Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting

Medical Policy

Section Medicine

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Description

A variety of outpatient cardiac hemodynamic monitoring devices have been proposed to decrease episodes of acute decompensation in patients with heart failure and thus improve quality of life and reduce morbidity. These new outpatient devices include bioimpedance, inert gas rebreathing, and estimation of left ventricular end diastolic pressure by arterial pressure during Valsalva or use of an implantable pressure sensor.

Background

Patients with chronic heart failure are at elevated risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have the additional risk of future episodes of decompensation, and death. Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute events such as coronary ischemia and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens. (1) Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of patients at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with patients to review signs and symptoms with a healthcare provider and with education or adjustment of medications as appropriate. These encounters may occur face-to-face in the office or at home, or via transmission telephonically or electronically of symptoms and conventional vital signs, including weight. (2)
Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Transthoracic echocardiography, transesophageal echocardiography (TEE), and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient but are not addressed in this policy. A variety of biomarkers and radiologic techniques may be utilized in the setting of dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

A number of novel approaches have been investigated as techniques to measure cardiac hemodynamics in the outpatient setting. It is postulated that real-time values of cardiac output or left ventricular end diastolic pressure (LVEDP) will supplement the characteristic signs and symptoms and improve the clinician’s ability to intervene early to prevent acute decompensation. Four methods will be reviewed here: thoracic bioimpedance, inert gas rebreathing, arterial waveform during Valsalva, and implantable pressure monitoring devices.

**Thoracic Bioimpedance**

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 the blood-filled aorta, which is the most conductive area. Changes in bioimpedance, measured at each beat of the heart, are inversely related to pulsatile changes in volume and velocity of blood in the aorta. Cardiac output is the product of stroke volume by heart rate, and thus can be calculated from bioimpedance. Cardiac output is generally reduced in patients with systolic heart failure. Acute decompensation is characterized by worsening of cardiac output from the patient’s baseline status. The technique is alternatively known as impedance +++ and impedance cardiography (ICG).

**Inert Gas Rebreathing**

This technique 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 rebreathing bag filled with oxygen mixed with a fixed proportion of two inert gases; typically nitrous oxide and sulfur 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 sulfur 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 carbon dioxide are measured continuously and simultaneously at the mouthpiece.

**Arterial Pressure during Valsalva to Estimate LVEDP**

Left ventricular end diastolic pressure (LVEDP) is elevated in the setting of acute decompensated heart failure. While direct catheter measurement of LVEDP is possible for patients undergoing cardiac catheterization for diagnostic or therapeutic reasons, its invasive nature precludes outpatient use. Noninvasive measurements of LVEDP have been developed based on the observation that arterial pressure during the strain phase of the Valsalva maneuver may directly reflect the LVEDP. Arterial pressure responses during repeated Valsalva maneuvers can be recorded and analyzed to produce values that correlate to the LVEDP.

**Pulmonary artery pressure measurement to estimate LVEDP**
LVEDP can also be approximated by direct pressure measurement of an implantable sensor in the pulmonary artery wall. The sensor is implanted via right heart catheterization and transmits pressure readings wirelessly to external monitors.

**Regulatory Status**

The following devices have received specific U.S. Food and Drug Administration (FDA) clearance for marketing through the 510(k) process:

- In June 1997, the "BioZ®" (SonoSite, Bothell, WA) thoracic impedance plethysmograph was cleared for marketing by the FDA through the 510(k) process. Several other impedance plethysmographs have been approved through the same process. The FDA determined that this device was substantially equivalent to existing devices for use in peripheral blood flow monitoring.

- In March 2006, the "Innocor®" (Innovision, Denmark) inert gas rebreathing device was cleared for marketing by the FDA through the 510(k) process. Several other inert gas rebreathing devices have been approved through the same process. The FDA determined that this device was substantially equivalent to existing devices for use in computing blood flow.

- In June 2004, the "VeriCor®" (CVP Diagnostics, Boston, MA) noninvasive LVEDP measurement device was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the following indication: “The VeriCor is indicated for use in estimating non-invasively, left ventricular end-diastolic pressure (LVEDP). This estimate, when used along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the clinician in the selection of further diagnostic tests in the process of reaching a diagnosis and formulating a therapeutic plan when abnormalities of intravascular volume are suspected. The device has been clinically validated in males only. Use of the device in females has not been investigated.”

Note: This policy only addresses use of these techniques in ambulatory care and outpatient settings.

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**Policy**

In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure/Valsalva, and implantable direct pressure monitoring of the pulmonary artery is considered **investigational**.

**Policy Guidelines**

There is a specific CPT code for bioimpedance:
93701: Bioimpedance-derived physiologic cardiovascular analysis

Prior to 2011, there were specific CPT category III codes for inert gas rebreathing:

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

0105T: during exercise

After January 1, 2011, inert gas rebreathing measurement should be reported using the unlisted code:

93799: Unlisted cardiovascular service or procedure.

Prior to 2010, there was a specific category III code for measuring LVEDP:

0086T: Left ventricular fill pressure indirect measurement by computerized calibration by the arterial waveform response to Valsalva maneuver.

After January 1, 2010, this testing should be reported using the unlisted code:

93799: Unlisted cardiovascular service or procedure.

There is no specific code for implantable direct pressure monitoring of the pulmonary artery. The unlisted code 93799 would be used.

Rationale

This policy was created by combining two existing policies in 2010; the most recent literature search for this policy was conducted with a search of the MEDLINE database for the period from May 2011 through May 2012.

Evaluation of a diagnostic technology typically focuses on the following 3 parameters: 1) technical performance; 2) diagnostic parameters (sensitivity, specificity, and positive and negative predictive value) in different populations of patients; and 3) demonstration that the diagnostic information can be used to improve patient outcomes. Additionally, when considering invasive monitoring, any improvements in patient outcomes must be outweighed by surgical and device-related risks associated with implantable devices.

Literature Review

Thoracic Bioimpedance/Impedance Cardiography (ICG)

In 2002, the Agency for Healthcare Research and Quality (AHRQ) published a technology assessment on thoracic bioimpedance, which concluded that limitations in available studies did not allow the agency to draw meaningful conclusions to determine the accuracy of thoracic bioimpedance compared to other hemodynamic parameters. (3) 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.

A number of small case series have reported variable results regarding the relationship between measurements of cardiac output 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. (4) 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. (5) Again, the changes in cardiac output as measured by thoracic bioimpedance closely tracked those measured by thermodilution. In contrast, Sageman and Amundson did not recommend the use of bioimpedance as a postoperative monitoring technique for patients who had undergone coronary artery bypass surgery. (6) 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. (7) The largest case series, the COST study, has been published in abstract form only. (8) 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 (Pearson’s correlation coefficient) =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.

Packer and colleagues reported on use of ICG to predict risk of decompensation in patients with chronic heart failure. (9) 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 up 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 patients 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 B-type natriuretic peptide (BNP). In a 2006 review article, Wang and Gottlieb comment 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. (10)

Thoracic bioimpedance may have an important role in the outpatient management of 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 short-term management of acutely ill hospitalized patients, to the long-term outpatient management of recently ill or hospitalized patients with severe chronic disorders." (11)

Inert Gas Rebreathing

In contrast to thoracic bioimpedance, relatively little literature has been published on inert gas rebreathing, although a literature search suggests that this technique has been used as a research tool for many years (12-15) 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.

Arterial pressure/ Valsalva LVEDP

Studies have shown high correlation between invasive and non-invasive measurement of left ventricular end diastolic pressure (LVEDP). For example, McIntyre and colleagues reported a comparison of pulmonary capillary wedge pressure (PCWP) measured by right heart catheter and an arterial pressure amplitude ration during Valsalva. The two techniques were highly correlated in both stable and unstable patients (R² [coefficient of determination] =0.80–0.85). (16) Sharma et al. performed simultaneous measurements of the LVEDP based on 3 techniques: direct measurement of LVEDP, considered the gold standard; indirect measurement using PCWP; and non-invasively using the VeriCor® device in 49 patients scheduled for elective cardiac catheterization. (17) The VeriCor® measurement correlated well with the direct measures of LVEDP (r=0.86) and outperformed the PCWP measurement, which had a correlation coefficient of 0.81 compared to the gold standard. In 2012, Silber and colleagues reported on finger photoplethysmography during Valsalva performed in 33 patients prior to cardiac catheterization. (18) LVEDP greater than 15 mm Hg was identified by finger photoplethysmography during Valsalva with 85% sensitivity (95% confidence interval [CI]: 54-97%) and 80% specificity (95% CI: 56-93%). However, literature searches did not identify any published articles that evaluated the role of non-invasive measurement of the LVEDP on the management of the patient. Therefore, evidence is inadequate to permit scientific conclusions regarding the clinical utility of this technology.

Implantable Direct Pulmonary Artery Pressure - LVEDP

The CHAMPION (CardiomemsHeart SensorAllowsMonitoring ofPressure toImproveOutcomes inNew York Heart Association [NYHA] Class III Patients) Trial Study was a prospective, single-blind, randomized, controlled, trial (RCT) conducted at 64 centers in the United States. (19) This trial was designed to evaluate the safety and efficacy of an implanted, passive, wireless, pulmonary artery pressure monitor developed by CardioMEMS for the ambulatory management of heart failure patients. The CardioMEMS device is implanted using a heart catheter system fed through the femoral vein and requires patients have an overnight hospital admission for observation after implantation.
The CHAMPION study enrolled 550 patients who had at least one previous hospitalization for heart failure in the past 12 months and were classified as having NYHA Class III heart failure for at least 3 months. Left ventricular ejection fraction (LVEF) was not a criterion for participation, but patients were required to be on medication and stabilized for 1 month before participating in the study if LVEF was reduced. All enrolled patients received implantation of the CardioMEMS pulmonary artery radiofrequency pressure sensor monitor and standard of care heart failure disease management. Heart failure disease management followed American College of Cardiology and American Heart Association guidelines along with local disease management programs. Patients were randomized by computer in a 1:1 ratio to the treatment group (n=270), which used data from the pulmonary artery pressure sensor in patient management or the control group (n=280), which did not incorporate pulmonary artery pressure sensor data into patient management. All patients took daily pulmonary artery pressure readings but were masked to their treatment groups for the first 6 months.

The primary efficacy outcome of this trial was the rate of heart failure-related hospitalizations in the 6 months after implantation. The primary safety outcomes were device-related or system-related complications and pressure-sensor failures. (20) The investigators reported a statistically significant reduction in readmissions for heart failure at 6 months by 30% in the treatment group (n=83) over the control group (n=120) (hazard ratio [HR]: 0.70, 95% CI: 0.60-0.84, p<0.0001). This benefit was maintained over the entire randomized follow-up (mean 15 months) (153 vs. 253 hospitalizations, respectively) (HR: 0.64, 95% CI: 0.55-0.75, p<0.0001). The primary safety outcomes, freedom from device-related complications was 98.6% with no occurrences of pressure-sensor failure. However, 15 adverse events occurred including 8 which were device-related and 7 which were procedure-related. Additionally, length of stay for these hospitalizations was significantly shorter in the treatment group when compared to the control group (2.2 days vs. 3.8 days, respectively, p=0.02). There was also benefit reported for other secondary outcomes. There were improvements in the secondary outcomes of mean pulmonary pressure and quality of life at 6 months. There was no difference in overall mortality, although the trial was not designed with sufficient power to evaluate mortality benefit. There were 15 deaths in the treatment group and 26 deaths in the control group at 6 months (HR: 0.77, 95% CI: 0.40-1.51, p=0.45).

A limitation of the CHAMPION trial is the lack of double-blinding. While the patients were blinded and efforts to maintain patient masking were undertaken, the clinicians were not blinded to treatment assignment. The unblinded clinicians were presumably also making decisions on whether to hospitalize patients, and these decisions may have been influenced by knowledge of treatment assignment. Also, the design of this trial does not allow comparison of the incremental risk of implanting a device compared to no implantation, since all patients had a device implanted. Furthermore, the CardioMEMS pulmonary artery pressure monitoring device was denied FDA approval in December 2011.

Stevenson and colleagues reported on the COMPASS-HF (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure Study) randomized trial in 2010. (21) The COMPASS trial evaluated outcomes on 274 patients implanted with a Medtronic hemodynamic monitoring system. Patients enrolled in the study were stabilized NYHA Class III or IV heart failure patients and had at least one heart failure-related event within the 6 months prior to enrollment. LVEF was not a criterion. Similar to the CHAMPION trial, all patients were implanted with the monitoring device and received standard heart failure disease treatment during the first 6 months post-implantation. One-half of the patients were randomized to incorporate pressure monitoring data into heart failure management, while information from the
other half of patients was not used in treatment decisions. The authors of this article reported 100 of 261 patients (38%) from both treatment groups had heart failure-related events during the 6 months’ follow-up despite weight-guided management. Separate reports on heart failure events by treatment group were not provided. Heart failure event risk increased with higher readings of chronic 24-hour estimated pulmonary artery pressure and at 18 mm Hg diastolic pressure, event risk was 20% and increased to 34% at 25 mm Hg and to 56% at 33 mm Hg. While pressure readings correlated with event risk, the authors noted optimal filling pressures and needed surveillance for event avoidance have not been established. The Medtronic Chronicle Hemodynamic Monitor was denied FDA approval in March 2007.

In 2011, Adamson et al. reported on the Reducing Decompensation Events Utilizing Intracardiac Pressures in Patients With Chronic Heart Failure (REDUCEhf) study that evaluated an implantable cardioverter-defibrillator (ICD) coupled with an implantable hemodynamic monitoring (IHM) system. (22) The REDUCEhf study was a prospective, randomized, multicenter, single-blinded trial of 400 patients with NYHA class II or III symptoms who were hospitalized for heart failure within the past 12 months and qualified for an ICD. The study had expected to enroll 1,300 patients, but after ICD lead failures had been reported in other studies, enrollment was limited to 400 patients. After the ICD was placed, an IHM sensor was implanted in the right ventricle. Similar to the COMPASS-HF and CHAMPION trials above, the treatment group of 202 patients received heart failure management that incorporated pressure monitoring information from the IHM compared to the control group of 198 patients that did not use pressure monitoring information in treatment planning. After 12 months of follow-up, rates of heart failure hospitalizations, emergency department visits, and urgent clinic visits did not differ between groups (HR: 0.99, 95% CI: 0.61-1.61, p=0.98). While the study was underpowered to detect differences in these events because of limited enrollment, there were no trends favorable to the monitoring group to suggest that the lack of difference was due to inadequate power.

Ongoing Clinical Trials

Additional clinical trials registered at online site ClinicalTrials.gov have the potential to add to our understanding of these devices in the management of chronic heart failure. The Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy (LAPTOP-HF) is a randomized trial to evaluate the safety and clinical effectiveness of an implantable device, the HeartPOD™ System or Promote® LAP System, for left atrial pressure measurements to manage heart failure. (NCT01121107) This trial began in April 2010 and is expected to enroll 730 patients for completion in 2013. The Prevention of Heart Failure Events with Impedance Cardiography Testing (PREVENT-HF)) trial will evaluate the impact of incorporating impedance cardiography readings into treatment planning using the BioZ Dx device in 500 patients. (NCT00409916) The PREVENT-HF trial will follow patients for 24-52 weeks and is expected to be completed in December 2012.

Summary

A variety of outpatient cardiac hemodynamic monitoring devices has been proposed to decrease episodes of acute decompensation in patients with heart failure and thus improve quality of life and reduce morbidity. These new outpatient devices include bioimpedance, inert gas rebreathing, and estimation of left ventricular end diastolic pressure by arterial pressure during Valsalva or use of an implantable pressure sensor.
The evidence is not sufficient to determine that hemodynamic monitoring of patients with heart failure improves outcomes. Evidence from randomized controlled trials for invasive pulmonary artery pressure monitoring has demonstrated a correlation between increased pressure readings and increased heart failure event risk. However, the optimal filling pressures and threshold readings for event avoidance have not been established. One report from the CHAMPION RCT noted that pressure readings may be used to reduce heart failure-related hospitalizations. However, this trial was single-blinded, and the decision to hospitalize patients may have been influenced by knowledge of group assignment. The REDUCEhf study was also single-blinded but reported no differences in heart failure event rates, including hospitalizations, emergency department visits, and urgent clinic visits, despite the inclusion of pressure monitoring readings in treatment planning. Also, the surgical risks of pressure monitoring devices must be balanced with improvements in net health outcomes and compared longer-term with outcomes of traditional management. Finally, FDA approval for invasive pulmonary artery pressure monitoring devices has been denied.

For other types of hemodynamic monitoring, there is little available evidence on efficacy. Randomized controlled trials, as well as studies that specifically address use of ambulatory cardiac hemodynamic monitoring compared with current care are lacking for thoracic bioimpedance, inert gas rebreathing, and arterial pressure/Valsalva techniques.

While some evidence suggests that intensive outpatient pulmonary artery pressure monitoring may reduce hospitalizations for patients with heart failure, convincing evidence that the use of these technologies improves health outcomes over standard, active heart failure patient management is not available. Therefore, these technologies are considered investigational.

Practice Guidelines and Position Statements

The 2009 American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Guidelines for the Diagnosis and Management of Heart Failure in Adults conclude that no role for periodic invasive or noninvasive hemodynamic measurements has been established in the management of heart failure. (23) “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.”

The 2011 update of the National Institute for Health and Clinical Excellence clinical guideline on chronic heart failure management does not include outpatient hemodynamic monitoring as a recommendation. (24)

No other professional society guidelines were found that address thoracic bioimpedance, inert gas rebreathing, arterial pressure/Valsalva, or implantable direct pressure monitoring of the pulmonary artery in the outpatient setting for the management of heart failure.

Medicare National Coverage

In November 2006, the Centers for Medicare and Medicaid Services (CMS) issued a decision memorandum on the second reconsideration of its coverage policy for thoracic electrical bioimpedance. (25) Medicare’s national coverage determination found thoracic bioimpedance 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 terminal 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 thoracic bioimpedance in these conditions, it acknowledges that there is a “…general absence of studies evaluating the impact of using thoracic bioimpedance for managing patients with cardiac disease….” Medicare concluded in its reconsideration that thoracic bioimpedance use in the management of hypertension is non-covered due to inadequate evidence.

Medicare also specified that thoracic bioimpedance is noncovered “in the management of all forms of hypertension (with the exception of drug-resistant hypertension…).” Medicare specified in its covered indications that:

“Contractors have discretion to determine whether the use of thoracic bioimpedance 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.”

There is no national Medicare coverage decision regarding inert gas rebreathing, arterial pressure with Valsalva, or implantable direct pressure monitoring.

References:


Codes

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