), GEN: 46 microV (CI: 2-91, $P = .40$), and PS: 16 microV (CI: 3-30, $P = .15$). PEAKST difference at peak was for EASI: 49 microV (CI: 19-220, $P = .02$), GEN: 48 microV (CI: -43-154, $P = .26$), and PS: 20 microV (CI: -51-32, $P = .65$).

Conclusion: Simultaneous direct comparison of three derived ECG methods shows overall and regional differences in accuracy across PS, GEN, and EASI. Median SUMST and PEAKST differences for PS are lower than for GEN and EASI, and show a more accurate reconstruction.

PMID: 18433164

33. 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).

European Heart Journal, 2018, Vol 39, issue 2, pp. 119-177.

Ibanez B, James S, Agewall S, Antunes MJ, Bucciarelli-Ducci C, Hector B, Caforio ALP, Crea F, Goudevenos JA, Hindricks S, Kastrati A, Lenzen MJ, Prescott E, Roffi M, Valgimigli M, Varenhorst C, Vranckx P, Widimsky P, ESC Scientific Document Group

Recommendations for initial diagnosis		
Recommendations	Class ^a	Level ^b
ECG monitoring		
12-lead ECG recording and interpretation is indicated as soon as possible at the point of FMC, with a maximum target delay of 10 min. ^{36,38}	I	B
ECG monitoring with defibrillator capacity is indicated as soon as possible in all patients with suspected STEMI. ^{44,45}	I	B
The use of additional posterior chest wall leads (V ₇ –V ₉) in patients with high suspicion of posterior MI (circumflex occlusion) should be considered. ^{8,46–49}	IIa	B
The use of additional right precordial leads (V ₃ R and V ₄ R) in patients with inferior MI should be considered to identify concomitant RV infarction. ^{8,43}	IIa	B
Blood sampling		
Routine blood sampling for serum markers is indicated as soon as possible in the acute phase but should not delay reperfusion treatment. ⁸	I	C

ECG = electrocardiogram; FMC = first medical contact; MI = myocardial infarction; RV = right ventricle; STEMI = ST-segment elevation myocardial infarction.
^aClass of recommendation.
^bLevel of evidence.

PMID: 28886621

34. 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: Task Force for the Management of Acute Coronary Syndromes in Patients Presenting without Persistent ST-Segment Elevation of the European Society of Cardiology (ESC).

European Heart Journal, 2017, Vol. 37, Issue 3, Pp. 267–315

Roffi M, Patrono C, Collet JP, Mueller C, Valgimigli M, Andreotti F, Bax JJ, Borger MA, Brotons C, Baris Gencer D, Hasenfuss G, Kjeldsen K, Lancellotti P, Landmesser U, Mehilli J, Mukherjee D, Storey R, Windecker S, Baumgartner H, Gaemperli O, Achenbach S, Agewall S, Badimon L, Baigent C, Bueno H, Bugiardini R, Carerj S, Casselman F, Cuisset T, Erol C, Fitzsimons D, Halle M, Hamm C, Hildick-Smith D, Huber K, Iliodromitis E, James S, Lewis BS, Lip GY, Piepoli MF, Richter D, Rosemann T, Sechtem U, Steg PG, Vrints C, Luis Z

PMID: 26320110

35. Third universal definition of myocardial infarction.

J Am Coll Cardiol, vol. 60, issue 16, pp. 1581-98.

Thygesen K, Alpert JS, Jaffe AS, Simoons ML, Chaitman BR, White HD; Joint ESC/ACCF/AHA/WHF Task Force for Universal Definition of Myocardial Infarction; Authors/Task Force Members Chairpersons, Thygesen K, Alpert JS, White HD; Biomarker Subcommittee, Jaffe AS, Katus HA, Apple FS, Lindahl B, Morrow DA; ECG Subcommittee, Chaitman BR, Clemmensen PM, Johanson P, Hod H; Imaging Subcommittee, Underwood R, Bax JJ, Bonow JJ, Pinto F, Gibbons RJ; Classification Subcommittee, Fox KA, Atar D, Newby LK, Galvani M, Hamm CW; Intervention Subcommittee, Uretsky BF, Steg PG, Wijns W, Bassand JP, Menasche P, Ravkilde J; Trials & Registries Subcommittee, Ohman EM, Antman EM, Wallentin LC, Armstrong PW, Simoons ML; Trials & Registries Subcommittee, Januzzi JL, Nieminen MS, Gheorghiade M, Filippatos G; Trials & Registries Subcommittee, Luepker RV, Fortmann SP, Rosamond WD, Levy D, Wood D; Trials & Registries Subcommittee, Smith SC, Hu D, Lopez-Sendon JL, Robertson RM, Weaver D, Tendera M, Bove AA, Parkhomenko AN, Vasilieva EJ, Mendis S; ESC Committee for Practice Guidelines (CPG), Bax JJ, Baumgartner H, Ceconi C, Dean V, Deaton C, Fagard R, Funck-Brentano C, Hasdai D, Hoes A, Kirchhof P, Knuuti J, Kolh P, McDonagh T, Moulin C, Popescu BA, Reiner Z, Sechtem U, Sirnes PA, Tendera M, Torbicki A, Vahanian A, Windecker S; Document Reviewers, Morais J, Aguiar C, Almahmeed W, Arnar DO, Barili F, Bloch KD, Bolger AF, Botker HE, Bozkurt B, Bugiardini R, Cannon C, de Lemos J, Eberli FR, Escobar E, Hlatky M, James S, Kern KB, Moliterno DJ, Mueller C, Neskovic AN, Pieske BM, Schulman SP, Storey RF, Taubert KA, Vranckx P, Wagner DR.

PMID: 22958960

36. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS: The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC), developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC, endorsed by the European Stroke Organisation (ESO)

European Heart Journal (2016) 37, 2893–2962

Authors/Task Force Members: Paulus Kirchhof (Chairperson) (UK/Germany), Stefano Benussi (Co-Chairperson) (Switzerland), Dipak Kotecha (UK), Anders Ahlsson (Sweden), Dan Atar (Norway), Barbara Casadei (UK), Manuel Castella (Spain), Hans-Christoph Diener (Germany), Hein Heidbuchel (Belgium), Jeroen Hendriks (The Netherlands), Gerhard Hindricks (Germany), Antonis S. Manolis (Greece), Jonas Oldgren (Sweden), Bogdan Alexandru Popescu (Romania), Ulrich Schotten (The Netherlands), Bart Van Putte (The Netherlands), and Panagiotis Vardas (Greece)

European Heart Journal (2016) 37, pp. 2911–2914

8. Integrated management of patients with atrial fibrillation

Most patients initially access the healthcare system through pharmacists, community health workers, or primary care physicians. As AF is often asymptomatic (“silent AF”), these healthcare professionals are important stakeholders to enable the adequate detection of AF and to ensure consistent management. The initial assessment should be performed at the point of first contact with the healthcare system, and is feasible in most healthcare settings (when an ECG is available).

[...]

8.3 Diagnostic workup of atrial fibrillation patients

AF is often found in patients with other, at times undiagnosed, cardiovascular conditions. Thus, all AF patients will benefit from a comprehensive cardiovascular assessment. [...]

8.3.1 Recommended evaluation in all atrial fibrillation patients

A complete medical history should be taken and all patients should undergo clinical evaluation that includes thorough assessment for concomitant conditions, establishing the AF pattern, estimation of stroke risk and AF-related symptoms, and assessment of arrhythmia-related complications such as thrombo-embolism or LV dysfunction. **A 12-lead ECG is recommended to establish a suspected diagnosis of AF**, to determine rate in AF, and to screen for conduction defects, ischaemia, and signs of structural heart disease. Initial blood tests should evaluate thyroid and kidney function, as well as serum electrolytes and full blood count. Transthoracic echocardiography is recommended in all AF patients to guide treatment decisions. Transthoracic echocardiography should be used to identify structural disease (e.g. valvular disease) and assess LV size and function (systolic and diastolic), atrial size, and right heart function. [...] Although biomarkers such as natriuretic peptides are elevated in AF patients, there is insufficient data to suggest that blood-based parameters are independent markers for AF. [...]

37. Accuracy of 22-lead ECG Analysis for diagnosis of acute myocardial infarction and coronary artery disease in the emergency department: a comparison with 12-lead ECG.

Ann Emerg Med, vol. 21, issue 1, 1992, pp. 1-9.

Justis DL, Hession WT

Study Objectives: To compare a new 22-lead ECG with the 12-lead ECG for diagnosis of acute myocardial infarction (AMI).

Design: Prospective study of all consenting patients presenting to the emergency department with chest pain.

Setting: urban hospital ED.

Type of Participants: 163 patients admitted with a cardiac-related diagnosis and complete data sets of 22- and 12-lead ECG results and creatine kinase-MB analysis

Interventions: Patient care and existing protocols were unaltered, with the exception of including the new 22-lead ECG.

Measurements and main results: Forty-one of 163 patients had an AMI as defined by creatine kinase-MB analysis. The 22-lead ECG provided a statistically significant improvement in sensitivity (83%) for AMI diagnosis over the 12-lead ECG (51%) with specificities of 76% and 99%, respectively.

Conclusion: When combined with clinical judgment, the 22-lead ECG could provide a 97.6% sensitivity for AMI diagnosis while reducing unnecessary admissions for "rule-out MI" by 69%.

PMID: 1539875

38. Right precordial leads V4R and V5R in ECG detection of acute ST elevation MI Associated with Proximal Right Coronary Artery Occlusion.

Computers in Cardiology, vol. 32, 1995, pp. 651-654.

Liu X, Tragardh E, Zhou SH, Pahlm O, Startt-Selvester RH, Gregg RE, Helfenbein ED, Lindauer JM

Abstract

ST elevation myocardial infarction (STEMI) in the right ventricle (RV) associated with right coronary artery (RCA) occlusion is known to have high hospital mortality. The hypothesis tested in this study is: right precordial leads V4R and V5R help detect STEMI in the right ventricle. ECGs from 1,970 subjects were collected in Ruijin Hospital (n=1,342), Shanghai, China and Lund University Hospital, Lund (n=565), Sweden. All ECGs were recorded with additional leads on the right precordial location in V4R and V5R. Our results show that the subjects with middle to upper RCA occlusion often show ST elevation in leads V4R and V5R and ST depression in lateral leads I, aVL, V5-V6, and are often undetected as STEMI or AMI in the standard 12-lead ECG. We conclude that adding V4R and V5R to standard ECG recording in assessing patients presenting with acute coronary syndrome is an easy and convenient way to increase the sensitivity of STEMI detection.

39. Acute myocardial infarction with isolated ST-segment elevation in posterior chest leads V7-9: „hidden“ ST-segment elevations revealing acute posterior infarction.

J Am Coll Cardiol, vol. 34, issue 3, 1999, pp. 748-53.

Matetzky S, Freimark D, Feinberg MS, Novikov I, Rath S, Rabinowitz B, Kaplinsky E, Hod H

Objectives: This study was done to determine whether electrocardiographic (ECG) isolated ST-segment elevation (ST) in posterior chest leads can establish the diagnosis of acute posterior infarction in patients with ischemic chest pain and to describe the clinical and echocardiographic characteristics of these patients.

Background: The absence of ST on the standard 12-lead ECG in many patients with acute posterior infarction hampers the early diagnosis of these infarcts and thus may result in inadequate triage and treatment. Although 4% of all acute myocardial infarction (AMI) patients reveal the presence of isolated ST in posterior chest leads, the significance of this finding has not yet been determined.

Methods: We studied 33 consecutive patients with ischemic chest pain suggestive of AMI without ST in the standard ECG who had isolated ST in posterior chest leads V7 through V9. All patients had echocardiographic imaging within 48 h of admission, and 20 patients underwent coronary angiography.

Results: Acute myocardial infarction was confirmed enzymatically in all patients and on discharge ECG pathologic Q-waves appeared in leads V7 through V9 in 75% of the patients. On echocardiography, posterior wall-motion abnormality was visible in 97% of the patients, and 69% had evidence of mitral regurgitation (MR), which was moderate or severe in one-third of the patients. Four patients (12%), all with significant MR, had heart failure, and one died from free-wall rupture. The circumflex coronary artery was the infarct related artery in all catheterized patients.

Conclusions: Isolated ST in leads V7 through V9 identify patients with acute posterior wall myocardial infarction. Early identification of those patients is important for adequate triage and treatment of patients with ischemic chest pain without ST on standard 12-lead ECG.

PMID: 10483956

40. Improved detection of posterior myocardial wall ischemia with the 15-lead electrocardiogram.

American Heart Journal, vol. 138, 5 pt 1, 1999, pp. 934-40.

Khaw K, Moreyra AE, Tannenbaum Ak, Hosler MN, Brewer TJ, Agarwal JB

Background: A routine 12-lead electrocardiogram is commonly obtained to evaluate for possible acute myocardial infarction during the initial screening of patients with chest discomfort. Posterior myocardial infarction is commonly missed because it is not usually visible in the standard leads. In this study, we compared the sensitivity and specificity of posterior chest leads (V(7), V(8), and V(9)) and 12-lead electrocardiography in detecting posterior injury pattern during single-vessel percutaneous transluminal coronary angioplasty.

Methods and Results: Three posterior chest leads in addition to the routine 12-lead electrocardiogram were monitored simultaneously during single-vessel percutaneous transluminal coronary angioplasty of the right, circumflex, and left anterior descending coronary arteries in a total of 223 patients. Posterior injury patterns (95%) were detected mostly during circumflex coronary occlusion. Posterior leads were able to detect injury pattern in 49% (36 of 74) of patients, whereas the 12-lead electrocardiogram was able to detect only 32% ($P < .04$). When all 15 leads were used to detect all ST elevations, sensitivity increased to 57%, with a specificity of 98% for the circumflex coronary artery. If maximal ST depressions in leads V(2) to V(3) are considered to be from posterior myocardial injury, then the overall sensitivity is increased to 69%.

Conclusions: Posterior leads significantly increased the detection of posterior injury pattern compared with the standard 12-lead electrocardiogram. Using all 15 leads significantly further improved the detection of circumflex coronary-related injury pattern over the standard 12-lead electrocardiogram.

PMID: 10539826

41. Improved detection of Coronary Artery Disease by Exercise Electrocardiography with the Use of Right Precordial Leads.

New England Journal of Medicine, vol. 340, 1999, pp. 340-5.

Michaelides AP, Psomadaki ZD, Dilaveris PE, Richter DJ, Andrikopoulos GK, Aggeli KD, Stefanadis CI, Toutouzas PK

Background: Exercise electrocardiography is an imperfect test for the detection of coronary artery disease. We attempted to improve the diagnostic accuracy of exercise testing as a noninvasive method for the detection of coronary artery disease by using a combination of the left and right precordial leads.

Methods: We studied 245 patients (218 men and 27 women) ranging from 32 to 74 years of age (mean [\pm SD], 52 ± 8) who underwent treadmill exercise testing, thallium-201 scintigraphy, and coronary arteriography. During exercise testing, each patient had one electrocardiogram recorded with the standard 12 leads and 3 right precordial leads (V_3R , V_4R , and V_5R), with the results for each set of leads recorded and analyzed separately.

Results: On the basis of coronary arteriography, 34 patients had normal coronary arteries, 85 had single-vessel disease, 84 had two-vessel disease, and 42 had three-vessel disease. The sensitivities of the standard 12-lead exercise electrocardiogram, exercise electrocardiography incorporating right precordial leads, and thallium-201 scintigraphy were 52 percent, 89 percent, and 87 percent, respectively, for the detection of single-vessel disease; 71 percent, 94 percent, and 96 percent for the detection of two-vessel disease; 83 percent, 95 percent, and 98 percent for the detection of three-vessel disease; and 66 percent, 92 percent, and 93 percent for the detection of any coronary artery disease. The specificities of the three methods for the detection of any coronary artery disease were 88 percent, 88 percent, and 82 percent, respectively.

Conclusions: Use of right precordial leads along with the standard six left precordial leads during exercise electrocardiography greatly improves the sensitivity of exercise testing for the diagnosis of coronary artery disease.

PMID: 9929523

42. Importance of posterior chest leads in patients with suspected myocardial infarction, but nondiagnostic, routine 12-lead electrocardiogram.

American Journal of Cardiology, vol. 83, issue 3, 1999, pp. 323-6.

Agarwal JB, Khaw K, Aurignac F, LoCurto A

Abstract

Criteria for reperfusion therapy in acute myocardial infarction require the presence of ST elevation in 2 contiguous leads. However, many patients with myocardial infarction do not show these changes on a routine 12-lead electrocardiogram and hence are denied reperfusion therapy. Posterior chest leads (V7 to V9) were recorded in 58 patients with clinically suspected myocardial infarction, but nondiagnostic routine electrocardiogram. ST elevation >0.1 mV or Q waves in $>$ or $=2$ posterior chest leads were considered to be diagnostic of posterior myocardial infarction. Eighteen patients had these changes of posterior myocardial infarction. All 18 patients were confirmed to have myocardial infarction by creatine phosphokinase criteria or cardiac catheterization. Of the 17 patients who had cardiac catheterization, 16 had left circumflex as the culprit vessel. We conclude that posterior chest leads should be routinely recorded in patients with suspected myocardial infarction and nondiagnostic, routine electrocardiogram. This simple bedside technique may help proper treatment of some of these patients now classified as having unstable angina or non-Q-wave myocardial infarction.

PMID: 10072216

43. Value of posterior and right ventricular leads in comparison to the standard 12-lead electrocardiogram in evaluation of ST-segment elevation in suspected acute myocardial infarction.

American Journal of Cardiology, vol. 79, issue 12, 1997, pp. 1579-85.

Zalenski RJ, Rydman RJ, Sloan EP, Hahn KH, Cooke D, Fagan J, Fligner Dj, Hessions W, Justis D, Kampe LM, Shah S, Tucker J, Zwicke D

Abstract

In this multicenter prospective trial, we studied posterior (V7 to V9) and right ventricular (V4R to V6R) leads to assess their accuracy compared with standard 12-lead electrocardiograms (ECGs) for the diagnosis of acute myocardial infarction (AMI). Patients aged >34 years with suspected AMI received posterior and right ventricular leads immediately after the initial 12-lead ECG. ST elevation of 0.1 mV in 2 leads was blindly determined and inter-rater reliability estimated. AMI was diagnosed by World Health Organization criteria. The diagnostic value of nonstandard leads was determined when 12-lead ST elevation was absent and present and multivariate stepwise regression analysis was also performed. Of 533 study patients, 64.7% (345 of 533) had AMI and 24.8% received thrombolytic therapy. Posterior and right ventricular leads increased sensitivity for AMI by 8.4% ($p = 0.03$) but decreased specificity by 7.0% ($p = 0.06$). The likelihood ratios of a positive test for 12, 12 + posterior, and 12 + right ventricular ECGs were 6.4, 5.6, and 4.5, respectively. Increased AMI rates (positive predictive values) were found when ST elevation was present on 6 nonstandard leads (69.1%), on 12 leads only (88.4%), and on both 6 and 12 leads (96.8%; $p < 0.001$). Treatment rates with thrombolytic therapy increased in parallel with this electrocardiographic gradient. Logistic regression analysis showed that 4 leads were independently predictive of AMI ($p < 0.001$): leads I, II, V3, V5R; V9 approached statistical significance ($p = 0.055$). The standard ECG is not optimal for detecting ST-segment elevation in AMI, but its accuracy is only modestly improved by the addition of posterior and right ventricular leads.

PMID: 9202344

44. Posterior Myocardial Infarction: the dark side of the moon.

Neth Heart Journal, 2007 Jan;15(1):16-21

Van Borselen OF, Verheugt FWA, Meursing BTJ, and Ophuis AJM.

Abstract

The clinical presentation of posterior myocardial infarction is not always easy, not even for the cardiologist. In this article a 70-year-old woman who presented with chest pain is described. The electrocardiogram at presentation showed marked ST-segment depression in leads V1 to V5 and slight ST-segment depression in leads I and aVL. There was ST-segment elevation in the posterior leads V7 to V9. Elevation of specific cardiac enzymes confirmed the diagnosis of myocardial infarction. True posterior myocardial infarction is difficult to recognise because the leads of the standard 12-lead electrocardiogram are not a direct representation of the area involved. Only with indirect changes in the precordial leads as such the diagnosis can be suspected. This review will highlight the electrocardiographic fine-tuned diagnosis of posterior myocardial infarction by using the posterior leads V7 to V9 leading to easier and faster recognition with consequences for treatment and improved prognosis.

True posterior myocardial infarction (PMI), the 'dead angle infarction' of the electrocardiogram (ECG), is often misjudged and this may be the reason for undertreatment. It is suggested to be one of the most commonly missed types of acute myocardial infarction (MI) electrocardiographic patterns.¹ The clinical presentation of PMI is not different from other myocardial infarctions, but the absence of 'traditional' electrocardiographic infarct signs such as ST-segment elevation can lead to errors or delay in the diagnosis. Correct interpretation and use of the ECG using the additional leads V7 to V9 can establish the electrocardiographic diagnosis of PMI.

[...]

Use of dorsal leads V7-V9

Mortality reduction is highest when reperfusion of the infarcted vessel is achieved within six hours of pain onset, with the best results during the first 'golden' hour.¹⁵⁻¹⁷ In search of faster and more reliable methods in identifying PMI, the extra posterior leads V7 to V9 significantly increase the detection of posterior injury patterns compared with the standard 12-lead ECG.[...]

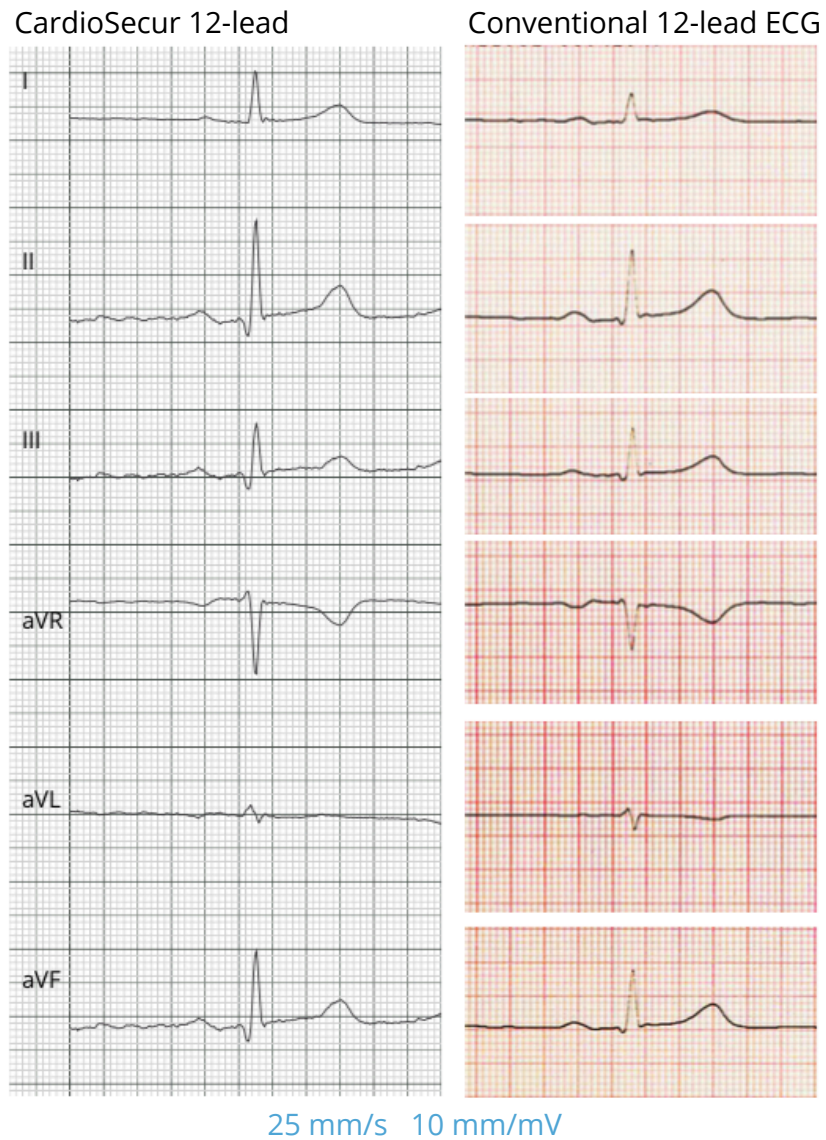
It is suggested that because of the greater distance between the infarcted area and the leads in PMI, an elevation of 0.5 mm is sufficient to justify the diagnosis of PMI followed by decisions in reperfusion treatment. Adjusted criteria provided an improved sensitivity from 49% in the 12-lead to 94% in 15-lead ECG. [...] An increase of the use of thrombolysis was seen with the increasing number of electrocardiographic leads demonstrating ST-segment elevation. [...] Posterior chest leads should be routinely recorded in patients with suspected MI and nondiagnostic routine ECG to establish the appropriate reperfusion treatment (including thrombolysis) of some of the patients now classified as having unstable or non-Q-wave MI. [...] Some authors claim that in specific cases ST-segment depression in the precordial leads is sufficient for thrombolysis. [...] By using the posterior leads V7 to V9 this uncertainty will not

be necessary in most cases. [...] Primary angioplasty has the advantage of establishing the diagnosis and therapy immediately. It should be emphasised that patients presenting with MI with co-existing PMI are at greater risk of complications, and acute therapy including thrombolysis and angioplasty should not be delayed.

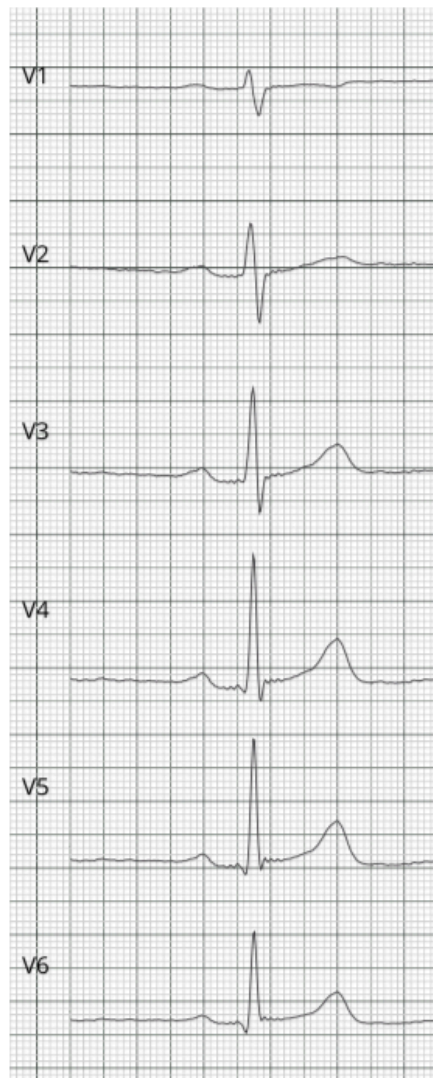
[...]

Appendix

Characteristic differences between CardioSecur and a conventional 12-lead ECG in the height of R-waves and T-waves.



CardioSecur 12-lead



Conventional 12-lead ECG



25 mm/s 10 mm/mV