Kansas City

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Electrocardiographic Body Surface Mapping

Policy Number: 2.02.23
Origination: 10/2009
Last Review: 10/2014
Next Review: 4/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for electrocardiography body surface mapping (BSM). This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Electrocardiographic body surface mapping is considered **investigational** for the diagnosis or management of cardiac disorders including acute coronary syndrome.

Description of Procedure or Service

Electrocardiographic body surface mapping (BSM) is an electrocardiographic (ECG) technique that uses multiple (generally 80 or more) electrocardiography leads to detect cardiac electrical activity. It is suggested that the use of multiple leads may result in improved diagnostic accuracy compared to the standard 12-lead ECG. No body surface mapping ECG devices with 80 or more leads are currently commercially available in the United States.

A number of studies have examined the association between electrocardiographic body surface mapping and acute myocardial infarction, but no prospective trials using body surface mapping to guide treatment have been conducted. Results of published studies have been variable and an Agency for Healthcare Research and Quality (AHRQ) review did not find statistically significant differences in the diagnostic accuracy of BSM and 12-lead ECG. Under ideal conditions, it is possible that BSM has a higher sensitivity than 12-lead ECG alone for acute coronary events. However, the data also suggest that the specificity may be lower, highlighting concerns regarding false-positive results. In clinical practice, patients with symptoms suspicious for ischemia are not diagnosed with 12-lead ECG alone but in combination with clinical presentation and serial cardiac enzymes. There is no evidence demonstrating that electrocardiographic BSM leads to changes in management that improve health outcomes. Therefore, the clinical utility of the body surface mapping technique, both in terms of benefits and risks and burdens, has not been demonstrated. Due to insufficient evidence that diagnostic accuracy is improved with BSM and the lack of evidence on clinical utility, this technique is considered investigational.

Background

Electrocardiographic body surface mapping (BSM) consists of an 80-lead disposable electrode array in the form of a vest that includes a conducting gel that is applied to the patient's chest and back. The vest can be applied in less than 5 minutes. This system displays clinical data in three forms; a colorimetric 3-D torso image, an 80-lead single beat view, and the 12-lead ECG. The colorimetric torso images are said to allow the practitioner to rapidly scan the heart for significant abnormalities.

Currently, in patients presenting to the emergency department with symptoms suggestive of myocardial ischemia, a standard 12-lead ECG is obtained. In the presence of ST segment elevation on the ECG,

personnel are activated to respond in a timely manner to open a presumed coronary artery occlusion, either by mechanical means though balloon angioplasty, or medically through intravenous thrombolytic drugs. The 12-lead ECG has a specificity of 94%, leading to relatively few erroneous interventions. However, the sensitivity is about 50%. These patients may be further stratified by scoring systems and time-sensitive cardiac enzymes, which may require up to 24 hours of monitored observation.

BSM is being considered as a method to assist in the rapid identification of patients who would benefit from earlier coronary artery intervention than currently achieved utilizing current standard of care. The negative predictive value of the test, which has the potential to identify patients who do not require further evaluation with serial cardiac enzymes and clinical observation, is not currently receiving attention as a research topic.

Regulatory Status
In March 2002, the device "PRIME ECG®" (Verathon, Bothell, WA) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that the device was substantially equivalent to existing devices for use in recording of ECG signals on the body surface. As of July 2014, neither the PRIME ECG device nor its successor, the Heartscape™ 3D ECG System are being marketed in the United States. Product code: DPS.

Note: This policy only addresses use of this technique in the diagnosis or management of acute myocardial infarction or acute coronary syndrome and not the diagnosis or management of coronary artery disease (CAD).

Rationale

This policy was originally created in 2007 and was regularly updated with searches of the MEDLINE database. The most recent literature search was performed through July 21, 2014. Following is a summary of the key literature to date:

Assessment of a diagnostic technology focuses on the following three parameters: 1) technical performance; 2) diagnostic accuracy (sensitivity, specificity, positive and negative predictive value) in relevant clinical populations; and 3) clinical utility, i.e., demonstration that the diagnostic information can be used to improve patient outcomes.

Technical Performance

The investigation of additional leads in electrocardiography and body surface mapping (BSM) is not new. Patterns of electric potentials in normal subjects have been established, and the significance of abnormal signals has been explored over past decades.

A 2006 publication describes the use of the 80-lead technique in the evaluation of patients with chest pain in the emergency department. 3 The authors comment that use of this approach has been hampered by slow acquisition time and the complexity of interpretation but that technologic advances are overcoming these limitations. However, they add that the future of BSM in emergency medicine is unclear and that more research is needed to define its benefits and limitations.

In 2007, Lefebvre and Hoekstra described the improvements in technical performance and ease of use in recent modifications to BSM technologies. A standardized vest improves lead placement, and changes to software direct clinicians' attention to locations on the body mapping that may be significant, possibly reducing the amount of training needed.

Diagnostic Accuracy

For patients with suspected ischemia, does electrocardiographic body surface mapping (BSM) improve the accuracy of diagnosis for acute myocardial infarction (AMI) and/or acute coronary syndrome (ACS), compared to standard 12-lead ECG?

In June 2012, the Agency for Healthcare Research and Quality (AHRQ) published a technology assessment on the diagnostic utility of electrocardiographic (ECG)-based signal analysis technologies for patients at low to intermediate risk of coronary artery disease (CAD). 5 Findings of the updated review were summarized in a 2013 publication by Leisy and colleagues. 6 The AHRQ literature review focused on studies evaluating U.S. Food and Drug Administration (FDA)-approved or cleared devices that are commercially available in the United States and can feasibly be used in most medical facilities. The 2012 assessment combined data from 10 studies on the PRIME ECG that involved patients with chest pain. Six of these were published by the same research group in Northern Ireland. The studies from Northern Ireland may have included a patient population that was higher risk than average, since some patients were treated in mobile cardiac care centers. Using a bivariate, random-effects model, the summary estimate for sensitivity was 71.1% (95% confidence interval [CI]: 45.6-87.8%), and for specificity was 90.2% (95% CI: 83.2-94.4%). The summary estimate for the positive likelihood ratio was 6.3 (95% CI: 3.3-12.1), and the summary negative likelihood ratio negative was 0.30 (95% CI: 0.16-0.56). These combined summary estimates were compared to estimates compiled from 10 studies reporting 12-lead ECG performance. (Eight of these 10 studies were also included in the analysis of PRIME ECG sensitivity, above). The pooled sensitivity was 43.1% (95% CI: 25.8-62.2%) and the pooled specificity was 94.4% (95% CI: 88.4-97.4%). The difference in sensitivity between the PRIME ECG and the 12-lead ECG were not significantly different, $p<0.078$. In addition, differences in specificity did not differ significantly, $p<0.234$.

Many of the individual studies have shown higher sensitivity for BSM and some have shown lower specificity. For example, in a retrospective study conducted at 4 centers, Ornato and colleagues reviewed the cardiac enzyme-confirmed cases of acute myocardial infarction (MI) against results of 12-lead ECG and BSM. 7 Due to a change in standard practice during the study, AMI was defined by either elevated troponin or heart-specific creatinine kinase (CK-MB). Of 647 patients, 58 (8.9%) were not analyzed due to lack of enzyme data. Sensitivity comparison between BSM and 12-lead ECG in the CK-MB group favored BSM (100% vs. 72.7%, respectively, $p=0.031$; $n=364$), and also in the troponin group (92.9% vs. 60.7%, respectively, $p=0.022$; $n=225$). Specificity for BSM was not significantly different from 12-lead ECG in either group (96.5% vs. 97.1 and 94.9 vs. 96.4, both respectively).

A 2013 study from Northern Ireland retrospectively reported on 645 consecutive patients with sudden out-of-hospital cardiac arrest initially attended by a mobile cardiac care unit. 8 Eighty patients survived initial resuscitation and 59 of these underwent ECG BSM and 12-lead ECG analysis by the physician leading the mobile unit. Twenty-four of the patients died pre-hospital and 35 were admitted to the hospital and underwent coronary angiography. Twenty-six of the 35 patients (75%) who received angiography had acute occlusion of a main coronary artery. Electrocardiographic BSM post-resuscitation showed ST-segment elevation in 23 of 35 patients (66%) and had had 88% sensitivity and 100% specificity for diagnosing acute coronary occlusion in these 35 patients. In contrast, the combination of either ST elevation myocardial infarction (STEMI) or ST segment depression on 12-lead ECG had a sensitivity of 46% and specificity of 100% for diagnosing acute coronary occlusion. A 2008 retrospective study from Northern Ireland included 755 patients presenting to the emergency department, mobile cardiac care, or in hospital with symptoms of ischemic chest pain. 9 Each patient's clinical course was guided by standard American College of Cardiology 12-lead ST segment criteria and subsequent cardiac enzymes, if electrocardiographically negative. A cardiologist blinded to the clinical details measured BSM retrospectively. AMI was defined by elevated cardiac troponin levels. The standard 12-lead electrocardiograph demonstrated a sensitivity of 45% and a specificity of 92% for detecting troponin-positive ischemia. When non-ST electrographic changes were permitted as part of the criteria for AMI, sensitivity increased (51% to 68%), but specificity decreased (71% to 89%). In this study, BSM performed with a sensitivity of 76% and specificity of 92%.

Fermann and colleagues found very different performance characteristics of BSM in comparison to 12-lead ECG from other studies. A convenience sample of 150 patients with chest pain presenting to the emergency department had BSM measured within 30 minutes of the standard ECG. Emergency physicians, who had been trained in BSM, interpreted both the BSM and the ECGs at the time of presentation. Both were stored electronically for review by a BSM expert over read; after the study had

ended, a convenience sample of 135 BSMs were over read. Of 43 patients, 10 (23.3%) judged to have normal BSM by the emergency physicians were found to have abnormal findings or frank infarction by the expert interpreter. Overall correlation between the emergency physicians and expert reviewer was only fair (correlation coefficient κ=0.627; 95% CI: 0.530-0.724). Sensitivity of both standard ECG and BSM were low at 10.5 (95% CI: 1.8-34.5) and 15.8 (95% CI: 4.2-40.5), respectively. This low sensitivity likely reflects the spectrum of patients in the study. Specificities were also comparable between the 2 groups at 90.1 (95% CI: 83.3-94.4) and 86.3 (95% CI: 78.9-91.4), respectively.

In 2010, O'Neil and colleagues published results from a secondary analysis of the Optimal Cardiovascular Diagnostic Evaluation Enabling Faster Treatment of Myocardial Infarction (OCCULT-MI) trial. 11 A multicenter (10-site), prospective, observational study, the OCCULT-MI trial enrolled 1,830 subjects presenting to the emergency department with moderate- to high-risk chest pain. Patients were simultaneously tested with 12-lead and 80-lead ECGs, with clinicians able to access the 12-lead results only. The patients were treated by standard care based on 12-lead result or clinical suspicion. Off-site clinicians, who were not involved in the patients' care, reviewed the 80-lead ECG and made a diagnostic determination, validated through multiple reviewers.

In this publication, 12-lead ECG was compared to 80-lead ECG mapping for detecting high-risk ECG abnormalities. Patients diagnosed with STEMI by 12-lead ECG (n=91), and patients with missing data (n=255) were excluded from the analysis on specificity and sensitivity. When detecting myocardial infarction (MI) and acute coronary syndrome (ACS), the 80-lead ECG mapping sensitivity was significantly higher than the 12-lead ECG for MI (19.4% vs. 10.7%, p=0.0014) and for ACS (12.3% vs. 7.1%, p=0.0025). The authors attributed these low sensitivity rates to the exclusion of STEMI patients in this analysis. Specificity for the 80-lead ECG mapping was significantly lower than the 12-lead ECG for MI (93.9% vs. 96.4%, p=0.0005) and for ACS (93.7% vs. 96.4%, p=0.0005). Positive and negative predictive values and negative and positive likelihood ratios were not statistically different between the 12-lead and 80-lead groups. The 80-lead ECG mapping resulted in the identification of 18 additional MI patients and 21 additional ACS patients who could potentially have benefited from more aggressive treatment. However, the 80-lead ECG mapping results were not incorporated into treatment decision making, and thus, no conclusions can be made from this study on the impact of this technology on patient outcomes. Also, the authors did not explore the impact of decreased specificity, and increased false-positive rates, on patient outcomes. Other limitations of this study include lack of enrollment of low-risk emergency department patients and the lack of power to detect differences in ACS diagnosis.

In 2012, Daly et al. also compared 12-lead ECG to 80-lead ECG mapping in a retrospective review of 2,810 consecutive patients admitted with ischemic-type chest pain. 12 All patients included in the study had coronary angiography and cardiac troponin levels during admission. The analysis was confined to patients with significant left main stem (LMS) coronary stenosis (greater than 70%), which was found in 116 (4.1%) patients. Of these 116 patients with LMS coronary stenosis, 92 (79%) had AMI, diagnosed when cardiac troponin levels were 0.03 µg/L or higher. BSM was found to be more sensitive for diagnosing AMI in patients with LMS coronary stenosis compared to 12-lead ECG. BSM detected STEMI in 85/92 patients for an 88% sensitivity, 83% specificity, 95% positive predictive value, and 65% negative predictive value. Twelve-lead ECG (using Minnesota 9-2 criteria) detected STEMI in 13 patients (11%), for a 12% sensitivity and 92% specificity. The c-statistic for the diagnosis of AMI in patients with LMS stenosis by 12-lead ECG was 0.580 (95% CI: 0.460–0.701, p=0.088) compared to 0.800 [95% CI: 0.720–0.881; p<0.001] using physician interpretation of BSM or 0.792 (95% CI: 0.690–0.894, p<0.001) using the "PRIME ECG®" algorithm.

A small 2014 study from the UK evaluated the 80-lead ECG mapping system (PRME-ECG) along with internally-developed software to create a BSM Delta map. 13 The study included 49 patients who presented to the emergency department with cardiac-sounding chest pain. Using the final diagnosis of ACS as the reference standard, the sensitivity and specificity of the BSM Delta map for diagnosing ACS were 71% (22/31) and 78%,(14/18) respectively. This compares to a sensitivity of 67% (21/31) and specificity of 55% (10/18) when 12-lead ECG was used. The authors did not analyze whether differences in diagnostic accuracy were statistically significant. Moreover, the BSM Delta mapping

software, an important part of the diagnostic process in this study, which may not be available outside of the European research setting.

Section summary

Numerous published studies compare the accuracy of BSM with standard 12-lead electrocardiography for the diagnosis of ACS. These studies are mostly retrospective and did not enroll the ideal clinical populations, i.e., consecutive patients presenting with clinical signs/symptoms of ischemia. They also tended to compare the accuracy of BSM alone with 12-lead EKG alone. This is less clinically relevant because 12-lead EKG is not used alone to diagnose ACS, but rather is combined with the clinical presentation and results of cardiac enzymes.

The 2012 AHRQ technology assessment did not find a statistically significant difference in the diagnostic accuracy of BSM compared to a standard 12-lead EKG. Among the individual studies, the difference in sensitivity is variable, and there is uncertainty around whether there is higher sensitivity that is clinically significant. The specificity of BSM may be lower than 12-lead EKG, as some studies report lower specificity but others do not. Because of the uncertainty in the sensitivity and specificity in the available studies, it is not possible to estimate the tradeoff between additional cases of ACS detected and false-positive results leading to further unnecessary testing. Further prospective studies are needed that include relevant clinical populations and that compare the incremental value of BMS when used as part of the overall diagnostic workup for ACS.

Clinical Utility

Does electrocardiographic body surface mapping lead to changes in management that improve health outcomes?

The 2012 AHRQ assessment, noted above, 5 did not identify any studies in patients at low to intermediate risk of CAD that provided evidence on the question of whether findings from ECG-based technologies other than the standard 12-lead ECG had an impact on patient management decisions or health outcomes. One study, the OCCULT-MI trial, was identified that addressed the issue of patient outcomes in a population of patients at moderate to high risk for CAD. This study is discussed above in the section on diagnostic accuracy. Primary results of the OCCULT-MI trial were published in 2009 by Hoekstra and colleagues. 11,14 Primary outcome in the OCCULT-MI trial was door-to-sheath time in 12-lead STEMI patients versus door-to-sheath time in patients with ST elevations noted on 80-lead testing. Secondary outcomes were clinical outcomes at 30 days and angiographic data. Of the 1,830 subjects, 91 had a discharge diagnosis of STEMI, 84 of whom underwent cardiac catheterization with a mean door-to-sheath time of 54 minutes. Twenty-five subjects (1.4% of the study population) met criteria for ST elevation in the 80-lead alone, 14 of whom underwent cardiac catheterization with a mean door-to-sheath time of 1,002 minutes (estimated treatment difference: 881; 95% CI: 181 to 1,079 minutes, respectively). Neither 30-day clinical outcomes, nor adverse events, differed significantly in the identified at-risk groups. These 25 patients were in addition to the 91 STEMI patients identified on 12-lead, leading the authors to conclude that the additional leads identified 27.5% more acute MI patients than 12-lead alone (25/91).

An editorial accompanying the publication of the OCCULT-MI trial acknowledged the limitation of 12-lead ECG in identifying patients with acute MI. However, a distinction was made between those patients for whom it is well established that early intervention is beneficial (i.e., STEMI on standard 12-lead ECG) and those for whom BSM is positive but 12-lead is not. It is not known whether these patients benefit from early intervention. The editorial suggested that the patients identified thusly are more similar to the non-ST elevation myocardial infarction (NSTEMI) patients based on peak troponin levels found in the Hoekstra et al. study (12) and that identification of these patients should not lead to a change in treatment.

Section summary

There are no studies that demonstrate how BSM can be used to change clinical management in ways that improve health outcomes. Indirect evidence suggests that BSM might be used in a subset of patients presenting with suspected ACS to reduce the time to diagnosis and thereby provide revascularization more expediently. Whether this strategy improves outcomes has yet to be demonstrated. In order to demonstrate clinical utility, the ideal study design is a randomized controlled trial in which patients are randomized to BSM or standard 12-lead EKG, and patients are followed for changes in management and clinical outcomes.

Summary

Electrocardiographic (ECG) body surface mapping (BSM) is an electrocardiographic technique that uses multiple (generally 80 or more) electrocardiography leads to detect cardiac electrical activity. The use of multiple leads may result in improved diagnostic accuracy of acute myocardial infarction or acute coronary syndrome, compared to that of the standard 12-lead ECG. No body surface mapping ECG devices with 80 or more leads are currently commercially available in the United States.

A number of studies have examined the association between electrocardiographic body surface mapping and acute myocardial infarction, but no prospective trials using body surface mapping to guide treatment have been conducted. Results of published studies have been variable and an Agency for Healthcare Research and Quality (AHRQ) review did not find statistically significant differences in the diagnostic accuracy of BSM and 12-lead ECG. Under ideal conditions, it is possible that BSM has a higher sensitivity than 12-lead ECG alone for acute coronary events. However, the data also suggest that the specificity may be lower, highlighting concerns regarding false-positive results. In clinical practice, patients with symptoms suspicious for ischemia are not diagnosed with 12-lead ECG alone but in combination with clinical presentation and serial cardiac enzymes. There is no evidence demonstrating that electrocardiographic BSM leads to changes in management that improve health outcomes. Therefore, the clinical utility of the body surface mapping technique, both in terms of benefits and risks and burdens, has not been demonstrated. Due to insufficient evidence that diagnostic accuracy is improved with BSM and the lack of evidence on clinical utility, this technique is considered investigational.

Practice Guidelines and Position Statements

The American College of Cardiology Foundation guidelines for electrocardiography standardization and interpretation recognize that while the studies of body surface maps from large electrode arrays have provided useful information about localization of ECG information on the thorax, at this time their complexity precludes their use as a substitute for the standard 12-lead ECG for routine recording purposes.

U.S. Preventive Services Task Force Recommendations

The use of 80-lead body surface mapping ECG is not a preventive service.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References

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Billing Coding/Physician Documentation Information

0178T Electrocardiogram, 64 leads or greater, with graphic presentation and analysis; with interpretation and report

0179T Electrocardiogram, 64 leads or greater, with graphic presentation and analysis; tracing and graphics only, without interpretation and report

0180T Electrocardiogram, 64 leads or greater, with graphic presentation and analysis;

interpretation and report only

0206T Computerized database analysis of multiple cycles of digitized cardiac electrical data from two or more ECG leads, including transmission to a remote center, application of multiple nonlinear mathematical transformations, with coronary artery obstruction severity assessment

Additional Policy Key Words

N/A

Policy Implementation/Update Information

10/1/09	New policy; considered investigational.
1/1/10	Coding updated.
4/1/10	No policy statement changes.
10/1/10	No policy statement changes.
4/1/11	No policy statement changes.
10/1/11	No policy statement changes.
4/1/12	No policy statement changes.
10/1/12	No policy statement changes.
4/1/13	No policy statement changes.
10/1/13	No policy statement changes.
4/1/14	No policy statement changes.
10/1/14	No policy statement changes.