Case Studies in Advanced Monitoring With the Chronicle® Device

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Three case studies illustrate the utility of advanced implantable hemodynamic monitors (IHMs). The cases include a 70-year-old with ischemic cardiomyopathy, chronic kidney disease, and recurrent volume overload; a 53-year-old with ischemic heart disease, mild effort-related angina, and New York Heart Association class III chronic heart failure; and a 21-year-old with severe dilated cardiomyopathy, all 3 patients having an IHM. The outcomes in these cases illustrate the capability of the IHM system for monitoring and detecting early changes in hemodynamic data and the use of these data to adjust medical therapies and reduce morbidity and risk of hospitalization. When pathologic hemodynamic changes are observed, this alerts the cardiologist to search for underlying causes, even when a patient on initial questioning denies any change in compliance or symptoms.
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Case 1

A 70-year-old man with ischemic cardiomyopathy, an ejection fraction of 20%, chronic kidney disease (serum creatinine of 2.8 mg/dL), and recurrent volume overload required repeated hospitalizations and emergency department visits. This is a very common clinical scenario, and the outpatient treatment of such labile patients must be carefully customized to avoid even minimal overdiuresis that would lead to an acute exacerbation of chronic kidney disease or undertreatment that would prolong the heart failure state, both of which could require acute care hospitalization. This is one type of patient who benefits from advanced hemodynamic monitoring with the Chronicle® Implantable Hemodynamic Monitor (IHM) (Medtronic, Inc., Minneapolis, MN) to more precisely guide medical therapy.

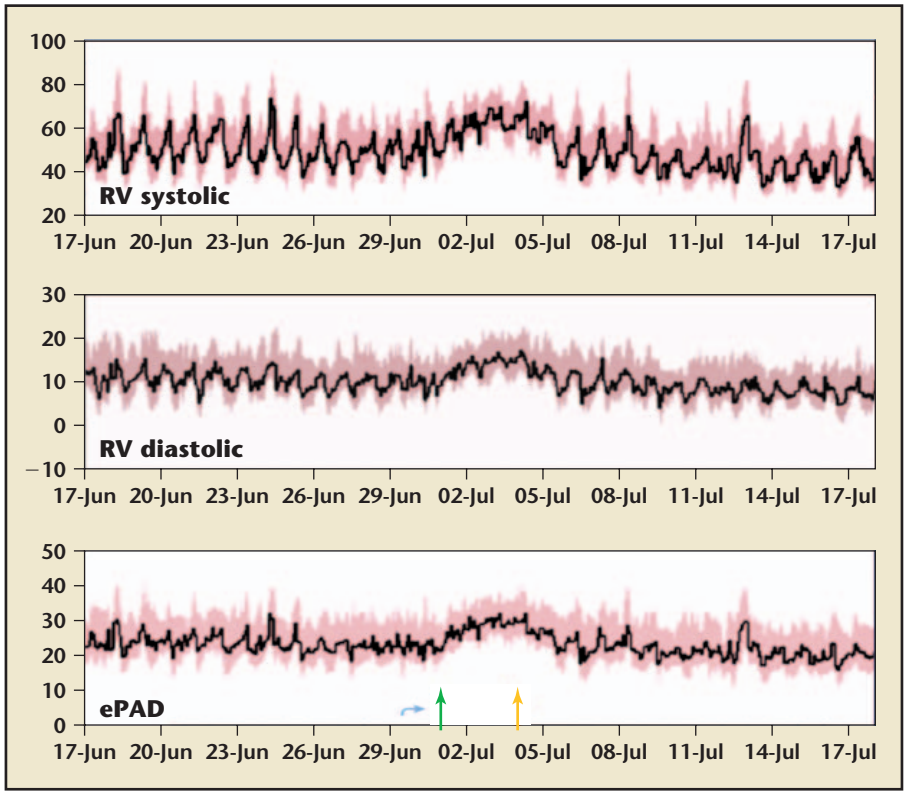


Figure 1. *Case 1: Implanted hemodynamic monitoring data for 1 month from a 70-year-old male patient with ischemic cardiomyopathy, chronic kidney disease, and recurrent volume overload. The green arrow indicates the start of a significant trend of increased right ventricular (RV) systolic, RV diastolic, and estimated pulmonary artery diastolic (ePAD) pressures. The arrows indicate the rise and fall of increased pressures, which occurred during the July 4th holiday weekend.*

Figure 1 shows a full month of some of the hemodynamic trend information for this patient, obtained with the IHM. The green arrow indicates the start of a significant trend of increased right ventricular (RV) systolic, RV diastolic, and estimated pulmonary artery diastolic (ePAD) pressures. Retrospectively we discovered that this coincided with the patient's dietary indiscretion over the July Fourth holiday weekend, including excessive salt and fluid intake. On July 4, 2000, the patient transmitted his pressure data (as our patients are instructed to do intermittently). At that time he reported the onset of a nonproductive cough without associated weight gain, dyspnea, or edema.

An increase in his filling pressures—RV systolic, RV diastolic, and ePAD pressures—was noted and, in response, the treating cardiologist added additional doses of the loop diuretic to the patient's regimen, along with instructions to be more compliant with the salt restriction. The patient's hemodynamics—RV systolic, RV diastolic, and ePAD pressures—responded to this treatment, quickly returning to baseline (Figure 1).

Of note on the hemodynamic tracings are the daily fluctuations commonly observed in patients with severe heart failure. For this patient, we had been able to establish the hemodynamic parameters that represented his unique optivolemic range. For the first 2 to 3 weeks after implantation, RV systolic and diastolic pressures, along with ePAD and other hemodynamic readings, were used in correlation with other IHM data, serum markers of renal function, and symptom status to establish this range; his optivolemic ePAD was 20-25 mm Hg. If his pressures dropped below this optivolemic level, hypoperfusion was observed, including symptoms of dizziness and fatigue and elevated serum creatinine levels into the 3.5-4.5 mg/dL range, from a baseline of 2.8 mg/dL. By maintaining his established optivolemic range, we were able to optimize his symptoms and renal function.

Figure 2 shows another 1-month pressure trend for the same patient. At a clinic visit on July 18 (green arrow at bottom left), he complained of a slight increase in exercise-induced angina, or at least perceived anginal symptoms, prompting us to increase his dose of β-blocker. Subsequently, as expected, his heart rate gradually decreased. His increased β-blocker use was accompanied by a gradual but consistent rise in RV systolic, RV diastolic, and ePAD pressures. Figure 2 (red arrow) shows the point at which we responded to the hemodynamic changes by recommending a small increase in diuretic and nitrate dose to control his anginal symptoms and lower his filling pressures.

The patient was seen again at the clinic about 6 weeks later, on August 30. On initial questioning, he did not complain of any change in symptoms, but when we reviewed his IHM-derived pressure data, which were uploaded on the morning of the clinic visit, we noted a sudden increase in RV diastolic pressure with a gradual rise in RV systolic pressure on the afternoon of August 26 (Figure 3). There was no change in heart rate. On closer questioning, the patient admitted to the onset of angina-type chest discomfort that evening and for the following 2 to 3 days. With the onset of these symptoms on August 26, he had taken 1 dose of nitroglycerin; then, on the

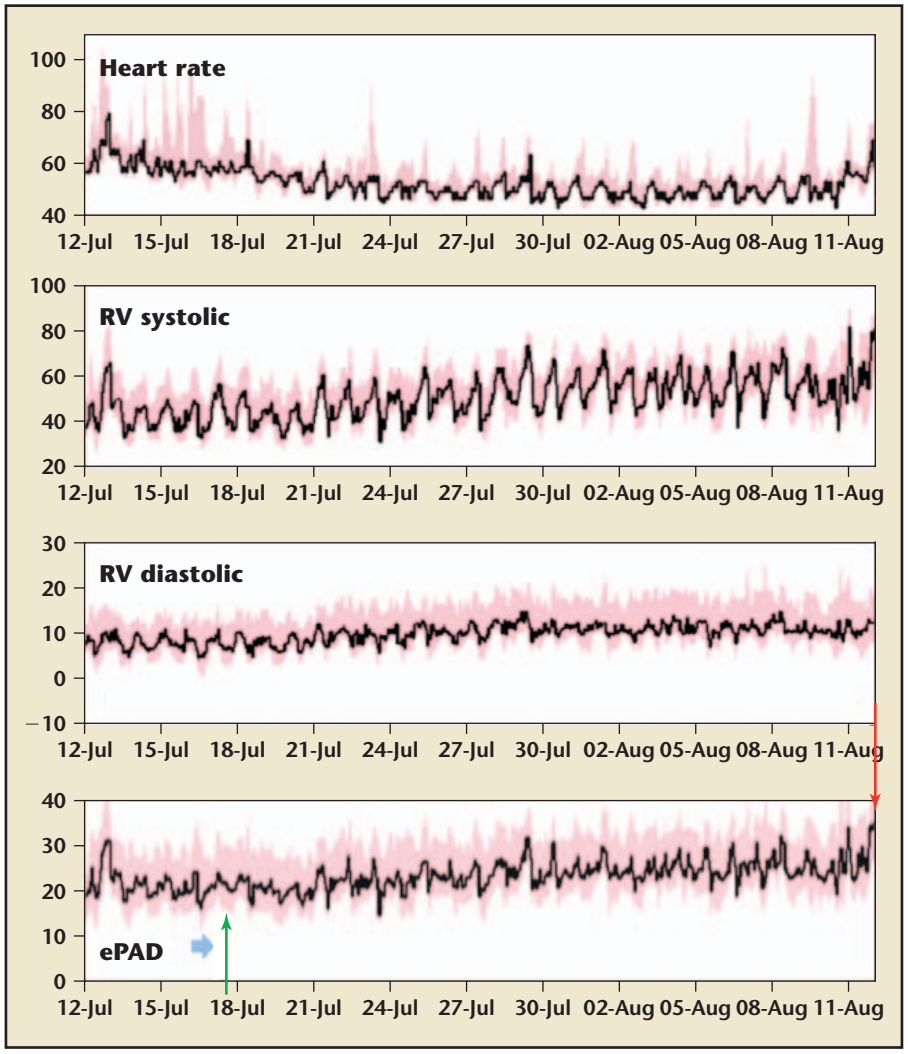


Figure 2. *Case 1: Implanted hemodynamic monitoring data from a 70-year-old male patient with ischemic cardiomyopathy, chronic kidney disease, and recurrent volume overload. His physicians recommended a small increase in diuretic and nitrate dose to control his anginal symptoms and lower his filling pressures. RV, right ventricular; ePAD, estimated pulmonary artery diastolic.*

evening of August 28, because of the persistent anginal symptoms, he tripled the dose of nitroglycerin, along with an extra dose of aspirin, and his symptoms resolved. There is a clear temporal relation between the exacerbation of his coronary insufficiency and the sudden increase in pressures observed in Figure 3, with normalization of filling pressures when his coronary insufficiency was adequately treated. Interestingly, his electrocardiogram showed new Q-waves inferiorly, consistent with possible inferior wall myocardial infarction. Because by that time he had been pain free for 2 days, he refused to be admitted to the hospital for further evaluation.

Having access to the hemodynamic data allowed us to focus our efforts on identifying the underlying events responsible for the pressure changes and thus to target therapy to restore his baseline state. During the year since this patient received the IHM device, giving his physicians access to the hemodynamic information that allows optimal medical therapy, he was able to avoid emergency department visits and hospitalization for heart failure exacerbations.

Case 2

A 53-year-old man with ischemic heart disease, mild effort-related angina, and New York Heart Association (NYHA) class III chronic heart failure symptoms underwent implantation of the IHM system. With adjustments to his medications guided by IHM data, his heart failure symptoms improved to NYHA II, with no further anginal episodes. In fact, despite having ischemic disease, he had only a slight medical history of angina at any time. As in many patients with chronic heart failure, we noted that relatively high filling pressures (ePAD $\approx$ 25 mm Hg) were needed to maintain his optivolemic state—minimizing his signs and symptoms of low cardiac output, fatigue, worsening renal function, and volume overload, particularly dyspnea.

During a routine clinic visit, the patient denied any change in his baseline symptoms, but on careful questioning about his medical regimen he admitted to taking occasional extra doses of furosemide as needed (as instructed), usually on weekends. When we reviewed his IHM-derived pressure tracings, the expected daily fluctuations in RV diastolic and ePAD pressures were noted. On closer examination, we saw a pattern of pressure elevations occurring at 7-day intervals (Figure 4, orange arrows).

After more careful questioning we discovered that the patient was usually taking his extra furosemide on Saturday or Sunday morning, after going out with a new girlfriend. It turned out that his girlfriend liked Chinese food. He would go to dinner

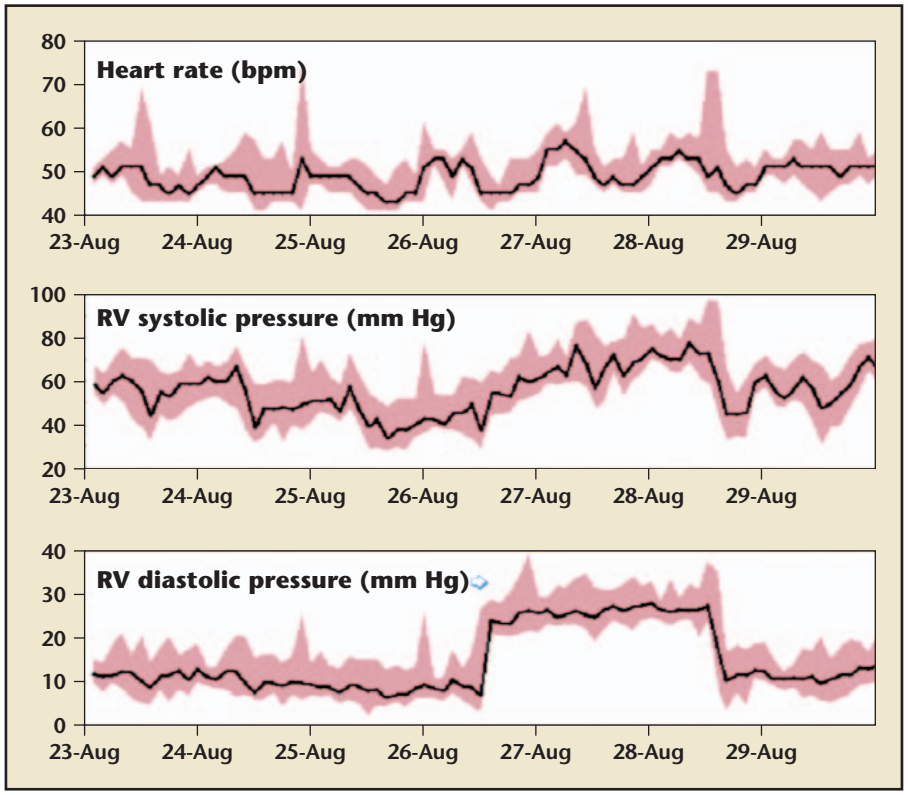
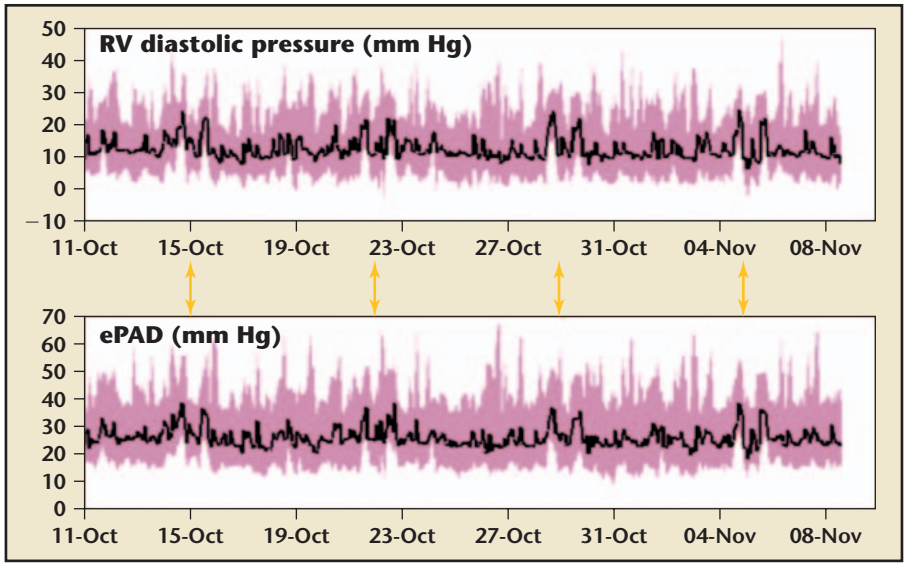


Figure 3. *Case 1: Implanted hemodynamic monitoring data from a 70-year-old male patient with ischemic cardiomyopathy, chronic kidney disease, and recurrent volume overload. This report shows a sudden increase in RV diastolic pressure (blue arrow) with a gradual rise in RV systolic pressure. RV, right ventricular; ePAD, estimated pulmonary artery diastolic.*

Figure 4. *Case 2: Implanted hemodynamic monitoring data from a 53-year-old male patient with ischemic heart disease, mild effort-related angina, and NYHA (New York Heart Association) class III chronic heart failure symptoms. Report shows a pattern of pressure elevations occurring at 7-day intervals. RV, right ventricular; ePAD, estimated pulmonary artery diastolic.*



with her, eat high-salt foods, become volume-overloaded, and then self-medicate with additional doses of furosemide. Fortunately, with more detailed instructions from us, he cut back on the salt intake and stopped these fluctuations in his hemodynamics and symptomatology. He admitted that this improved his weekends, because after eating less salty food he was not short of breath.

Case 3

A 21-year-old woman with severe dilated cardiomyopathy was receiving therapy aided by IHM monitoring. She contacted us on December 16 with worsening symptoms of heart failure and volume overload. She was told to report to the emergency department, but she refused to do so because it was the Christmas holidays. We recommended that she take an extra dose of metolazone and told her to call if she did not improve, and we asked her to call in her IHM-derived hemodynamic data in 3 days. Unfortunately, she did not comply with our requests and we did not hear from her until December 28. On reviewing the IHM-derived hemodynamic data (Figure 5) we saw that her use of the additional metolazone (green arrow) led to a gradual decrease in RV systolic and diastolic pressures. However, soon after, the pressures started to rise again.

On December 28 (Figure 5, green line), the patient called with complaints of increased dyspnea. Some very ominous signs were noted on her IHM data: a drop in heart rate and, very important, a drop in RV pulse pressure. Our experience with many patients monitored by IHM has shown that this syndrome almost always indicates a severe metabolic abnormality, usually hyperkalemia. The patient initially refused to come to the hospital, but relented when her condition continued to

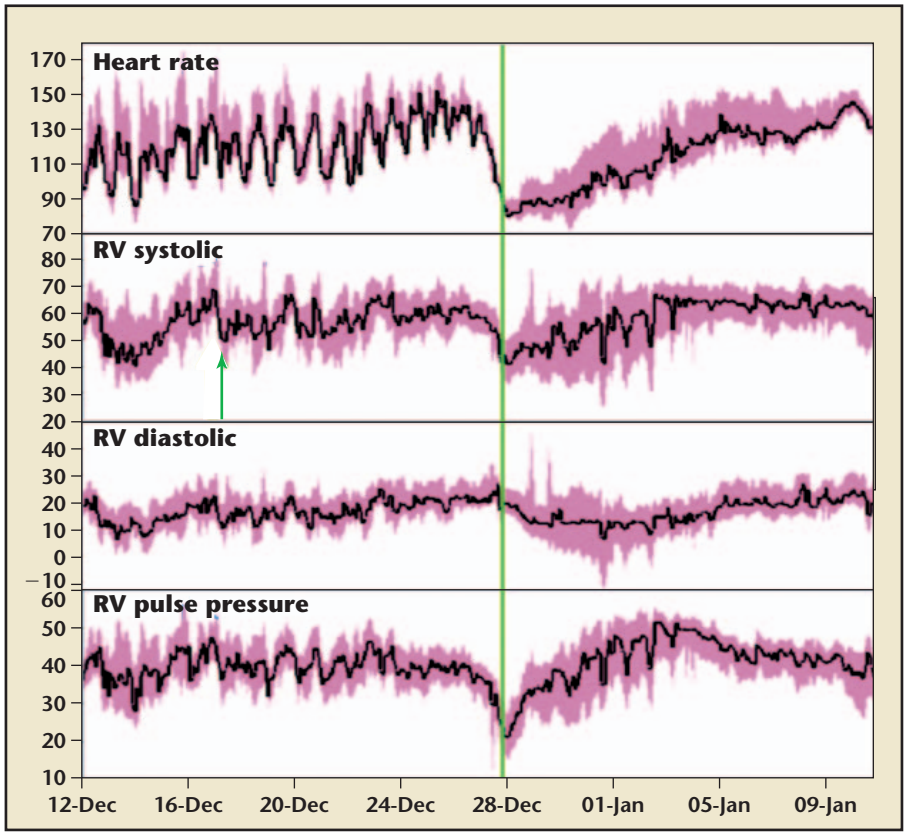


Figure 5. *Case 3: Implanted hemodynamic monitoring data from a 21-year-old female patient with severe dilated cardiomyopathy. RV, right ventricular.*

deteriorate. She arrived at the emergency department in cardiogenic shock with renal and liver failure (shock liver).

We initiated aggressive resuscitation efforts, including high-dose intravenous inotropic therapy and dialysis. She survived this episode, and, because of her age and continued signs and symptoms of end-stage heart failure, a left ventricular assist device (LVAD) was placed. After demonstrating compliance for more than 6 months with the LVAD, she underwent cardiac transplantation. We believe that the data from the IHM device gave us an important early warning, which probably saved her life. Without our insistence that she come to the hospital, based primarily on seeing her drop in heart rate and pulse pressure, she probably would have died.

Summary

These cases illustrate the early warning capability of the IHM system and its ability to allow physicians to

Main Points

- An implantable hemodynamic monitor (IHM) system allows monitoring of hemodynamic data that enables the physician to detect early changes, adjust medications, and advise on compliance with dietary restrictions.
- In a 70-year-old man with ischemic cardiomyopathy, chronic kidney disease, and recurrent volume overload, IHM data were used to establish a unique optivolemic range. It was then possible to optimize his symptomatic state and renal function by maintaining this baseline. With changes in the hemodynamic data, the treating physician could identify the underlying event and target therapy to restore his baseline state.
- In a 53-year-old man with ischemic heart disease, mild effort-related angina, and New York Heart Association class III chronic heart failure symptoms, a pattern of pressure elevations that deviated from his optivolemic state alerted the physician to a pattern of dietary indiscretions, which were then corrected.
- In a 21-year-old woman with severe dilated cardiomyopathy, ominous signs noted on her transmitted IHM data—a drop in heart rate and in right ventricular pulse pressure—alerted her physicians to the seriousness of her condition. Intervention based on data from the IHM was probably life saving.
- These cases illustrate the utility of the IHM as an early warning system, allowing response to hemodynamic exacerbations before clinical deterioration occurs. When pathologic hemodynamic changes are observed, it alerts the treating physician to search for underlying causes, even when the patient denies any change in compliance or clinical status.

more accurately monitor the condition of patients with heart failure and to respond to hemodynamic exacerbations before clinical deterioration occurs. In addition, when pathologic hemodynamic changes are observed, it alerts the treating physician to search for underlying causes, even when the patient on initial questioning denies any change in compliance or clinical status. These cases, then, illustrate the most important use of the IHM system: the ability to adjust medical therapies to make volume adjustments and thus reduce morbidity and the risk of hospitalization for patients with heart failure. ■