New Approaches to Monitoring Heart Failure Before Symptoms Appear

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Intrathoracic impedance monitoring (approved by the US Food and Drug Administration) and implantable hemodynamic monitoring (IHM), which is under investigation, are promising techniques for the improved management of heart failure by detecting early changes in fluid status or hemodynamic congestion. Routine outpatient surveillance of intrathoracic impedance data from implanted devices may significantly reduce the currently high rates of hospital admission/readmission for patients with heart failure. IHM systems may extend such monitoring capabilities. Both emerging approaches for monitoring patients with heart failure may alert clinicians (and possibly patients) to impending decompensation before symptoms appear.
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Despite contemporary evidence-based management, heart failure morbidity and mortality remain high.[1] Based on New York Heart Association class ranking, functional status remains poor in 30% to 40% of patients with heart failure. Hospital admission/readmission rates for heart failure remain unacceptably high. For example, readmission rates at 2 days, 1 month, and 6 months following a hospitalization for heart failure are 2%, 20%, and nearly 50%, respectively. Evidence suggests that these high rates of hospitalization are due, in large part, to a failure to recognize impending episodes of heart failure decompensation until the opportunity for outpatient intervention has been lost and to inadequate inpatient diuresis during hospitalization.[2,3] Given the shortcomings of currently available approaches to monitoring and managing heart failure, several new approaches have been developed over the past few years. In

particular, implantable devices and new device features have been developed to improve the detection of worsening heart failure before symptoms occur. These approaches to heart failure assessment are predicated on the observation that there may be a prolonged period of slow deterioration (ie, fluid retention and development of hemodynamic congestion) over days to weeks before symptomatic congestion and subsequent overt decompensation ensue.[2]

If the latter observation is correct, it raises the following question: Can implantable monitors predict worsening heart failure? For this to be true, there must be an asymptomatic period of time when fluid retention occurs and is detectable, in some way, on a chronic outpatient basis and heralds the onset of an acute episode of decompensation. While traditional approaches to monitoring patients with heart failure (eg, assessment of daily weights) have failed to improve hospitalization rates,[4] two new ways of detecting such a change in fluid status or hemodynamic congestion (ie, increased ventricular filling pressures) are showing promise. These two new approaches include the use of either intrathoracic impedance monitoring or implantable hemodynamic monitoring (IHM) systems. If, in fact, these approaches accurately monitor clinical status in patients with heart failure and the aforementioned question is answered in the affirmative, another question follows: Can we use such technology to prevent hospitalizations for heart failure exacerbations? This article examines the potential roles of intrathoracic impedance monitoring (approved by the US Food and Drug Administration [FDA]) and IHM (under investigation) for the management of heart failure and attempts to answer these questions, based on currently available data.

Monitoring Patients with Heart Failure

Traditionally, clinicians have relied solely on subjective reports of signs, symptoms, and physical limitations, with or without access to daily weights, to monitor patients with heart failure. Unfortunately, these signs and symptoms, such as dyspnea, edema, fatigue, and exercise intolerance, have poor sensitivity and specificity for worsening heart failure, and their absence does not exclude the presence of elevated pulmonary capillary wedge pressures (ie, hemodynamic congestion).[5,6] Moreover, the use of daily weight monitoring, even when automated by a home monitoring system, does not prevent episodes of worsening heart failure requiring hospitalization.[4] This may be one reason why hospitalization rates for heart failure remain so high, despite having therapies that effectively improve the natural history of the disorder. That is, our ability to determine the likelihood of episodes of worsening heart failure is poor, as we cannot easily determine whether patients are "wet" or "dry," and late recognition of worsening signs and symptoms—particularly of congestion—precludes the opportunity for early intervention.

Furthermore, the majority of patients are hospitalized with heart failure exacerbations present with signs and symptoms of congestion, with normal blood pressures.[3] In fact, approximately 90% of patients admitted to the hospital for heart failure are judged to be wet,[3] yet most provide too little warning of volume overload for adequate outpatient intervention. It is also discouraging that during the course of "aggressive" inpatient treatment, suboptimal weight reductions are achieved, with more than 50% of patients either gaining weight or losing just 5 pounds or less during their hospitalizations, suggesting that our ability to estimate how wet patients are is also poor.[3] Although they appear improved, many patients are discharged with signs and symptoms related to pulmonary congestion that are not being identified clinically.[3] This may explain, in part, the very high readmission rates following hospitalization for heart failure. Thus, a better approach is needed for monitoring patients with heart failure, in and out of the hospital, to provide clinicians with the objective information necessary to optimize our medical treatments and best meet treatment goals.

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Intrathoracic Impedance Monitoring

The concept behind intrathoracic impedance monitoring is as follows: (1) electricity travels better through water (a conductor) than through air (an insulator); (2) as the lungs take on water during fluid retention or worsening hemodynamic congestion, impedance to the flow of electricity from a pacemaker or defibrillator lead implanted in the heart to the pacemaker or defibrillator device generator (or "can") is reduced; (3) this fall in intrathoracic impedance can be measured and compared with the patient's own baseline and

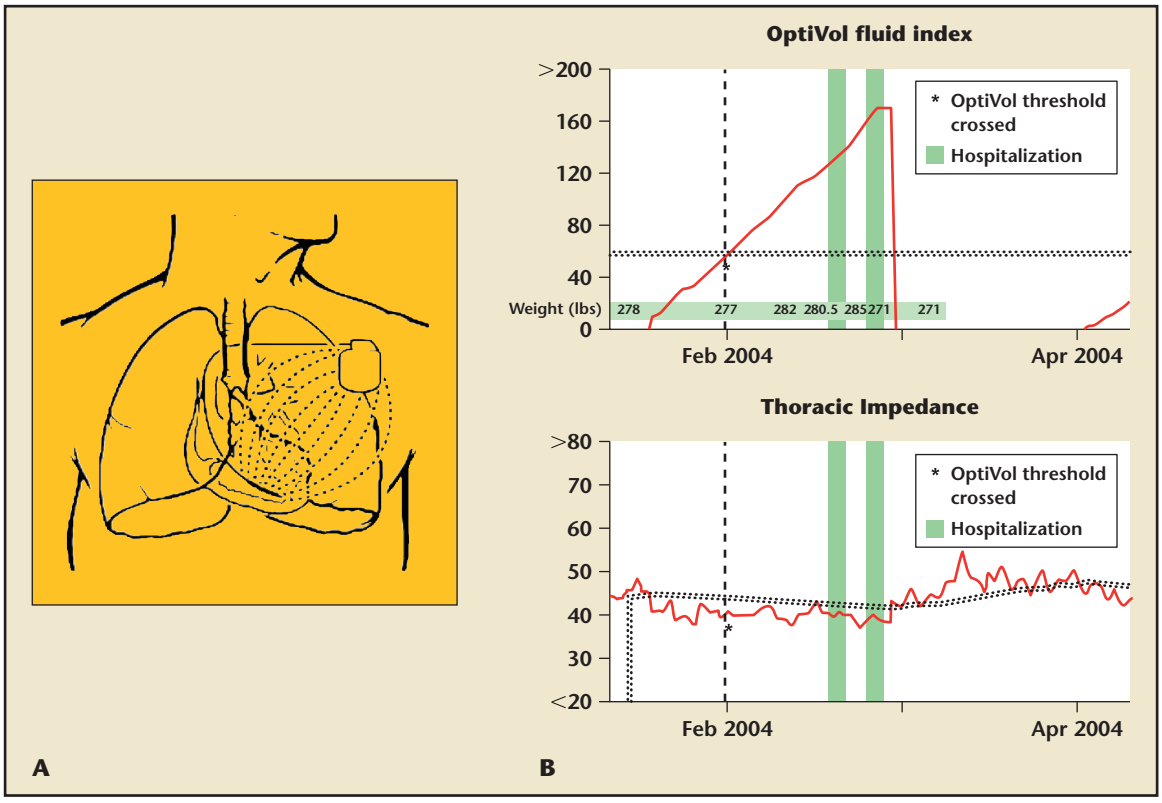

Figure 1. A. *A device for measuring intrathoracic impedance.* **B.** *Case example of a sustained change (decrease) in impedance preceding a heart failure hospitalization.*

used as a measure of change of clinical status. Figure 1 demonstrates this concept of intrathoracic impedance, as measured with an implanted device. In addition, this figure shows a single-case example of a sustained change (decrease) in impedance leading up to a heart failure hospitalization. This case is discussed in more detail below.

With this approach, intrathoracic impedance is assessed at multiple times throughout the day and is averaged and then graphed longitudinally over time. The raw impedance data may be displayed and viewed as a way to assess changes in intrathoracic fluid status and left ventricular filling pressure. Although changes in the impedance value correlate well with changes in left ventricular filling pressure, the ability to determine an absolute value for left ventricular filling pressure is currently limited. The impedance changes can also be analyzed mathematically to increase the value of the data. This approach, using an automated detection algorithm for impedance changes to indicate potential episodes of worsening heart failure, is also discussed below.

Several lines of evidence support the use of intrathoracic impedance as a measure of clinical status in heart failure and as an indicator of worsening episodes of heart failure. Animal studies provided early proof of the concept, by demonstrating that impedance values changed as expected with changes in ventricular filling pressures. These animal studies were followed by a landmark proof-of-concept study in humans, the Medtronic Impedance Diagnostics in Heart Failure Trial (MIDHeFT).[7] In their study of 33 patients, Yu and colleagues found that 10 patients had 25 hospitalizations for fluid overload. A detectable decrease in intrathoracic impedance was seen about 2 weeks before hospitalization for worsening heart failure. In contrast, worsening heart failure signs and symptoms were not reported until 2 to 3 days, on average, before the event. Thus, intrathoracic impedance performed much better than

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signs and symptoms in providing an early indication of impending heart failure decompensation.

In addition, the MIDHeFT study demonstrated a good correlation between fluid removal during treatment of decompensation with diuretics during hospitalization (as seen by a reduction in the pulmonary capillary wedge pressure and net fluid intake and output record) and the intrathoracic impedance at admission ($R = -0.7$, $P < .001$). This latter observation suggests that intrathoracic impedance may be a useful adjunct to routine clinical assessment in guiding diuresis during hospitalization. This possibility is important clinically, given the aforementioned high rate of inadequate diuresis during heart failure hospitalization. A tool that enabled clinicians to better determine how much fluid volume overload is present at admission and to observe it over time might facilitate adequate diuresis and help avoid under- or over-diuresis.

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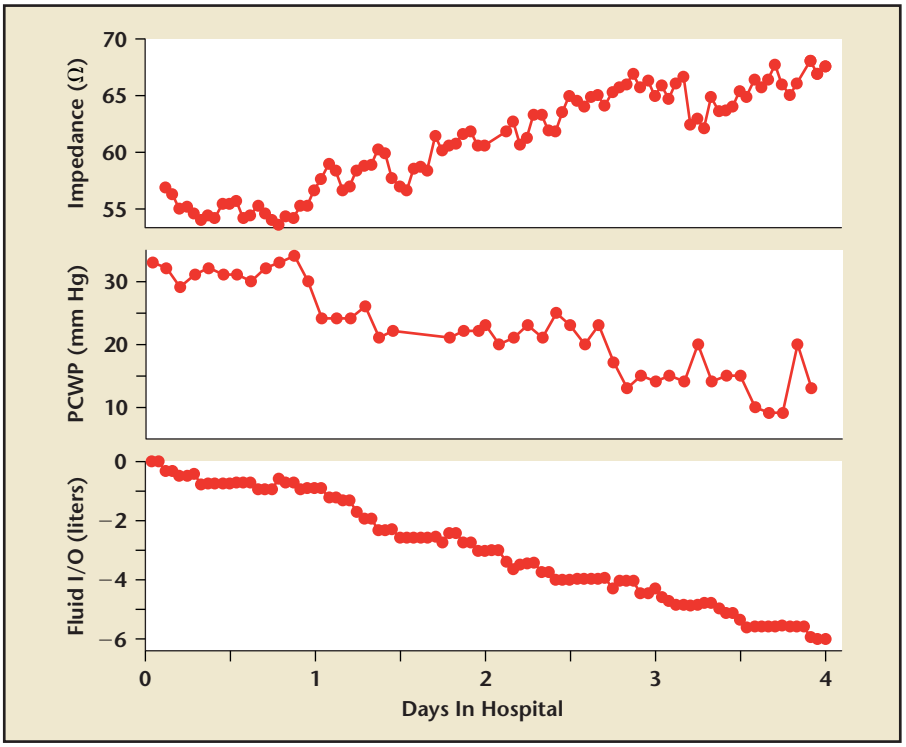
An example from the MIDHeFT trial illustrates the potential inpatient utility of intrathoracic impedance monitoring. Figure 2 shows, from top to bottom, changes in impedance, changes in pulmonary capillary wedge pressure, measured with a Swan-Ganz catheter, and the net fluid intake and output of a patient over a 4-day period of hospitalization and diuresis. As the middle and bottom panels of the figure show, this patient underwent a diuresis resulting in a net negative fluid balance of approximately 6 liters over the 4 days of hospitalization. This was associated with a very significant and progressive fall in the pulmonary capillary wedge pressure, as would be expected. In addition, as shown in the top panel, there was an associated increase in the impedance level indicating that the lungs were getting drier during this period of diuresis. In this example, the correlation between the improvement in impedance and the fall in pulmonary capillary wedge pressure is striking. This result is indicative of the larger MIDHeFT experience. It suggests that changes in intrathoracic impedance may be used to monitor the adequacy of diuresis during treatment of volume-overloaded patients.

For patients who already have implanted devices with impedance monitoring capabilities, this approach may prove to be acutely less invasive and thus possibly safer, as well as useful in guiding treatment—particularly diuretic therapy.

For the management of chronic heart failure, an automatic algorithm has been developed, using intrathoracic impedance information, to indicate worsening heart failure. This algorithm was developed with data from the MIDHeFT trial. The OptiVol® fluid index (Medtronic, Inc., Minneapolis, MN) represents the accumulation of consecutive day-to-day differences between the Daily and computed Reference impedance values. (The initial Reference value is calculated as a 4-day average of raw impedance values, and later, Reference values show

Figure 2. *Changes in impedance (top panel); pulmonary capillary wedge pressure (PCWP), measured with a Swan-Ganz catheter (middle panel); and net fluid intake and output (I/O; bottom panel) of a patient with an intrathoracic impedance monitoring device, over a 4-day period of hospitalization and diuresis.*



directional changes of the Daily impedance values.) As the impedance falls and remains below the reference value for some days, an elevation is seen in the OptiVol fluid index (Figure 1). When Daily impedance increases above the Reference impedance, the OptiVol fluid index resets to zero. However, because the algorithm was developed to identify episodes of volume overload, only positive deflections are seen in the fluid index. The index may return to zero, indicating that the impedance value has returned to above the Reference value, but it will not fall below zero because it has not been tested against volume depletion or dehydration events. Applying this algorithm retrospectively to Yu and colleagues' data[7] allowed the ascertainment of a cut-off value (OptiVol fluid index $>$ 60 Ohm-days) that indicated impending hospitalization events 76% of the time with only 1 false alarm every 322 days. Thus, as a diagnostic test, in this study the OptiVol fluid index performed well in indicating events.

Of course, additional prospective validation of the algorithm and cut-off value is needed, and studies are underway to evaluate this. For example, the Fluid Accumulation Status Trial (FAST)[8] has reported preliminary findings consistent with those in the MIDHeFT, and larger ongoing studies will evaluate the potential of the OptiVol fluid index not only to indicate the likelihood of episodes of worsening heart failure but also to prevent them. Finally, since the time of FDA approval of the intrathoracic impedance monitoring feature, a wealth of useful case examples have accumulated that also demonstrate how intrathoracic impedance monitoring may be used in heart failure management.

A series of case examples illustrate the clinical utility of intrathoracic impedance monitoring. In addition to demonstrating the concept of intrathoracic impedance monitoring, Figure 1 depicts plots of impedance and the OptiVol fluid index over a period of months in a heart failure patient implanted with a combined cardiac resynchronization therapy–implantable cardioverter defibrillator (CRT-ICD) device with impedance monitoring capabilities. At the time of implantation, the impedance monitoring feature was investigational, so the impedance data derived from the device were not available to guide clinical management. As shown, the impedance value fell below the reference line for many days before the first hospitalization (depicted by the first shaded vertical bar). This resulted in a progressive increase in the OptiVol fluid index over time. Around the first of February, in this example, the OptiVol fluid index cut-off of 60 was crossed. At this time, the patient had no signs or symptoms of worsening heart failure, and his weight remained stable at its presumed baseline (ie, dry weight) of around 277 pounds.

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About 3 weeks later, the patient developed increased shortness of breath and fatigue, abdominal bloating, and paroxysmal nocturnal dyspnea, and he was hospitalized. Thus, impedance monitoring interpreted according to the algorithm derived from the MIDHeFT trial was capable of indicating this hospitalization, offering an opportunity for early intervention even without any signs and symptoms of congestion or changes in weight. The patient's weight was 282 pounds at the time of admission, a gain of 5 pounds from his dry weight. Based on history, physical examination, weight change, and a mildly elevated B-type natriuretic peptide level, the patient was judged to be "mildly wet" and treated with intravenous diuretic therapy, resulting in a 1.5 pound reduction in weight. He was discharged home after 3 days. However, as revealed by impedance monitoring (viewed retrospectively), his congestion was not resolved. Specifically, the raw impedance values remained below baseline, and the fluid index remained substantially elevated and above the cut-off indicating worsening heart failure. Thus, it is perhaps not surprising that the patient experienced increased symptoms that resulted in rehospitalization a week later.

Clinically, it was then appreciated that he was more substantially hypervolemic than believed before, and more aggressive treatment with intravenous diuretics was initiated. This time, he experienced weight loss of about 14 pounds and was eventually discharged home, symptom-free. It is worth noting that his discharge weight of 271 pounds was substantially lower than his previously presumed dry weight of 277-278 pounds.

This case illustrates two common clinical scenarios: a worsening of heart failure that seems to result in an unavoidable hospitalization and an incomplete treatment of the hypervolemic state during hospitalization, resulting in early rehospitalization. It also demonstrates the limitation of

daily weights, particularly when the dry weight is wrongly presumed or unknown. There are many possible explanations for this common clinical situation of hospitalization and rehospitalization for heart failure, including process issues (hospital bed shortages, nursing shortages), financial aspects (reimbursement issues surrounding length of stay and rehospitalization within 30 days), or clinical judgments and decisions (patient looks and feels better, weight has decreased). Use of objective impedance data from an implanted device, rather than weight change and symptoms, might have prevented not only the first but also the second hospitalization, since fluid status could have been monitored daily and treatment adjusted accordingly on both an inpatient and outpatient basis.

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The second case reviews a situation in which the intrathoracic impedance fell rather precipitously. It illustrates how the totality of diagnostic information available through interrogation of an implanted device (again, in this case, a CRT-ICD device) may be used to understand an episode of worsening heart failure. Figure 3 shows that the patient was initially doing quite well. The Daily impedance value tracked closely with its reference line, and the patient was asymptomatic. Then suddenly, within a single day, there was an abrupt fall in the impedance value and a marked increase in the fluid index to a value above the cut-off threshold. This was associated with acute and persistent worsening of shortness of breath over the next few days, but no chest pain, palpitations, or other cardiac symptoms. Eventually, the patient was hospitalized due to this deterioration of his clinical status.

What clinical event caused such an abrupt change in the impedance value and fluid index? Clues to help answer this question may be found through inspection of additional data obtained from implantable devices. On closer investigation of this case, it was found that there was a 30- to 36-hour period of atrial fibrillation associated with a rapid ventricular response (Figure 4). At the time the patient arrived at the emergency department, the atrial fibrillation had resolved, so the apparent precipitant of this episode of worsening heart failure may have been missed by the treating physicians. This may be what happens to many of our patients when they present with worsening heart failure, and no obvious precipitating cause is discovered at presentation. In this case, the arrhythmia broke spontaneously and the patient's clinical status began to return to baseline. However, shortness of breath persisted, resulting in the hospitalization.

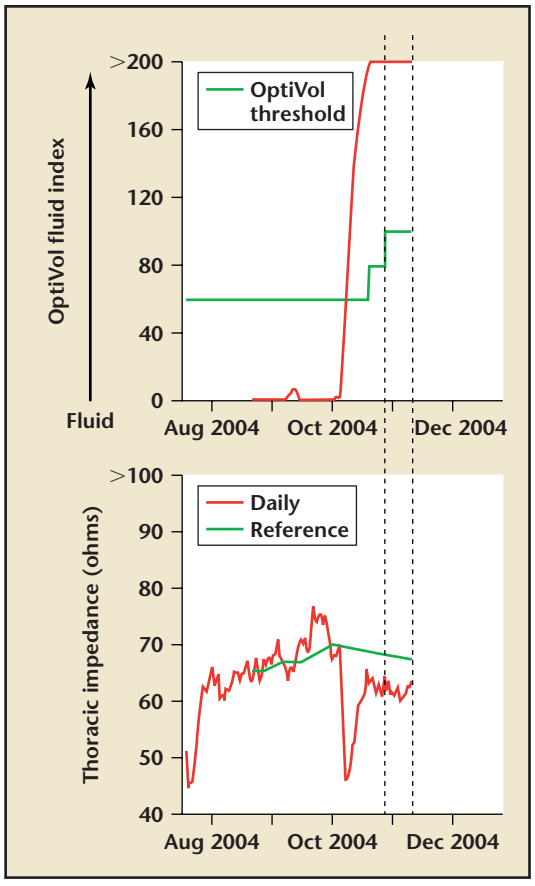

Figure 3. *Changes in intrathoracic impedance measured by an implanted device, showing an episode of worsening heart failure. Top shows OptiVol fluid index, and bottom shows thoracic impedance.*

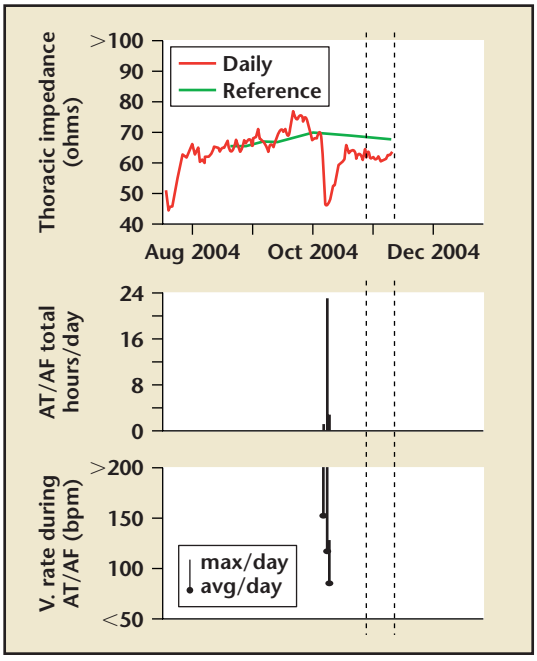

Figure 4. *Further data on the same patient shown in Figure 3, showing a period of atrial fibrillation (AT/AF) associated with a rapid ventricular response (V rate).*

In addition to monitoring atrial and ventricular rhythm and rate data, some implantable devices provide information on heart rate variability, patient activity level, and a variety of other parameters that may prove useful in evaluating clinical status in heart failure.[9]

Implantable Hemodynamic Monitoring

Beyond impedance monitoring, the next generation of implantable devices includes hemodynamic monitoring. In addition to providing early warning of decompensation, these devices may hold the potential to provide a tool for the day-to-day management of heart failure patients. Several IHM devices and systems are currently under investigation; none are currently approved by the FDA. These devices allow either continuous or intermittent assessment of hemodynamics, generally focused on the direct measurement or estimation of left-sided filling pressure. One such monitor, the Chronicle® IHM (Medtronic, Inc.), has undergone extensive evaluation in clinical trials, where it has been shown to be safe, to provide an accurate estimate of left ventricular filling pressure, and to reduce the number of worsening heart failure events.[2,10,11] This system uniquely enables the continuous assessment of cardiac hemodynamics and provides the collected information to the clinician via a secure website. Other systems look to empower patients to self-manage left ventricular filling pressure, not unlike the way diabetics self-manage their glucose levels through the use of a glucometer. The potential for these investigational devices to revolutionize the management of heart failure is substantial.

A closer look at how the Chronicle IHM functions provides further support for the potential of this system to enable better monitoring and management of heart failure. The Chronicle IHM looks like a pacemaker but is in fact a dedicated monitoring device. Its single lead resides in the right ventricular outflow track, continuously measuring numerous hemodynamic parameters. It is used in conjunction with a system that transmits the information to a secure website, enabling remote access to the clinician. The device measures right ventricular systolic and diastolic pressures, and provides an estimate of the pulmonary artery diastolic pressure, which in turn is a proxy for left ventricular filling pressure. A variety of other parameters, such as core body temperature, patient activity level, heart rate, and indices of right ventricular contractility are also measured. These data can be viewed by clinicians via the internet and then used in performing clinical assessments and making management decisions. Early clinical studies involving this hemodynamic monitoring system sought to support its validity, demonstrating that it accurately measures pressures and that accuracy is maintained over time. It has also been studied in observational proof of concept trials, demonstrating that one can use this device to better manage patients, to improve their symptoms, and to reduce the risk of heart failure hospitalization.[2,10] Finally, preliminary data from a 274-patient randomized, controlled trial support the potential utility of this approach.[11]

A case example of how one might use this IHM system to better manage patients with heart failure demonstrates this potential utility. The patient was randomized to the blinded-care arm of the aforementioned randomized controlled trial. This meant that the clinician did not have access to the IHM data during the randomized follow-up period. The patient called her heart failure nurse practitioner 5 days after

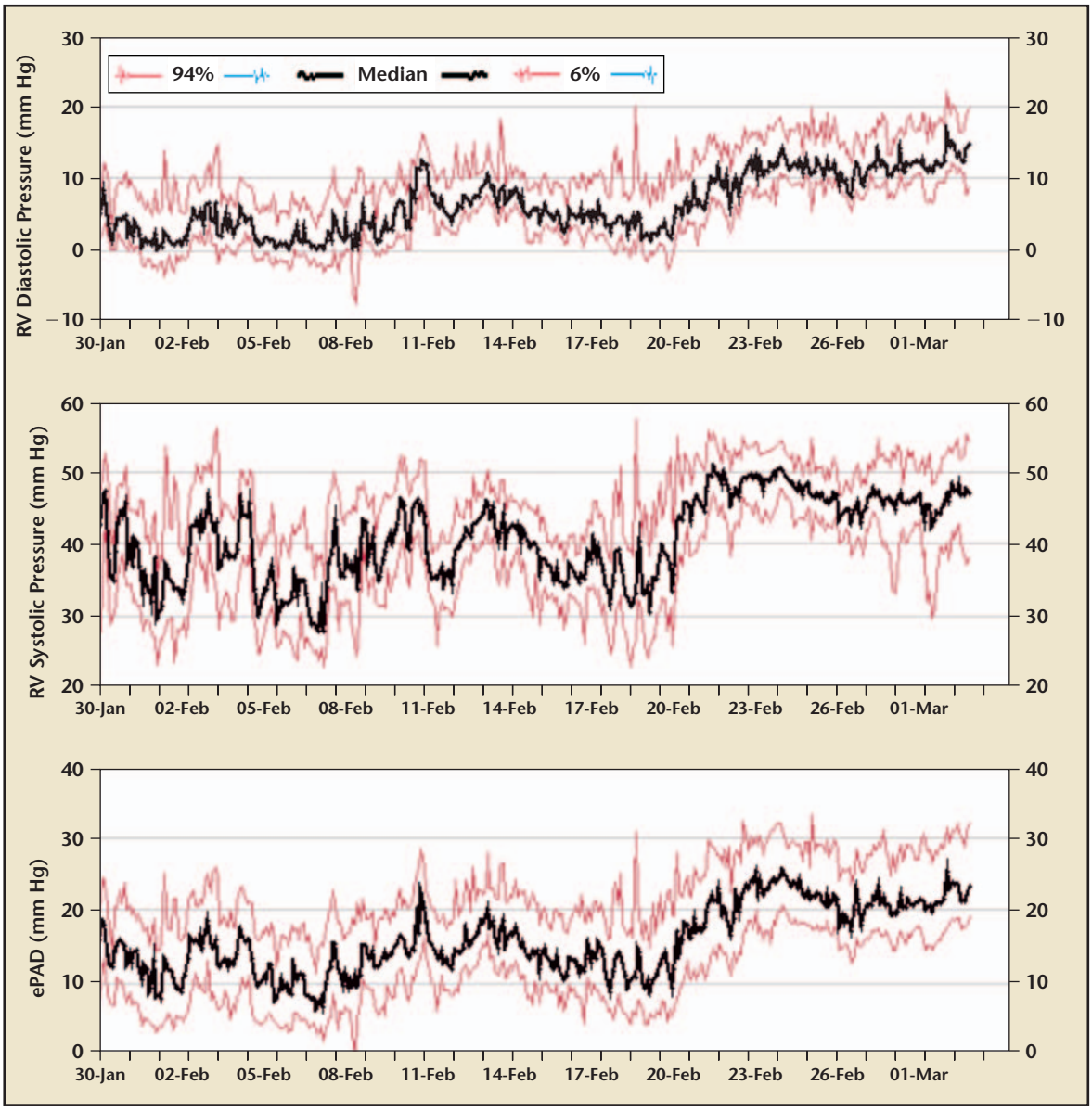

Figure 5. *Data from an implantable hemodynamic monitoring system, showing an upward trend in ventricular filling pressures, beginning soon after Valentine's Day. RV, right ventricular; ePAD, estimated pulmonary artery diastolic pressure.*

Valentine's Day, complaining of severe bloating and increased shortness of breath. Of note, her weight was stable. She was asked to transmit hemodynamic data to the secure website and to visit the clinic for an unscheduled (urgent) visit. The data were analyzed only in retrospect because, as mentioned, the patient was randomized to the blinded arm of the study. Inspection of the hemodynamic data showed an upward trend in ventricular filling pressures, beginning soon after Valentine's Day (Figure 5).

What happened? The patient had celebrated Valentine's Day by going out to dinner at an Indian restaurant. She was very thirsty over the next few days, resulting in an increase in her fluid intake, leading to cardiac decompensation. Following the clinic visit, her diuretic dose was increased and her filling pressures returned to her previously compensated baseline. Armed with this hemodynamic information in advance

of clinical deterioration, clinicians may be able to avert episodes of worsening heart failure altogether.

Summary

Assessment of volume status and ventricular filling pressures in heart failure using traditional methods can be quite challenging, because they are both insensitive and nonspecific. Routine outpatient surveillance of intrathoracic impedance data obtained from implanted devices, in combination with symptoms and laboratory tests, may significantly reduce hospitalizations for decompensated heart failure. This hypothesis is being tested in large-scale prospective randomized controlled trials. IHM systems may extend such monitoring capabilities, through the direct and objective assessment of ventricular filling pressures. Both emerging approaches for monitoring patients with heart failure may alert clinicians (and possibly patients) to impending decompensation even before symptoms appear. ■

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Main Points

- Hospital admission/readmission rates for heart failure remain unacceptably high due, in large part, to a failure to recognize impending episodes of heart failure decompensation and to inadequate diuresis during hospitalization.
- New implantable devices have been developed to improve the detection of worsening heart failure during the period of slow deterioration before symptoms and subsequent overt decompensation ensue.
- Intrathoracic impedance monitoring provides raw data on intrathoracic fluid status and left ventricular filling pressure. Impedance changes can also be analyzed mathematically to increase the value of the data.
- In the MIDHeFT trial, intrathoracic impedance performed much better than signs and symptoms in providing early warning of impending heart failure decompensation.
- The MIDHeFT study also demonstrated that intrathoracic impedance may be a useful adjunct to routine clinical assessment in guiding diuresis during hospitalization.
- An automatic algorithm has been developed using intrathoracic impedance information to indicate worsening heart failure; the OptiVol fluid index represents the accumulation of consecutive day-to-day differences between daily and computed reference impedance values.
- Applying the algorithm retrospectively to the MIDHeFT study data allowed the ascertainment of a cut-off value (OptiVol fluid index > 60) that indicated 76% of hospitalization events with only 1 false alarm every 322 days.
- The next generation of implantable devices include hemodynamic monitoring systems; in addition to providing early warning of decompensation, these devices may provide a day-to-day management system for heart failure.
- The Chronicle Implantable Hemodynamic Monitoring system enables the continuous assessment of hemodynamics and provides this information to the clinician via a secure website, providing an accurate estimate of left ventricular filling pressure.