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MP 2.02.08 Noninvasive Measurements of Cardiac Hemodynamics in the Ambulatory Care-Outpatient Setting

Medical Policy

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Description
In the intensive care unit, hemodynamic monitoring using a pulmonary artery catheter (also referred to as right heart catheterization) is commonly used to provide prognostic information and guide treatment decisions. Cardiac output is usually measured as part of such monitoring in patients with heart failure, shock syndromes, and after coronary artery bypass graft surgery. Techniques include thermodilution, dye dilution, or the Fick method, although thermodilution is most often used. Thoracic electrical bioimpedance and inert gas rebreathing are 2 techniques that have been investigated for many years as a noninvasive alternative for measuring cardiac output.

Bioimpedance is defined as the electrical resistance of tissue to the flow of current. For example, when small electrical signals are transmitted through the thorax, the current travels along blood-filled aorta, which is the most conductive area. Changes in bioimpedance, resulting from the pulsatile changes in volume and velocity of blood in the aorta, are inversely proportional to the stroke volume (cardiac output equals the stroke volume times heart rate). Inert gas rebreathing is based on the observation that the absorption and disappearance of a blood soluble gas is proportional to cardiac blood flow. The patient is asked to breathe and rebreathe from a rubber bag filled with oxygen mixed with foreign gases; typically nitrous oxide and sulphur hexafluoride. The nitrous oxide is soluble in blood and is therefore absorbed during the blood’s passage through the lungs at a rate that is proportional to the blood flow. The sulphur hexafluoride is insoluble in blood and therefore stays in the gas phase and is used to determine the lung volume from which the soluble gas is removed. These gases and CO-2 are measured continuously and simultaneously at the mouthpiece.

Development of a noninvasive measurement would permit more convenient and safer monitoring in the intensive care unit, and could be used for monitoring in other settings, such as the emergency room, on the general medical floor, or outpatient clinic. In the outpatient clinic thoracic bioimpedance has been investigated as a technique to optimize drug therapy in
patients with congestive heart failure. Echocardiography, transesophageal echocardiography (TEE), and Doppler ultrasound are other noninvasive methods for monitoring cardiac output.

The BioZ™ is a device approved for marketing by the U.S. Food and Drug Administration (FDA) that measures thoracic bioimpedance.

Innocur (Innovision, Denmark) is an inert gas rebreathing device. It has not yet been reviewed by the FDA.

Innocur (Innovision, Denmark), an inert gas rebreathing device, received FDA approval through the 510(k) approval process in March 2006 as substantially equivalent to two predicate technologies, thermodilution and the direct Fick method. The Innocor device is approved for the determination of a number of hemodynamic parameters, principally cardiac output.

Note: This policy only addresses use of this technique in ambulatory care and outpatient settings.

Policy

In the ambulatory care and outpatient setting, thoracic bioimpedance and inert gas rebreathing are considered investigational.

Policy Guidelines

In 2002 the following CPT code was introduced:

93701: Bioimpedance, thoracic, electrical

In 2005, the following CPT codes were introduced:

0104T: Inert gas rebreathing for cardiac output measurement; during rest
0105T: ; during exercise

Rationale

**Thoracic Bioimpedance**

A variety of small case series have reported inconsistent results regarding the relationship between measurements of cardiac output (CO) determined by thoracic bioelectric impedance and thermodilution techniques. For example, Belardinelli and colleagues compared the use of thoracic bioimpedance, thermodilution, and the Fick method to estimate cardiac output in 25 patients with documented coronary artery disease and a previous myocardial infarction. (1) There was a high degree of correlation between cardiac output as measured by thoracic bioimpedance and other invasive measures. Shoemaker and colleagues reported on a multicenter trial of thoracic bioimpedance compared to thermodilution in 68 critically ill patients. (2) Again, the changes in cardiac output as measured by thoracic bioimpedance closely tracked those measured by thermodilution. In contrast, Sageman and colleagues did not recommend the use of bioimpedance as a postoperative monitoring technique for patients who had
undergone coronary artery bypass surgery. (3) In this study of 50 patients, only a poor correlation was found between thermodilution and bioimpedance, due primarily to the postoperative distortion of the patient’s anatomy and the presence of endotracheal, mediastinal, and chest tubes. In a study of 34 patients undergoing cardiac surgery, Doering and colleagues also found that there was poor agreement between thoracic bioimpedance and thermodilution in the immediate postoperative period. (4) The largest case series, the COST study, has been published in abstract form only. (5) In this case series, estimations of cardiac output using thermodilution methods and thoracic bioimpedance were performed in 191 patients who underwent right heart catheterization for a variety of clinical indications. Linear regression analysis revealed an overall correlation of $r = 0.73$. The authors concluded that cardiac output can be reliably measured with either thermodilution or thoracic bioimpedance, and that bioimpedance has the additional value of being noninvasive.

The noninvasive nature of thoracic bioimpedance has prompted interest in a variety of outpatient applications. For example, there is interest in using thoracic bioimpedance as a technique to promote optimization of drug therapy in patients with congestive heart failure or hypertension, provide early detection of rejection in heart transplant recipients, or optimize the programming of pacemakers. However, there are no controlled studies in the published literature that validate this outpatient application of thoracic bioimpedance or provide comparisons to other noninvasive cardiac diagnostic techniques, such as echocardiography.

Since this policy was first issued in 2000, there has been minimal additional literature focusing on the potential applications of thoracic bioimpedance in the outpatient setting, and no literature specifically focusing on the improved health outcomes in patients undergoing thoracic bioimpedance. As noted in a 2000 editorial, thoracic bioimpedance may have an important role in the outpatient management of congestive heart failure, but ‘earlier studies have not sought to evaluate the clinical importance of the data generated by impedance cardiography. They have not determined whether evaluation of the status of the central circulation by impedance cardiography can predict clinical events and, thus, be used to alter the treatment of patients. Obtaining such information is critical if the use of impedance cardiography is to expand from its present application where it has excelled, in shortterm management of acutely ill hospitalized patients, to the long term outpatient management of recently ill or hospitalized patients with severe chronic disorders.’ (6)

2006 Update

A review of the peer-reviewed literature on MEDLINE for the period of October 2001 through February 2006 identified no clinical trials that would alter the above conclusions. As noted in a review article, the issue continues to be how the use of thoracic bioimpedance can be used in the outpatient to improve patient management, either in terms of diagnosis, risk stratification, and monitoring patients with cardiovascular conditions. (7) In 2002, the Agency for Healthcare Research and Quality (AHRQ) published a technology assessment on TEB, which concluded that limitations in available studies did not allow the agency to draw meaningful conclusions to determine whether the accuracy of TEB compared to other hemodynamic parameters. (8) The agency also found a lack of studies focusing on clinical outcomes and little evidence to draw conclusions on patient outcomes for the following clinical areas:

- Monitoring in patients with suspected or known cardiovascular disease;
- Acute dyspnea;
- Pacemakers;
- Inotropic therapy;
- Post-heart transplant evaluation;
- Cardiac patients with need for fluid management; and
- Hypertension.

In 2001, the American College of Cardiology/American Heart Association issued guidelines for chronic heart failure. (9) These guidelines indicate that bioimpedance:

“cannot be recommended at the present time because the accuracy of bioelectrical parameters has not been defined in patients with chronic HF and it has not been shown to be more valuable than routine tests, including the physical examination. Moreover, it is not clear whether serial noninvasive hemodynamic measurements can be used to gauge the efficacy of treatment or to identify patients most likely to deteriorate symptomatically during long-term follow-up.”

No other professional society guidelines addressing TEB were found. Therefore, the policy statement is unchanged.

Inert Gas Rebreathing

In contrast to thoracic bioimpedance, there is relatively little published literature on inert gas rebreathing, although a literature search suggests that this technique has been used as a research tool for many years. (10-12) A literature search did not identify any clinical articles exploring how inert gas rebreathing may be used to improve patient management in the outpatient setting.

Medicare Policy

In August 2003, the Centers for Medicare and Medicaid Services issued a decision memorandum on the reconsideration of its coverage policy for thoracic electrical bioimpedance (TEB) and the consideration of expanding the scope of the policy to include management of hypertension. (13) After reconsideration, Medicare’s national coverage determination found TEB to be reasonable and necessary for the following indications:

1. Differentiation of cardiogenic from pulmonary causes of acute dyspnea;
2. Optimization of atrioventricular interval for patient with A/V sequential cardiac pacemakers;
3. Monitoring of continuous inotropic therapy for patients with congestive heart failure;
4. Evaluation for rejection in patients with a heart transplant as a predetermined alternative to myocardial biopsy; and

While Medicare allows for coverage of TEB in these conditions, it acknowledges that there is a “…general absence of studies evaluating the impact of using TEB for managing patients with cardiac disease...” The agency also removed the previously covered indication for “suspected
or known cardiovascular disease,” noting that it had written this too broadly. In addition, Medicare concluded in its reconsideration that TEB use in the management of hypertension is non-covered due to inadequate evidence.

In January 2004, Medicare issued a new revised national coverage decision after request for more clarity and guidance on TEB coverage. (14) With this revision, Medicare specified in its covered indications that:

“Contractors have discretion to determine whether the use of TEB for the management of drug-resistant hypertension is reasonable and necessary. Drug-resistant hypertension is defined as failure to achieve goal BP in patients who are adhering to full doses of an appropriate three-drug regimen that includes a diuretic.”

Medicare also specified that TEB is noncovered “in the management of all forms of hypertension (with the exception of drug-resistant hypertension…).”

There is no national Medicare coverage decision regarding inert gas rebreathing.

2007 Update
The policy was updated with a literature search using MEDLINE in November 2007. A number of studies have been published since the last update describing the use of thoracic bioimpedance (also referred to as impedance cardiography) in a various clinical situations.

Hypertension. Smith reported on the use of impedance cardiography (ICG) as a method to improve blood pressure control in 164 patients with hypertension whose blood pressure was not controlled on one to three medications. (15) The study was conducted in 11 primary care centers. Results were reported (this was not an intention-to-treat analysis) on blood pressure control at 3 months for 95 patients in the standard treatment arm and 69 in the hemodynamic (ICG) arm. Decisions about changes in treatment were guided by results of ICG which was obtained at the initial visit and at monthly follow-up visits. As one example of ICG use, ACE inhibitors were added if ICG showed high vascular resistance. At the end of 3 months, 77% of the ICG group achieved blood pressure control (< 140/90) compared to 55% in the standard treatment group; reductions in diastolic blood pressure were also greater in the ICG group (12 mm Hg vs. 5 mm, respectively). This study excluded patients taking more than 3 medications. Other exclusions included a history of heart failure, “abnormal” laboratory findings, atrial fibrillation, or ejection fraction < 40%. While these results are interesting, larger studies with longer follow-up will be needed to determine if the improvements in blood pressure are sustained and of sufficient magnitude to potentially lead to improved outcomes. The use of the technology in a broader spectrum of patients may also need further evaluation.

Evaluation of dyspnea. Peacock reported findings on a “convenience” sample of 89 patients age 65 and older who presented to an emergency department with dyspnea. (16) The final diagnosis was heart failure in 48% and obstructive lung disease in 22%. After receiving the results of impedance cardiography (ICG), such as vascular resistance and cardiac index, the 31 practitioners in this study changed their working diagnosis in 13% of cases and changed medications administered in 39%. Findings from this study are limited due to small sample size, approach to patient selection, and unclear effects on relevant patient outcomes. Lo reported on a study of 52 patients who presented with acute dyspnea to emergency departments in Taiwan. (17) Compared to standard care (history, examination, and laboratory testing), they reported that addition of ICG improved sensitivity (75% vs. 60%) and specificity (88% vs. 66%) for determining cardiac cause of dyspnea. Again, implications of these findings are limited by the small sample size and the uncertain impact on outcomes.
Heart Failure. Packer reported on use of ICG to predict risk of decompensation in patients with chronic heart failure. (18) In this study, 212 stable patients with heart failure and a recent episode of decompensation underwent serial evaluation and blinded ICG testing every 2 weeks for 26 weeks and were followed for the occurrence of death or worsening heart failure requiring hospitalization or emergent care. During the study, 59 patients experienced 104 episodes of decompensated heart failure: 16 deaths, 78 hospitalizations, and 10 emergency visits. A composite score of 3 ICG parameters was a strong predictor of an event during the next 14 days ($p = 0.0002$). Patients noted to have a high-risk composite score at a visit had a 2.5 times greater likelihood of a near-term event and those with a low-risk score had a 70% lower likelihood when compared to ones at intermediate risk. However, the impact of use of these results on clinical outcomes is not known.

While results of more studies of ICG are being published, many studies are limited by small populations and uncertainty about the impact on clinical outcomes. In addition, not all studies have evaluated additional novel markers such as BNP (brain natriuretic peptide). In a 2006 review article, Wang comments that there are limited data concerning improved outcomes using ICG in the clinical setting and that given the data, ICG use should be limited to the research setting. (19) Thus, the policy statement is unchanged; this remains investigational.

The literature review found no studies of the impact of inert gas rebreathing on clinical management. Published studies do indicate this approach is still being evaluated. (20) The policy statement is unchanged.

2008-2009 Update
The policy was updated with a MEDLINE search conducted for the period December 2007 through March 2009. No clinical trials were found that evaluated the use of this technology compared to alternative techniques.

Heinroth et al. (21) presented data from the use of ICG that was based on cardiac output measurements. These data were used to guide the optimization of AV and interventricular interval timing of cardiac resynchronization therapy (CRT) devices. In this study from Europe, 46 patients with heart failure (left ventricular ejection fraction < 35%, NYHA III–IV) and left bundle branch block (> 130 ms) in sinus rhythm were evaluated 3–5 days after implantation of a CRT device by means of ICG. Cardiac output was measured with and without biventricular pacing using a standard protocol. Mean cardiac output without pacing was 3.66 ± 0.85 L/min, and it significantly increased to 4.40 ± 1.1 L/min ($p <0.05$) with simultaneous biventricular pacing and an AV interval of 120 ms. Optimizing both intraventricular and AV intervals further increased cardiac output to 4.86 ± 1.1 L/min ($p <0.05$). The proportion of nonresponders to CRT was reduced by 56% following AV- and intraventricular-interval modification using ICG guidance. The authors concluded that further work is needed to determine the utility of ICG-derived data in determining AV and intraventricular intervals for individual patients.

Other small comparative studies reviewed for this update evaluated the reliability of inert gas rebreathing techniques in comparison with standard invasive methods and the reproducibility of cardiac output measurements by different rebreathing methods. None of these studies addressed the impact of inert gas rebreathing on clinical management of heart failure or improvement in patient outcomes.

The 2009 American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Guidelines for the Diagnosis and Management of Heart Failure in Adults (22) conclude that no role for periodic invasive or noninvasive hemodynamic measurements that has been established in the management of heart failure. *Most drugs used for the treatment of HF [heart failure] are prescribed on the basis of their ability to improve symptoms or survival rather than
their effect on hemodynamic variables. Moreover, the initial and target doses of these drugs are selected on the basis of experience in controlled trials and are not based on the changes they may produce in cardiac output or pulmonary wedge pressure.”

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