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Pilot Study Evaluating a Prototype ECV Device for the Detection of Coronary Ischemia and the Diagnosis of Heart Disease

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Abstract

This pilot study evaluates the capability of a prototype six lead ElectroCardioVision (ECV) device and its software to rapidly and accurately recognize ischemia in the emergency room setting in patients presenting with chest pain and/or shortness of breath. It was also used to screen for heart abnormalities that may merit further medical work up. The ECV showed substantially greater sensitivity than a traditional ECG with respect to ischemia and potentially superior diagnostic capabilities. With respect to screening for heart abnormalities, the ECV almost matched the sensitivity of a 12 lead ECG read by an experienced cardiologist and was significantly superior on specificity. This has the potential for improving the speed and accuracy of diagnosing ischemic heart disease and other cardiac diseases that may not be identified using the traditional ECG. Despite the vast diagnostic value of the traditional ECG, having a faster, more portable, automated device has the tremendous potential in cutting costs associated with ischemic heart disease. Many limitations existed in this small study, yet consistent and superior qualities were identified, which should prompt further evaluation to determine its applicability in the real world.

Background and Significance

When all age groups are considered, ischemic heart disease (IHD) is the most common cause of death both in men and women. Postmortem studies on accident victims and military casualties in western countries has shown that coronary arteriosclerosis often begins to develop prior to age 20 and is widespread even among adults who are asymptomatic. Sudden death may be unheralded and is a common presenting manifestation of IHD.

The ECG is a mainstay in the diagnosis of acute and chronic coronary syndromes. The findings depend upon several key factors including the duration (hyperacute/acute vs evolving/chronic), extent (transmural vs subendocardial), and localization (anterior vs inferior-posterior) of ischemia or infarction as well as the presence of other underlying abnormalities. The ECG may also provide information on prognosis.

However, conventional ECG has shortcomings that have long been recognized. It has low sensitivity to minor ECG changes, which may correspond to early pathology; poor sensitivity, 34% alone and 46% when compared to dynamic changes in ST segment elevation between serial ECGs, and rarely rises to 80-87% after evaluating serial evolution of all ECG abnormalities (ST segment, T or Q waves, or LBBB). The diagnosis of ischemia is even more difficult to establish with bundle branch block, left ventricular hypertrophy with strain, and paced rhythms.

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The question we intend to answer is more basic: what is the specificity and sensitivity of this ECV to diagnose ischemia in the emergency room based on one initial read. Given the fact that many of the patients may be medicated or have preexisting conditions this is a difficult real world test of the technology. We also intend to compare its capabilities to a traditional ECG.

Traditionally, diagnosis of ischemia requires an additional work up beyond the ECG.
If it is determined in follow up studies that this technology is sensitive enough a negative evaluation may preclude more invasive and expensive tests which would result in reduced treatment costs and hospital stays.

The ability to do automated reads with limb leads without undressing the patient in a shorter period of time is another potential benefit. This is a six lead device more appropriate for mass screenings and emergency settings.

Traditional ECGs require a significant amount of expertise to evaluate heart disease. Several studies have examined the accuracy of computer ECG interpretation programs and have suggested that computer analysis cannot substitute for physician interpretation of ECGs. Evaluation is partly an art not simply a science. We also know that for many types of heart disease speed of treatment contributes to better outcomes.

The ability of an EMT, or any health profession in the out patient setting, without the training of a cardiologist, to get a fast and accurate diagnosis at the site of a cardiac emergency, may result in faster treatments and better outcomes.

This is a pilot study. The objective is to do a preliminary assessment of a new prototype ECG technology for diagnosing ischemia. We cannot in this study evaluate the full range of capabilities of this device which include diagnosing other cardiac conditions and real time monitoring. Nor will we definitively determine the use of this device in the angina treatment protocol.

Methodology

The basic design of this study is to compare one read from the ECV with one read from the 12 lead ECG both conducted at the time of admittance to the emergency room. The results from those reads will be compared to the definitive diagnosis determined by a cardiologist after reviewing the entire patient history and work up. Our objective was to determine the ability of both devices to identify ischemia and screen for heart abnormalities based on only one read.

In order to test the ECV device, patients were randomly selected from Maimonides Medical Center's (MMC) emergency department, based on initial complaint of chest pain/discomfort/pressure, and/or shortness of breath. The time of day was also random, from early morning hours to late night and the study collected as few as 1, but as many as 10 patients at a time throughout the course of seven months spanning summer, fall, and winter months, randomizing our sample. During that time 109 patients were selected

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based on the above inclusion criteria by checking the computer system for those new patients with the above complaints, of which 9 patients refused to participate. After full explanation and consent, the ECV electrodes were placed on the wrists and ankles (4 leads) of each patient (or the existing electrodes were used) and analyzed for a full minute. At no time did our encounter with the patient alter the medical status or work up, which was left to the discretion of the MMC emergency department staff. A copy of the patients' ECG and emergency department work up, including history, physical findings, lab results, radiology, and medications given was then obtained.

After all data were collected, a blinded, board certified cardiologist read only the ECG of each patient, and on a scale of 1-5, rated the likelihood of ischemia, where 1= very unlikely, 2= unlikely, 3= can't tell (50/50), 4= likely, and 5= very likely. He then determined if heart disease was present or not, based on the electrical abnormalities on the ECG, and then again rated the ECG given the patient's risk factors. Risk factors included age, gender, diabetes mellitus, hypertension, tobacco use, hypercholesterolemia, and family history of heart disease. 4 of 98 (4.1%) of the initial "1-5" ratings were not changed because of the given risk factors.

The next part of the study was to determine the actual likelihood of ischemia, by review of the entire patient record, including all obtainable information from all diagnostic modalities that were used in the patient's workup by a second cardiologist blinded to the initial ECG reading. These additional modalities included cardiac enzymes (troponin-I, CK-MB, and myoglobin), echocardiogram, stress testing, and coronary angiography, as well as the patient's history. A scale of 1-5 was also constructed with estimated likelihoods of ischemia. The scale (Table 1) represents general guidelines for the cardiologist, however the final rank was determined by the cardiologist's best judgement:
A second index was created to screen for heart disease which was made by the cardiologist after analyzing all of the patient's existing data, differing from the cardiologist's determination which was based solely on the presenting ECG. The index was based on the existence of any heart abnormality whether electrical or mechanical.

Analysis

At the end of the data collection phase we had usable data from 98 patients. Two were not included because no ECGs were done on the patients for their specific workup.

The five point ischemia scale was transformed into a three level scale by first subtracting 3 from the scale which resulted in a "-2, -1, 0, + 1, + 2" scale. The scale was further collapsed to effectively became a (-), (0), and (+) scale, where (-) was a match for "unlikely to have ischemia," (0) was a match for "can't tell" (usually due to a lack of complete workup or ECG with the above mentioned limitations, or (+) which was a positive match for ischemia. The objective was to reduce mismatches because of slight classification differences.

We then compared the ischemia index with the definitive diagnosis. We conducted an analysis to compare the standard 12 lead ECG read by a cardiologist, and the automated ECV. We found that the automated ECV outperformed a first read ECG by an experienced cardiologist in detecting both ischemia and heart

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disease. With respect to ischemia, the sensitivity using the admitting, standard 12 lead ECG was 28%, compared to the automated ECV which was 63%. The specificity for ischemia for both devices was about the same at 50%. These numbers are conservative given the fact that 25 patients of 98 were not fully worked up, therefore limiting the number of true positive results. With respect to specificity, the results were generally the same. Since very few initial ECG reads were changed by the cardiologist after risk factors were given, the analysis was only on the initial read.

With respect to the use of the ECV for heart screening the sensitivity was 80% for the ECG and 72% for the ECV, which was not a statistically significant difference. The specificity was 27% for ECG and 66% for the ECV, which was statistically significant.

About half of all ECG reads fell into the "can't tell" category as compared to 19 % for the ECV. In addition, as mentioned about 25% of the cases had a definitive diagnosis of can't tell. Removing those cases would improve the results but we decided to keep this analysis as conservative as possible.

The random probability for being in the (+), (0) or (-) level is 33%. The cardiologist performed matches correctly 41% of the time and the ECV 49% of the time. Using the binomial distribution, the cardiologist's performance was just less than 2 standard deviations from the 33% level, while the ECV's performance was >3 standard deviation from randomness.

For the ECV we were provided with a flow chart on how to calculate the ischemic rank objectively. The prototype device also provides a numerical measure of the likelihood of heart disease. It appears that the ECV measures were consistent enough with the doctors' scales to achieve excellent research results.

One of the sample limitations is the fact that 43 out of 98 patients had ischemia as the cause of their initial complaint, and 83 out of 98 patients had heart disease. This high prevalence of heart disease increases the difficulty of separating the "normals" from the heart patients. It is likely that in a population of largely normal individuals both devices would produce better sensitivities and specificities.

We are not aware in the literature of any automated device that with minimal intervention outperforms an ECG with a trained cardiologist. In that context the results are even more remarkable. While the sample was relatively small, the test of one read using blinded cardiologists is a very demanding real world test and our findings are consistent with similar findings in Russia were the device has been approved..

Based on the above findings, the device merits further testing for both identifying specific heart conditions, and for screening populations.

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Table 1

Very unlikely (1) <15%- (4 or more of the following points)

- Chest pain non-diagnostic of ischemia
- <2 risk factors
- Troponins <0.1
- Nuclear scan normal
- ECG stress test normal
- Coronary angiography <50% vessel stenosis
- Normal ECG or Non-labile ECG abnormality not diagnostic of ST elevation MI

Unlikely (2) 16-49%- (3 of the following points)

- Chest pain non-diagnostic of ischemia
- Troponins <0.1
- Nuclear scan normal
- ECG stress test normal
- Coronary angiography <50% vessel stenosis
- Normal ECG or Non-labile ECG abnormality not diagnostic of ST elevation MI

Can't tell (3) 50%- Incomplete workup with either non specific ECG abnormalities, or left ventricular hypertrophy with strain, or bundle branch block, or paced rhythm, or rapid atrial fibrillation

Likely (4) 51-85%- Troponins <0.1 with 2 of the following:

- Chest pain consistent with ischemia
- Nuclear scan with reversible ischemia
- Abnormal ECG stress test
- Angiography demonstrating >70% stenosis in vessel conforming to area of ischemia
- Segmental or diffuse ST depression on ECG >1mm

Very likely (5) >85%- Transmural MI (convex ST elevation and T or Q waves) or Troponins ≥ 0.1, with any of the following points:

- Chest pain consistent with ischemia
- Nuclear scan with reversible ischemia
- Angiography demonstrating >70% stenosis in vessel conforming to area of ischemia
- Segmental or diffuse ST depression on ECG >1mm