The Omnicardiogram

Study of a Proposed Method for Detecting Coronary Heart Disease in an Asymptomatic Population

By C. Paul Nay, M.D., William B. Kannel, M.D., William P. Castelli, M.D., and Patricia M. McNamara

SUMMARY
A proprietary, commercial technique has been proposed by its inventor as a noninvasive method of detecting subtle electrocardiogram abnormalities, not apparent by conventional means. To study the ability of the omnicardiogram to detect latent coronary heart disease in an asymptomatic population, 200 normal electrocardiograms from the Framingham Study cohort were analyzed by this technique. One-half of these consisted of the last normal electrocardiogram prior to development of clinical coronary heart disease. The omnicardiogram showed a higher degree of sensitivity than did the electrocardiogram to coronary heart disease, indicating an increased risk of myocardial infarction in this group. The low specificity of this technique as indicated by the large percentage of false positives shows that the omnicardiogram is not diagnostic of coronary heart disease in asymptomatic persons with normal electrocardiograms.

Additional Indexing Words:
Electrocardiogram
Coronary risk factors
Myocardial infarction
Framingham Study

Coronary heart disease is the largest single cause of sudden and unanticipated death in the United States. About one-third of the total amount of life insurance death claims paid annually are for this condition. The need for simple, safe and noninvasive means for early detection of persons with, or predisposed to, such a widespread and lethal illness for insurance and prophylactic purposes is self evident.

Epidemiologic studies of population groups have clearly identified many characteristics of persons who have a high coronary heart disease risk potential, but it is still impossible, on an individual basis, to identify persons who in fact will develop overt disease within any given period of time. Reasonably precise estimates for groups of individuals can be obtained by synthesizing the known risk factors into a multiple logistic coronary risk profile.

The electrocardiogram is the only established, noninvasive means of diagnosing coronary heart disease in a living person. However, the majority of persons who subsequently demonstrate severe coronary heart disease clinically or at autopsy have perfectly normal electrocardiograms just prior to the onset of clinical manifestations.

The Omnicardiogram
A recent commercial technique has been proposed to uncover abnormalities in the standard twelve-lead electrocardiogram, not recognizable by ordinary means of interpretation. This technique, called omnicardiography by its proponent, Joseph Levitt, D.Sc., of Data Displays, Incorporated, New York City, consists of mathematically transforming the usual linear form of the electrocardiogram complex into a different, roughly circular shape. Unfortunately, the precise mathematical data are patent protected by the inventor of the process and thereby not known to us. The resulting omnicardiogram is then mechanically superimposed on a previously determined "normal" template which establishes the normal boundaries for the transformed electrocardiogram complex.

The boundaries of normal for the template have been produced from electrocardiograms taken on patients demonstrated to have a normal coronary artery circulation by cardiac catheterization with cinearteriography. The normal omnicardiogram is one in which the transformed electrocardiogram complex falls within a crescent-shaped area enclosed between two different sized circles, tangent at one point (fig. 1).

In performing the omnicardiogram analysis, two separate cardiac cycles are chosen at random from leads I, II, V4, V6 and/or V5 of the standard resting electrocardiogram. These traces are enlarged, digitized and fed to a computer which is programmed to perform the conversion to the nonlinear form. The omnicardiogram plots are automatically drawn...

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Figure 1

Normal template. The shaded area represents the confines of normal for each transformed ECG complex.

and superimposed on the normal template, resulting in two separate omnicardiogram patterns for each of the four or five electrocardiogram leads used (fig. 2).

Method of Scoring

The computer scores each cycle as either "In" (normal) or "Out" (abnormal) recorded as "I" or "O". Rarely, the omnicardiogram trace falls exactly on the border of normal, and in this case the cycle is scored "Borderline" or "B". Three or more Outs in eight to ten cycles is considered a positive (abnormal) omnicardiogram. Less than three cycles scored Out is considered a negative (normal) omnicardiogram. Occasionally, when there is doubt that three cycles are unequivocally abnormal, the omnicardiogram is considered borderline (fig. 3).

Advantages

The obvious advantages of the procedure are that it is noninvasive, it allows a simple positive or negative interpretation, eliminating subjective prejudice and observer variation, and it allows further studies of electrocardiogram files without additional patient visits to a medical facility.

But, most important, if this technique could be shown to be able to detect subtle electrocardiogram abnormalities not apparent by conventional methods, which are both sensitive and specific for coronary heart disease, a valuable new diagnostic tool would be at hand.

Results

Preliminary Study

The decision to test this method in a representative asymptomatic population sample was reached after a preliminary survey was conducted using electrocardiograms from the medical files of the Massachusetts Mutual Life Insurance Company. In this preliminary test, normal electrocardiograms obtained from insurance and employee files on 22 cases known to have developed overt coronary heart disease within five years were sent to the Omnicardiogram Laboratory in New York City for analysis. In 12 of these cases there were also normal exercise electrocardiograms performed using double the standard Master's exercise technique. Of these 22 cases, 15 (68%) were interpreted by the omnicardiogram as abnormal; 4 (18.5%) were normal; and 3 (13.5%) were borderline.

An additional 100 normal electrocardiograms were then sent from employee files, all males and all free, clinically, of coronary heart disease for at least ten years after the recording of the electrocardiogram. From this group of 100, 82 omnicardiograms were normal; 15 were abnormal; and 3 were borderline.

Framingham Study

It was decided on the basis of this encouraging preliminary survey that further study of this procedure with a more representative asymptomatic population group would give a better indication of the true sensitivity and specificity of the omnicardiogram in detecting coronary heart disease. To this end, a joint study-venture was undertaken by the medical department of the Massachusetts Mutual Life Insurance Company and the Heart Disease Epidemiology Study at Framingham, Massachusetts.

Photocopies of 200 normal (by Framingham Study

<table>
<thead>
<tr>
<th>IDENTIF. #</th>
<th>LEAD AND CYCLE</th>
<th>OCG INTERPRETATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>00 I II X4 X5 X6</td>
<td>I - (NORMAL OCG)</td>
</tr>
<tr>
<td>B</td>
<td>00 10 00 II II</td>
<td>0 - (ABNORMAL OCG)</td>
</tr>
</tbody>
</table>

Figure 3

Method of scoring. This represents the OCG findings in two ECGs, A and B. A is a normal OCG since less than three cardiac cycles of ten are scored "O" or abnormal. B is abnormal since five of ten cycles are scored "O."
criteria) electrocardiograms were obtained from the Study files. These electrocardiograms were identified by Framingham file number only. They were then checked for quality of reproduction and forwarded to Dr. Levitt in New York City for omnicardiogram analysis in groups of 25 each. The omnicardiogram analysis reports were returned to the Massachusetts Mutual Life Insurance Company medical department.

One hundred of these electrocardiograms were from members of the Framingham cohort and were their last normal electrocardiograms prior to development of coronary heart disease. The other 100 were normal electrocardiograms obtained from age- and sex-matched controls without clinical evidence of coronary heart disease. The initial results of the omnicardiogram analysis, using the Levitt criteria for scoring, are indicated in table 1.

At this point it was obvious that the omnicardiogram had a rather high degree of sensitivity (76%) when compared to conventional electrocardiography; however, the large number of false positives in the group without coronary heart disease (54%) was disappointing, indicating a low specificity.

An attempt was then made to reread each omnicardiogram manually, using as the criterion for abnormal 50% of cycles out instead of 3 of 8 or 3 of 10; and, when this was done the results were slightly better as indicated in table 2. While this seemed to be somewhat better, we were still left with 46% false positives indicating a diminished sensitivity.

Male versus Female

Recognizing that subtle differences exist in the normal electrocardiogram pattern in males and females, it was decided to separate these two groups. In this study there were 71 males and 29 females in each group of 100, about the same sex ratio for coronary heart disease as in the total Framingham cohort. The results in each sex, using Levitt's omnicardiogram criteria, are given in table 3.

The results for males alone were quite comparable to the over-all findings obtained by considering males and females together. The female group showed a surprising high degree of sensitivity but with even less specificity than found in the men. From these data, it would appear that simply being female is enough to account for an abnormal omnicardiogram.

Hypertension as a Factor

A recent study of 66 male patients with chest pain syndrome, using the omnicardiogram and coronary arteriography suggested that elevated blood pressure was a significant factor in the production of an abnormal omnicardiogram. It also implied that the omnicardiogram would be useful in detection of coronary heart disease in the absence of hypertension. In this series of 100 cases, who subsequently developed clinical coronary heart disease, there were 59 subjects with systolic blood pressure over 140 mm Hg. In the 100 cases without coronary heart disease there were 37 subjects with systolic blood pressure more than 140 mm Hg (table 4).

As indicated in table 4, there is no real difference in the ability of the omnicardiogram to predict coronary heart disease in the absence of hypertension. There was a 10% lower prevalence of omnicardiogram positives in the normotensives.

Cases by Omnicardiogram Either 100% Positive or Negative

By applying the most rigid criteria for normal and abnormal, we abstracted those cases in which the omnicardiogram was 100% normal (all complexes in) and those which were 100% abnormal (all complexes out). Of the 100 electrocardiograms prior to coronary heart disease there were 16 cases that were 100% abnormal and four that were 100% normal by omnicardiogram analysis. Of the 100 electrocardiograms in the cases without coronary heart disease there were nine cases that were 100% abnormal and 12 that were 100% normal on the omnicardiogram analysis (table 5).

In this instance, again, a false-negative ratio of 20% in the cases prior to coronary heart disease and a false-positive ratio of 43% in the cases without coronary heart disease was obtained. This would indicate that consistency of positivity or negativity, as indicated by the number of complexes per electrocardiogram scored In or Out, had little bearing on the ability of the omnicardiogram to predict overt coronary heart disease.

Table 1

<table>
<thead>
<tr>
<th>Automated OCG Analysis of Cases Submitted for Study</th>
<th>Positive</th>
<th>Negative</th>
<th>Borderline</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 cases*</td>
<td>76</td>
<td>21</td>
<td>3</td>
</tr>
<tr>
<td>100 controls</td>
<td>54</td>
<td>43</td>
<td>3</td>
</tr>
</tbody>
</table>

*Last normal ECG prior to coronary heart disease.

Table 2

<table>
<thead>
<tr>
<th>Manual Analysis of OCGs Using Stricter Criteria for Abnormal</th>
<th>Positive</th>
<th>Negative</th>
<th>Borderline</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 cases*</td>
<td>63</td>
<td>37</td>
<td>0</td>
</tr>
<tr>
<td>100 controls</td>
<td>46</td>
<td>34</td>
<td>0</td>
</tr>
</tbody>
</table>

*Last normal ECG prior to coronary heart disease.
Comparison of Omnicardiogram with Critical ECG Rereading

The 41 electrocardiograms that were either 100% abnormal or 100% normal were given to four experienced electrocardiogram readers in the medical department of the Massachusetts Mutual Life Insurance Company as complete unknowns. They were told only that a number of them were the last normal electrocardiograms prior to clinical episodes of coronary heart disease. They were asked to read the electrocardiograms in a very critical fashion to try to identify any characteristics which would point to the individuals who subsequently developed coronary heart disease. All others were to be read as normal.

The results of this study are summarized in Table 6 and it is obvious that by reading electrocardiograms in a critical way they were unable to predict from minor changes which electrocardiograms indicated impending myocardial infarction. They were also unable to anticipate the results to be expected from the omnicardiogram in these cases.

In this small sample, the omnicardiogram proved to be more sensitive as an indicator of coronary heart disease than the findings of a conventional electrocardiogram interpretation; however, once again the lack of specificity was exhibited.

Discussion

Assessment of the usefulness of the electrocardiogram for the indication of coronary heart disease is a complex matter. Other than electrocardiogram findings of myocardial infarction itself, no pathognomonic electrocardiogram finding is terribly efficient when examined in the light of false positives and false negatives. Even electrocardiographic evidence of myocardial infarction itself would not show up well by that criterion.

The design of the study was to determine whether the omnicardiogram had any unique capabilities for uncovering preclinical coronary disease not apparent from a competent scrutiny of the standard electrocardiogram. It is well recognized that certain electrocardiographic abnormalities may be hallmarks of preclinical ischemic myocardiopathy, especially electrocardiogram-left ventricular hypertrophy and intraventricular block. While not pathognomonic, these electrocardiographic abnormalities (and, to a lesser extent, nonspecific ST-T wave abnormalities) have been found to be associated with a marked excess rate of overt coronary heart disease. In the Framingham cohort, electrocardiogram-left ventricular hypertrophy is associated with a marked (tenfold) increased risk of lethal coronary attacks which persists at threefold after adjustment for coexisting hypertension. This finding carries a risk of coronary mortality every bit as great as the risk associated with electrocardiographic evidence of myocardial infarction. In persons with atherogenic traits — such as hyperlipidemia, hypertension and impaired glucose tolerance — the appearance of these electrocardiographic abnormalities can reasonably be taken to indicate the existence of ischemic myocardiopathy.

However, not all persons who go on to develop overt coronary heart disease exhibit these electrocardiographic abnormalities and, in fact, many have a normal conventional electrocardiogram on the examination preceding their coronary attack (i.e., within

Table 4

<table>
<thead>
<tr>
<th>OCG Analysis of Total Cases to Normotensives</th>
<th>Positive</th>
<th>Negative</th>
<th>Borderline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive cases*</td>
<td>76%</td>
<td>21%</td>
<td>3%</td>
</tr>
<tr>
<td>Normotensives</td>
<td>66%</td>
<td>32%</td>
<td>2%</td>
</tr>
<tr>
<td>Males only</td>
<td>75%</td>
<td>25%</td>
<td>0%</td>
</tr>
<tr>
<td>Positive cases*</td>
<td>54%</td>
<td>43%</td>
<td>3%</td>
</tr>
<tr>
<td>Normotensives</td>
<td>44%</td>
<td>54%</td>
<td>2%</td>
</tr>
<tr>
<td>Males only</td>
<td>38%</td>
<td>60%</td>
<td>2%</td>
</tr>
</tbody>
</table>

*Last normal ECG prior to coronary heart disease.

Table 5

<table>
<thead>
<tr>
<th>OCG Analysis of Cases with All Complexes Scored Either In or Out</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% Positive (O)</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>20 cases*</td>
</tr>
<tr>
<td>21 controls</td>
</tr>
</tbody>
</table>

*Last normal ECG prior to coronary heart disease.

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Table 3

<table>
<thead>
<tr>
<th>OCG Analysis of Cases Separated by Sex</th>
<th>Positive</th>
<th>Male</th>
<th>Female</th>
<th>Negative</th>
<th>Male</th>
<th>Female</th>
<th>Borderline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100 cases*</td>
<td>50 (70%)</td>
<td>26</td>
<td>90%</td>
<td>19 (27%)</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Controls*</td>
<td>34 (48%)</td>
<td>20</td>
<td>70%</td>
<td>35 (49%)</td>
<td>8</td>
<td>28%</td>
<td>2</td>
</tr>
</tbody>
</table>

*71 males and 29 females in each group.
Critical Rereading of Electrocardiograms by OCG as 100% Abnormal or 100% Normal.

<table>
<thead>
<tr>
<th></th>
<th>Abnormal</th>
<th>Normal</th>
<th>Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 cases*</td>
<td>9</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>21 controls</td>
<td>6</td>
<td>14</td>
<td>1</td>
</tr>
</tbody>
</table>

*Last normal ECG prior to coronary heart disease.

one year on the average). It is not illogical to postulate that these ostensibly "normal" electrocardiograms differ in some respects from those of persons who were free of impending infarction. It was claimed by the developers of the omnicardiogram that this was the case. Examination of this hypothesis by comparing the omnicardiogram findings in the antecedent normal electrocardiogram tracings of those who went on to myocardial infarction versus those who remained free of one, revealed that there were, indeed, significantly more positives (76%) than negatives (21%) in the cases than in the controls (54% and 43%, respectively). But the fact that 54% of those who remained free of myocardial infarction were also positive indicates a low specificity to go along with the high sensitivity.

While a small percentage of false positives is not unusual in any diagnostic test used in a general population study, a false positive test for such a serious and lethal condition as coronary heart disease in asymptomatic persons has traumatic emotional and financial implications.

In our opinion, the omnicardiogram does not have any unique capability to diagnose coronary heart disease in a general population group not possessed by the ordinary twelve-lead electrocardiogram. It may, however, be useful as a screening procedure to identify high coronary-risk subjects. This we have not tested, but we feel that an abnormal omnicardiogram is probably associated with an increased probability of myocardial infarction (estimated at twofold). Whether this is independent of other risk factors, elevated blood pressure in particular, is hard to say and would require further prospective epidemiologic study in a general population sample.

Acknowledgment

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References

The omnicardiogram Study of a proposed method for detecting coronary heart disease in an asymptomatic population.

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