Integrating Device Monitoring into the Infrastructure and Workflow of Routine Practice

Philip B. Adamson, MD, FACC

The Heart Failure Institute at Oklahoma Heart Hospital and the Department of Physiology, University of Oklahoma Health Sciences Center, Oklahoma City, OK

Monitoring strategies for patients with heart failure vary. Physical assessment and patient reporting are often unreliable and inconsistent. Continuous physiologic information from implanted devices identifies the progression to congestion in patients with chronic heart failure earlier in the process than traditional methods. Common themes of a successful system will require a means to provide device-based data to interested providers who then can interpret the information in the context of either remote or face-to-face clinical assessment.
[Rev Cardiovasc Med. *2006;7(suppl 1):S42-S46*]

Key words: Heart failure • Remote management • Congestive heart failure • OptiVol

Monitoring strategies for patients with heart failure vary depending on the infrastructure dedicated to the practice group and range from patient-initiated emergency department visits because symptoms become unbearable to weekly telephone contact with frequent in-office assessment to avert volume accumulation.[1-5] Several models of organized heart failure treatment programs are available with a variety of measured impact on important clinical outcomes.[1-5] Most profound may be the Trans-European Network-Home-Care Management System (TEN-HMS) that demonstrated a significant

survival benefit from instituting specially trained nurse calls to recently hospitalized patients with heart failure.[5]

Common to all successful heart failure treatment programs is frequent monitoring of patients, which can be achieved by involving patients in their own care with daily weights and almost immediate access to healthcare providers. Whereas this labor-intensive approach to the care of patients with heart failure is very effective, it is not without significant cost. Ancillary healthcare providers, including advanced practice nurses, physician assistants, and specially trained registered nurses can bear much of the labor burden in the frequent follow-up approach, but the fundamental assessment during frequent patient assessments generally relies on filling pressure estimation based on physical examination. Unfortunately, study after study demonstrates that the sensitivity and specificity of physical examination is questionable at best, and even in the hands of "heart failure specialists," significantly elevated filling pressures remain undiscovered by physical assessment.[6-8] Additionally, physical assessment can only be made at a moment in time and cannot be continuous, which may be important when assessing a chronic disease such as heart failure. Patient involvement in monitoring by acquiring daily weights is important, but the sensitivity of daily weights in predicting a heart failure exacerbation is very low.[8] Despite the inherent limitations of physical examination and daily weights, frequent patient contact presumably increases medical adherence and encourages lifestyle changes that profoundly impact outcomes in patients with heart failure.

A new era of monitoring is upon us and uses continuous assessment of physiologic parameters derived from implanted devices. It became apparent that implanted therapeutic devices, such as implantable cardioverter defibrillators or cardiac resynchronization devices, provide a tremendous amount of meaningful physiologic information to deliver therapy.[9-13] Great strides in monitoring heart failure patients may be possible if this continuously acquired data can be captured and presented to the provider in an easy to understand fashion. Continuously acquired data have the potential to provide an early warning of impending decompensation by documenting physiologic changes long before the traditional markers, such as weight and symptoms, alert providers of impending decompensation.

Physical assessment can only be made at a moment in time and cannot be continuous, which may be important when assessing a chronic disease such as heart failure.

Traditional monitoring strategies can be classified as "reactive" in the sense that they rely on symptoms to develop before therapy is altered. Device-based monitoring may provide information to form the basis of a "proactive" system that may allow earlier intervention in the progression to congestion. The purpose of this review is to examine the current tools available for heart failure management with a practical suggestion for integrating the newest of tools derived from device-based monitoring into a daily clinical practice.

Device-Based Monitoring in Heart Failure

A variety of physiologic parameters can be detected from implanted devices. One of the first large-scale studies investigating the monitoring potential of devices implanted in patients with heart failure examined heart rate variability derived from sensed atrial-to-atrial interval in a cardiac resynchronization therapy (CRT) device in the context of the double-blinded placebo-controlled MIRACLE trial.[9] This study found that CRT improved heart rate variability compared to clinically matched individuals who had an inactive device. The meaning of this and subsequent findings with heart rate variability relies on an understanding of what the measurement signifies.

Heart rate variability originates from the constant interaction of the 2 limbs of the autonomic nervous system at the sino-atrial node level.[14] In particular the "amount" of variability is linearly related to the "amount" of cardiac vagal control.[14] Chronic heart failure or acute decompensated heart failure is associated with increased cardiac sympathetic discharge and withdrawal of cardiac vagal control, resulting in reduced heart rate variability.[10] This aspect of heart failure pathophysiology led to the hypothesis that the behavior of continuously measured heart rate variability as heart failure decompensation led to heart failure hospitalization may provide an earlier warning compared to traditional markers such as weights or

A variety of physiologic parameters can be detected from implanted devices.

symptoms. In 34 hospitalized patients, heart rate variability persistently declined before hospitalization and an automatic detection system found significant changes on average 17 days before the patient presented to the healthcare provider with symptoms of heart failure.[10] Device-based heart rate variability also predicted long-term survival and risk for heart failure hospitalization.[10]

Clinical use of this information focuses on relative risk for imminent heart failure decompensation, which can guide need for follow-up.[11] Table 1 illustrates a strategy for using device-based heart rate variability in clinical practice.[11] This information can be accessed through Internet-based information systems or directly from the device using a programmer in the office. Not only does continuous heart rate variability predict clinical events, but the measurement also has significant implications about heart failure pathophysiology. When one considers changes in heart rate variability and other physiologic markers, such as intracardiac hemodynamic information[15] or intrathoracic impedance,[12] one can conclude that volume accumulation leading to decompensation as a syndrome begins many days before the point that patients consider symptoms to be severe enough to contact the healthcare provider. Figure 1 illustrates a new look at heart failure pathophysiology leading to acute congestion decompensation identifying multiple physiologic parameters that change long before the patient exhibits changes in New York Heart Association (NYHA) symptom classification or weight.

The "reactive" approach to heart failure care systems is very effective, but this paradigm typically intervenes late into the progression to congestion. This is due to a reliance on symptoms and weight changes or the random chance that a frequent office visit will "catch" the patient early enough. Using an insensitive instrument such as the physical examination, however, may decrease the likelihood that volume accumulation would be discovered, even if the patient was seen early in the progression. In contrast, proactive systems that incorporate device-based continuous monitoring are more likely to enter the progression with an instrument that has higher sensitivity and specificity for discovering volume accumulation.

Table 1
Clinical Application of Continuously Measured Heart Rate Variability

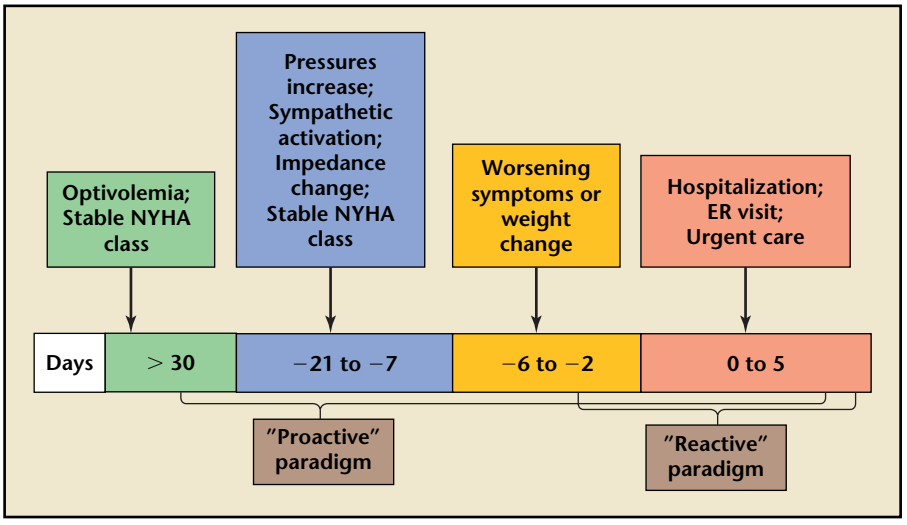
HRV Value (SDAAM)	Predicted Event Risk	Suggested Action
< 50 ms	High	Every 2-4 wk
50-100 ms	Intermediate	Every 6-8 wk with remote monitoring monthly
> 100 ms	Low	Every 12-16 wk with remote monitoring monthly
Persistent decline for 7 days	High	As for < 50 ms

HRV, heart rate variability; SDAAM, standard deviation of 5-minute median atrial-atrial intervals. Adapted with permission from Adamson PB.[11]

Information Integration in Practice Settings

Information from implanted devices, either stand-alone monitoring systems or components of therapeutic devices, can be accessed remotely using Internet-based systems or in patient encounters using a programmer interface. Access to this information in a practice setting, however, may be difficult and requires coordination between the implanting physician(s) and those responsible for heart failure management. It is very important, both from the patients' and the

Figure 1. *A new understanding of the progression to congestion from an implanted device perspective compared to the traditional monitoring approach. NYHA, New York Heart Association; ER, emergency room.*



provider groups' perspectives, that the information flow is seamless. It is not reasonable to require the patient to be the party responsible for information retrieval. Asking the patient, "what did the EP doctor say?" is not fair and does not portray to the patient that the system of care is adequate. Instead, free access to device monitoring information to both those responsible for the device function and those responsible for the daily heart failure management is required for successful application of device-based information systems. Each healthcare provider group has different needs for frequency and content of the accessible information. For example, electrophysiology providers may only need a quarterly assessment of battery life and arrhythmia burden, whereas the heart failure provider may need monthly assessment of atrial fibrillation burden, heart rate variability, OptiVol® fluid index (Medtronic, Inc. Minneapolis, MN), or patient activity. Each of these components of the Cardiac Compass® (Medtronic, Inc.) can be important to guide therapy decision-making either remotely or in the office (Figure 2).

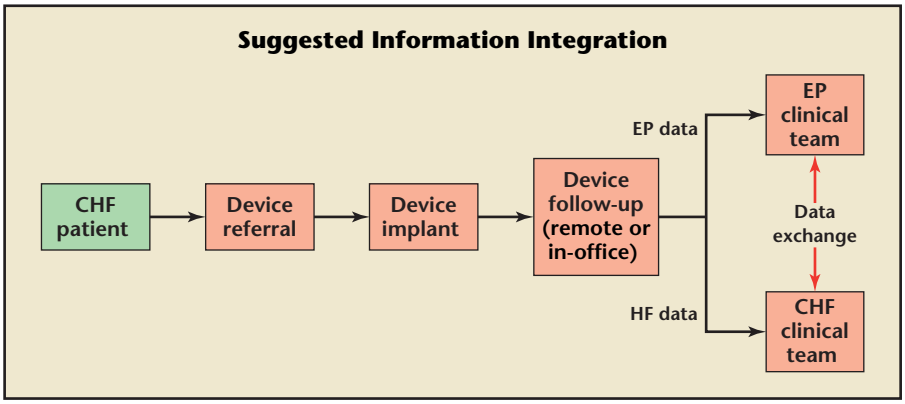
Practical Considerations

The flow of information from device to provider includes several potential steps. Device monitoring features can be viewed as a component of the vital signs measured at each clinic visit or as a means to obtain "vital signs" remotely. An efficient flow of information may have a variety of different structures. For example, some heart failure clinics have a dedicated programmer used to interrogate the device and obtain device-based information. Many of these providers have special training to make basic programming changes and evaluate device settings, whereas others simply obtain diagnostic information contained in the device. As patients check in for their visit, device diagnostics can be printed for the provider at the same time that vital signs are obtained. Nursing personnel can be trained to print the Heart Failure Management Reports, which can be a component of the basic information used during the visit. An alternative system downloads device information through a special heart failure programmer that is not capable of changing device programming. The downloaded information is sent over a telephone connection and the Heart Failure Management Report is sent by fax from a central processing center. Finally, a very reasonable approach is to ask patients to download information using their in-home system (eg, CareLink®; Medtronic, Inc.). The Heart Failure Management Report can then be reviewed online at the patient visit. Sometimes patients forget to download their device diagnostics, which makes it important to have some means to interrogate the device in the office visit.

Remote review of data not associated with an office visit may be a convenient means to reduce intensive in-office follow-up needs for some patients. Heart rate variability, for example, has been proposed to guide needs for follow-up based on absolute variability levels or change in variability over time. Eventually new device systems, such as implantable hemodynamic monitors, will allow remote assessment of right ventricular pressure. Heart failure care providers with experience in interpreting device information can dedicate appropriate time for Internet review of data and make decisions about management. This approach can reduce the follow-up burden on busy heart failure programs and open more opportunities to see new patients.

Coordination of visits with the electrophysiology provider can also increase efficiency and improve patient satisfaction. It is important, however, to clearly identify which provider will interrogate device information and then develop seamless communication between the groups. This approach will minimize duplication and still allow information to be shared with the interested provider.

Figure 2. *Suggested data flow in a practice that includes implanting physicians and those responsible for medical management of heart failure. CHF, congestive heart failure; EP, electrophysiology; HF, heart failure.*



Conclusions

Continuously acquired physiologic information derived from implanted devices identifies the progression to congestion in patients with chronic heart failure earlier in the process than traditional methods. Developing a system for integrating the physiologic data from implanted devices

into a heart failure practice requires coordination and cooperation between those responsible for heart failure care and the electrophysiology or implanting service. The exact nature of an effective information flow system will depend on local needs and practice characteristics. Common themes of a successful system will require a means to provide device-based data to interested providers who then can interpret the information in the context of either remote or face-to-face clinical assessment. This may require access to device programmers with printing capability, secured access to Internet information systems for heart failure practitioners, and open communication to achieve potential improvement in patient flow and clinical outcomes. ■

References

1. Fonarow G, Stevenson LW, Walden JA, et al. Impact of a comprehensive heart failure management program on hospital readmission and functional status of patients with advanced heart failure. *J Am Coll Cardiol*. 1997;30:725-732.
2. Rich MW, Beckham V, Wittenberg C, et al. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. *N Engl J Med*. 1995;333:1190-1195.
3. Gregory D, DeNorio D, Konstam MA. The economic effect of a tertiary hospital-based heart failure program. *J Am Coll Cardiol*. 2005;46:660-666.
4. Whellan DJ, Hasselblad V, Peterson E, et al. Metaanalysis and review of heart failure disease management randomized controlled clinical trials. *Am Heart J*. 2005;149:722-729.
5. Cleland JGF, Louis AA, Rigby AS, et al. Noninvasive home telemonitoring for patients with heart failure and high risk of recurrent admission and death: the trans-european-network-home-care management system (TEN-HMS) study. *J Am Coll Cardiol*. 2005;45:1654-1664.
6. Capomolla S, Ceresa M, Pinna G, et al. Echo-Doppler and clinical evaluations to define hemodynamic profile in patients with chronic heart failure: accuracy and influence on therapeutic management. *Eur J Heart Fail*. 2005;4:624-630.
7. Stevenson LW, Perloff JK. The limited reliability of physical signs for estimating hemodynamics in chronic heart failure. *JAMA*. 1989;117:204-206.
8. Lewin J, Ledwidge M, O'Loughlin C, et al. Clinical deterioration in established heart failure: what is the value of BNP and weight gain in aiding diagnosis? *Eur J Heart Fail*. 2005;7:953-957.
9. Adamson PB, Kleckner KJ, VanHout WL, et al. Cardiac resynchronization therapy improves heart rate variability in patients with symptomatic heart failure *Circulation*. 2003;108:266-269.
10. Adamson PB, Smith AL, Abraham WT, et al. Continuous autonomic assessment in patients with symptomatic heart failure: prognostic value of heart rate variability measured by an implanted cardiac resynchronization device. *Circulation*. 2004;110:2389-2394.
11. Adamson PB. Continuous heart rate variability from an implanted device: a practical guide for clinical use. *Congest Heart Fail*. 2005;11:327-330.
12. Yu CM, Wang L, Chau E, et al. Intrathoracic impedance monitoring in patients with heart failure: correlation with fluid status and feasibility of early warning preceding hospitalization. *Circulation*. 2005;112:841-848.
13. Fantoni C, Raffa S, Regoli F, et al. Cardiac resynchronization therapy improves heart rate profile and heart rate variability of patients with moderate to severe heart failure. *J Am Coll Cardiol*. 2005;46:1875-1882.
14. Katona PG, Jih F. Respiratory sinus arrhythmia: noninvasive measurement of parasympathetic cardiac control. *J Appl Physiol*. 1975;39:801-805.
15. Adamson PB, Magalski A, Braunschweig F, et al. Ongoing right ventricular hemodynamics in heart failure: clinical value of measurements derived from an implantable monitoring system. *J Am Coll Cardiol*. 2003;41:565-571.

Main Points

- Common to all successful heart failure treatment programs is frequent monitoring of patients, which can be achieved by involving patients in their care with daily weights and almost immediate access to healthcare providers.
- Implanted therapeutic devices, such as implantable cardioverter defibrillators or cardiac resynchronization devices, provide a tremendous amount of meaningful physiologic information to deliver therapy.
- Continuously acquired data have the potential to provide an early warning of impending decompensation by documenting physiologic changes long before the traditional markers, such as weight and symptoms, alert providers of impending decompensation.
- Proactive systems that incorporate device-based continuous monitoring are more likely to enter the progression with an instrument that has higher sensitivity and specificity for discovering volume accumulation.
- Common themes of a successful system will require a means to provide device-based data to interested providers who then can interpret the information in the context of either remote or face-to-face clinical assessment.