# The Role of Implantable Hemodynamic Monitors to Manage Heart Failure

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**KEYWORDS**

• Disease management • Heart failure • Hemodynamics • Hospitalization • Left atrial pressure • Pulmonary artery pressure • Quality of life

**KEY POINTS**

- Heart failure is associated with high rates of hospitalization and rehospitalization.
- Current approaches to monitoring heart failure have done little to reduce these high rates of hospitalization and rehospitalization.
- Implantable hemodynamic monitors provide direct measurements of intracardiac and pulmonary artery pressures in ambulatory patients with heart failure.
- Heart failure care guided by implantable hemodynamic monitors reduces the risk of heart failure hospitalization and improves quality of life.

## INTRODUCTION

Heart failure represents a major and growing public health concern, associated with high rates of hospitalization and rehospitalization. Heart failure is the primary diagnosis in more than 1 million hospitalizations annually in the United States.[1] It is associated with the highest rate of hospital readmission compared with all other medical or surgical causes of hospitalization.[2] Approximately 25% of discharged patients are readmitted within 30 days and about 67% are readmitted within 1 year, following the index hospitalization.[2–4] Lack of improvement in health-related quality of life after discharge from the hospital is a powerful predictor of rehospitalization and mortality.[5]

Hospitalization for heart failure results in a substantial economic burden. In 2012, the US total economic burden from heart failure was estimated at $31 billion.[1] The direct costs of heart failure in the United States are estimated at $21 billion annually; of this amount, 80% of costs are from hospitalizations.[6] Without improvements in current clinical outcomes, the US total economic burden from heart failure is expected to rise to $70 billion annually by the year 2030.[1,6] Consequently, a major goal in heart failure management is to keep patients well and out of the hospital and to reduce these costs.

Unfortunately, current approaches to monitoring patients with heart failure have generally focused on insensitive noninvasive markers of heart failure clinical status and failed to improve quality of life or to reduce hospitalization rates. Worsening heart failure symptoms, changes in vital signs, and weight gain are late and unreliable markers of worsening heart failure. Implantable hemodynamic monitors, which remotely provide direct measurement of intracardiac and pulmonary artery pressures (PAP) in ambulatory patients with heart

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failure, enable a proactive approach that shifts the focus from crisis management to stability management in patients with heart failure. This article reviews current knowledge on the role of implantable hemodynamic monitors in heart failure management.

## LIMITATIONS OF CURRENT STANDARD OF CARE MONITORING IN HEART FAILURE

Noninvasive remote monitoring of patients with heart failure generally involves regularly scheduled structured telephone contact between patients and health care providers and/or the electronic transfer of physiologic data using remote access technology via electronic devices. This approach allows for the assessment of symptoms, vital signs, and daily weights, and other noninvasive parameters of interest. The efficacy of such noninvasive monitoring methods remains uncertain, although a growing body of evidence suggests that its value is limited.

Two recent large meta-analyses of randomized controlled trials and observational cohort studies suggest that remote monitoring of symptoms, vital signs, and daily weights may be beneficial for reducing death, hospitalizations, and rehospitalizations for heart failure.[7,8] In contrast, two recent large prospective randomized controlled trials challenge these findings.

In a study sponsored by the National Institutes of Health called TELE-HF, 1653 patients recently hospitalized for heart failure were randomized to undergo either remote monitoring or usual care.[9] Remote monitoring was accomplished by means of a telephone-based interactive voice-response system that collected daily information about symptoms and weight that was reviewed by clinicians, providing the opportunity for outpatient intervention to avoid hospitalization. There was no significant difference between groups in the primary end point of readmissions or death for any cause at 180 days. Hospitalizations for heart failure, the number of days in hospital, and the total number of hospitalizations were not significantly reduced by use of the remote monitoring system.

Similarly, the European randomized controlled TIM-HF trial assigned patients with heart failure with reduced left ventricular ejection fractions (LVEF) to daily remote monitoring, including an electrocardiogram, blood pressure measurement, and assessment of body weight, coupled with medical telephone support or to usual care directed by the patient's local physician.[10] After 2 years of follow-up, there was no significant difference in the primary end point of all-cause mortality or in the composite of cardiovascular death or heart failure hospitalization between the two groups.

One reason for the failure of noninvasive remote monitoring to consistently improve clinical outcomes may be the relatively low sensitivity of changes in symptoms, vital signs, and daily weights to predict heart failure hospitalizations. For example, the sensitivity of weight change in predicting worsening heart failure events is on the order of only 10% to 20%.[11,12] In addition, weight gain and symptoms of clinical congestion (eg, worsening shortness of breath) are late manifestations of worsening heart failure. Thus, when these changes occur, the opportunity to prevent heart failure hospitalization may already be lost. Earlier markers of worsening heart failure may include autonomic adaptation and changes in intrathoracic impedance reflective of increasing lung water.[12–16] However, because clinical congestion, weight change, autonomic adaptation, and changes in intrathoracic impedance are all preceded for many days or weeks by increases in intracardiac pressure and PAP (or hemodynamic congestion), targeting pressure changes in the monitoring and management of heart failure may provide the earliest opportunity for intervention and avoidance of heart failure hospitalizations (**Fig. 1**). This is the premise supporting the use of implantable hemodynamic monitors in the management of heart failure.

## IMPLANTABLE HEMODYNAMIC MONITORING

A variety of approaches to remote ambulatory monitoring of intracardiac pressure and PAP have been developed over the years. Devices targeting measurement of right ventricular pressure, PAP, and left atrial pressure (LAP) have been studied. Recently, one system for PAP monitoring received regulatory approval in the United States, ushering in a new era of implantable hemodynamic monitoring for the management of patients with heart failure.

### *Right Ventricular Pressure Monitors*

The ability to estimate pulmonary artery end-diastolic pressure (ePAD) from the right ventricle (RV) was described in 1995.[17] Based on the observation that RV pressure at the time of pulmonary valve opening is equal to pulmonary artery diastolic pressure, RV pressure at the time of RV maximum change in pressure over time (dP/dt) was considered the ePAD and this correlated with directly measured pulmonary artery diastolic pressures at baseline, during isometric work, and during the Valsalva maneuver. This observation