Computerized 2-lead Resting Electrocardiogram Analysis for the Diagnosis of Coronary Artery Disease

Medical Policy

Section: Medicine

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Description

Computerized 2-lead resting electrocardiogram analysis (e.g., multifunction cardiogram) is a computerized analysis of a 2-lead resting electrocardiogram that has been proposed for use as a diagnostic test for coronary artery disease (CAD). This policy will review the evidence on accuracy and clinical utility of the multifunction cardiogram.

The standard 12-lead resting electrocardiogram (ECG) has limited diagnostic accuracy in the detection of coronary artery disease (CAD). Because of its limited accuracy, the resting ECG has only a limited role in the diagnosis of chronic CAD. Stress testing, either at rest or with exercise, combined with single-photon emission computed tomography (SPECT) or echocardiographic imaging, is the most common initial test in the diagnostic work-up of chronic CAD. Sensitivities and specificities for stress testing vary but generally fall in the 75-90% range. Cardiac angiography is the gold standard for diagnosing CAD and is used in situations in which CAD needs to be confirmed following stress testing.

The multifunction cardiogram is intended to improve on the performance of the standard ECG for diagnosing CAD. The study device records a 2-lead ECG tracing for 82 seconds, using leads II and V5 together with proprietary hardware and software. The analog ECG tracing is then amplified, digitized, down-sampled to a rate of 100 Hz, and encrypted for digital transmission. The digitized information is transmitted to a central server for further analysis. At the central server, the tracings undergo a series of mathematical transformations and signal averaging. There are 6 mathematical transformations included: power spectrum, coherence, phase angle shift, impulse response, cross-correlation, and transfer function. Following these transformations, the patterns found in the tracing are compared to a large reference database collected by the manufacturer. A severity score is generated, indicating the likelihood that CAD is present. The severity score ranges from 0-20, with a score of 4.0 suggested as the cutoff for the presence of clinically significant CAD.

Regulatory Status

There is at least one commercially available multifunction cardiogram, the 3DMP device, manufactured by Premier Heart™, LLC (Port Washington, NY). In April 2003, the 3DMP device...
was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in ECG analysis.

**Related Policies**

2.02.04 Signal-Averaged Electrocardiography

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**Policy**

Computerized 2-lead resting electrocardiogram analysis (e.g., multifunction cardiogram) is considered investigational for diagnosing coronary artery disease.

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**Policy Guidelines**

There is a CPT category III code specific to this algorithmic analysis:

0206T: Algorithmic analysis, remote, of electrocardiographic-derived data with computer probability assessment, including report.

An appropriate CPT code from the 93000-93010 range would be reported separately for a 12-lead ECG if performed.

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**Rationale**

This policy was created with literature review in November 2010. The policy has been updated with a literature review using MEDLINE, with the last update covering the period of September 2010 through September 2011.

**Literature Review**

Articles were retrieved that included primary data on the accuracy, predictive value, or clinical utility of multifunction cardiogram for the diagnosis of CAD. The available evidence on the accuracy of multifunction cardiogram consists of several cross-sectional studies that evaluate the performance characteristics of the test in patients with suspected CAD, using coronary angiography as the gold standard.

**Review of Evidence**

Grube et al. (1) is the largest study on the accuracy of multifunction cardiogram for diagnosing coronary artery disease (CAD). The study population consisted of 562 patients with no prior history of coronary revascularization who were scheduled to receive coronary angiography over a 1-year period at one institution in Germany. All patients underwent multifunction cardiogram and coronary angiography, with results of each modality interpreted independently and blinded to the results of the other test(s). A total of 139 (24.7% of total) patients were excluded from analysis, 17 because of poor-quality ECG tracing and 122 because full risk-factor data were not available, leaving 423 patients in the final analysis. Obstructive coronary disease, defined as at
least 1 stenosis greater than 70%, was diagnosed in 47.5% of patients (201/423). The reported sensitivity and specificity of multifunction cardiogram were 89.1% and 81.1%, respectively. The positive predictive value (PPV) was 79.4%, and the negative predictive value (NPV) was 90.0%. The calculated area under the curve by receiver operating characteristic (ROC) analysis was 84.3% (95% confidence interval [CI]: 80.2-88.4%).

Grube et al. (2) published a companion article on 213 patients scheduled for angiography who had previously undergone revascularization. The protocol and analysis for this study was identical to the first article, except for the presence or absence of prior revascularization. A total of 41 patients were excluded from analysis, leaving a final sample of 172 patients. In this sample, obstructive coronary disease, defined as at least 1 stenosis greater than 70%, was diagnosed in 32% of patients (55/172). The estimated sensitivity and specificity were 90.9% and 88.9%, respectively. The PPV was 62.7% and the NPV was 97.8%.

Weiss et al. (3) included 200 ambulatory patients who were scheduled to undergo coronary angiography at one institution in New York. All patients underwent multifunction cardiogram; however, 64 patients (32% of total) had ECG tracings of insufficient quality and were excluded from analysis, leaving 136 patients in the final sample. The authors did not state that the test results were interpreted in an independent and blinded manner. Obstructive coronary disease, defined as at least 1 stenosis greater than 60%, was diagnosed in 57.4% of patients (78/136). The reported sensitivity and specificity of multifunction cardiogram were 89.1% and 81.1%, respectively. The PPV was 79.4%, and the NPV was 90.0%. The calculated area under the curve by ROC analysis was not reported.

Hosokawa et al. (4) enrolled 222 patients who were scheduled to receive coronary angiography over an approximately 6-month period from 5 medical centers in Asia. All patients underwent multifunction cardiogram and coronary angiography, with results of each modality interpreted independently and blinded to the results of the other test(s). A total of 33 patients (14.9% of total) were excluded from analysis, 3 because of poor-quality ECG tracing and 30 because coronary angiograms were not available for interpretation, leaving 189 patients in the final analysis. Obstructive coronary disease, defined as at least 1 stenosis greater than 60%, was diagnosed in 40.7% of patients (77/189). The reported sensitivity and specificity of multifunction cardiogram were 94.8% and 86.6%, respectively. The PPV was 78.4% and the NPV was 97.1%. The calculated area under the curve by ROC analysis was 91.4% (95% CI: 86.8-96.1%).

A meta-analysis of these studies was published by Strobeck et al. (5) This combined analysis included 1,072 patients from the 4 studies described above. Hemodynamically significant CAD was diagnosed in 43.4% of patients (467/1,072). The calculated sensitivity and specificity were 91.2% and 84.6%, respectively. The PPV was 78% and the NPV 94%. The area under the curve by ROC analysis was 88.1% (95% CI: 86–90.3%). Using a severity score of 4.0 as the cutoff for a positive test, the likelihood ratio positive was 5.9, and the likelihood ratio negative was 0.10. There were only minor differences between centers in the sensitivity and specificity; the statistical significance of these differences was not tested.

For the update covering the period of November 2010 through November 2011, there were no relevant citations identified through MEDLINE.

**Practice Guidelines and Position Statements**

None
Summary

A total of 4 studies from 3 clinical series report on the accuracy of multifunction cardiogram for diagnosing CAD. These studies report sensitivities and specificities that are in the high range, with sensitivity ranging from 89.1–94.8% and specificity in the range of 81.1–88.9%. However, these studies have several limitations that limit their internal and external validity. In all of the studies, the population is a convenience sample of patients who were already scheduled for angiography. These patient populations are thus subject to a referral or “work-up” bias in that the population of patients that might be considered for the multifunction cardiogram in clinical practice is not the same population that is being referred for angiography. Also, the number of patients enrolled but not included in the analysis was relatively high, ranging from 14.9–32% of the total number of patients enrolled. This high rate of exclusion from analysis leaves the potential for a biased estimate of the sensitivity and specificity of the test. Finally, in one of the 3 series, the angiogram and multifunction cardiogram were not interpreted in an independent, blinded manner, thus potentially leading to additional bias.

There are no studies that attempt to determine the clinical utility of the multifunction cardiogram. Even if this test does have good accuracy for diagnosing CAD, its role in clinical practice would still need to be determined. Use of the multifunction cardiogram to screen for CAD would be a departure from usual practice, as screening for CAD has not been shown to improve outcomes. In the non-acute setting, the traditional resting ECG has a limited role in diagnosing CAD. The most common method for diagnosing CAD for this purpose is stress testing. There is no evidence comparing the accuracy of multifunction cardiogram to stress testing. The comparison to angiography, while useful from a research perspective, has a limited role in determining clinical utility given that multifunction cardiogram would not be used as a replacement for angiography.

Because of these limitations, the evidence is not sufficient to determine the impact of the computerized 2-lead resting electrocardiogram analysis (e.g., multifunction cardiogram) on health outcomes, and therefore the use of this device is considered investigational.

Medicare National Coverage Determination

None

References:


5. Strobeck JE, Shen JT, Singh B et al. Comparison of two-lead, computerized, resting ECG signal analysis device, the MultiFunction-CardioGram, or MCG (a.k.a. 3DMP), to quantitative coronary angiography for the detection of relevant coronary artery stenosis (>70%) – a meta-analysis of all published trials performed and analyzed in the US. Int J Med Sci 2009; 6(4):143-55.

Codes

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Multifunction Cardiogram