Heart failure is a clinical syndrome that affects 5 million persons in the United States and results in substantial morbidity and mortality. Despite advances in pharmacological management, 50% of patients with chronic heart failure will die within 5 years of the diagnosis. The progression of left ventricular dysfunction and severe symptomatic decompensation often requiring hospitalization remain essential features of the heart failure syndrome. Heart failure is responsible for 11 million visits to healthcare providers’ offices, causes or contributes to more than 3.5 million hospitalizations annually, and remains the leading cause of hospitalization for those 65 years or older. The estimated economic burden of heart failure is $20 billion to $40 billion per year. This amount includes the cost of care delivered by healthcare providers, expenses related to hospital and nursing home services, and the cost of medications, home healthcare, and other medical durables.1

Managing patients with heart failure requires an accurate clinical assessment of the patients’ hemodynamic status. Subtle changes in volume status or intracardiac filling pressures may affect functional status, hemodynamic status, ventricular performance, and survival. In particular, elevated filling pressures (ie, increased jugular venous pressure, central venous pressure, right and left atrial and ventricular pressures, and pulmonary artery pressure) may lead to neurohormonal activation, which acts as a compensatory mechanism to support a failing heart. Without appropriate interventions, persistent neurohormonal activation leads to worsening cardiac function and deleterious outcomes of advanced heart failure.1

In order to prevent progression of heart failure, patients require frequent physical examination and judicious monitoring of their hemodynamic status to optimize therapy. Unfortunately, patients with com-

* This article has been designated for CE credit. A closed-book, multiple-choice examination follows this article, which tests your knowledge of the following objectives:
1. Identify nursing care for patients with implantable hemodynamic monitoring systems (IHMSSs)
2. Describe the various implications for the use of IHMSSs
3. Discuss the differences between indirect and direct hemodynamic monitoring and physiological parameters of IHMSSs

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pensated heart failure often do not have physical findings of high filling pressures, so the reliability of the physical examination is limited.\(^2\)\(^4\) Furthermore, the inability to detect worsening heart failure (ie, before a patient experiences dyspnea; gains weight; or has increased jugular venous distension, organ distension, especially in the lungs or liver, and peripheral edema) results in treatment delays or frequent hospital admissions with invasive and expensive therapeutic interventions. Indirect hemodynamic assessment through noninvasive techniques such as echocardiography can provide information on left ventricular ejection fraction as well as qualitative and quantitative measurements of the cardiac structures.

However, direct measurement of hemodynamic parameters via right-sided heart catheterization is the most objective and preferred standard for guiding therapy for heart failure. Right-sided heart pressures provide diagnostic, therapeutic, and prognostic information in the treatment of heart failure. But right-sided heart catheterization is often inconvenient, associated with significant risks, limited to the acute care setting, and only provides data when patients are supine. Consequently, the benefit of a convenient, continuous, objective, and ambulatory method for measuring hemodynamic pressures is widely supported in the management of heart failure therapy.

The Implantable Hemodynamic Monitoring System

The implantable hemodynamic monitoring system (IHMS) known as the Chronicle (Medtronic, Inc, Minneapolis, Minn) measures and records hemodynamic pressures and associated clinical data. The device has most recently completed a multicenter phase 3 clinical trial; approval of the device in 2005 by the Food and Drug Administration is anticipated. The monitoring system consists of an implantable, computerized electrical device, which resembles a pacemaker (the implantable hemodynamic monitor or IHM), connected to a specialized right ventricular lead (Figure 1). The IHM contains a lithium–manganese dioxide power source, integrated circuitry, and a radiofrequency transmission coil sealed in a titanium can. The right ventricular lead is an insulated metal wire with a unipolar pressure sensor tip. An external programmer is used to set the monitor functions. The device can continuously store data or record real-time beat-to-beat signals, providing an instantaneous hemodynamic profile.

Real-time waveform data are accessed via the programmer. Each patient carries a pagerlike device called an external pressure reference that calibrates the IHM to changes in barometric pressure. Additionally, a telephone-sized device called the interactive remote monitor is given to each patient to allow remote (home) data downloads via the telephone to a central computer server. Data analysis can then be done by retrieving the stored data telemetrically via the Internet through a secured access site. Figure 2 shows the components of the IHMS.

Nursing Considerations Associated With Use of the Implantable Hemodynamic Monitoring System

The IHM is implanted via a simple outpatient surgical procedure similar to insertion of a conventional transvenous pacemaker. Patients are given a local anesthetic, and the IHM is implanted in a pectoral pocket of the upper left side of the chest. The right ventricular lead is implanted in the high-velocity blood flow region of the right ventricular outflow tract to minimize development of thrombus or fibrous growth around the sensor. Care is taken in placing the lead within the subclavian vein to prevent clamping the body of the lead between the clavicle and the first rib, which can cause lead fracture over time. Figure 3 is a radiographic illustration of an IHM in place. Potential complications asso-
Associated with placement of the IHM are as follows:
- dysrhythmias,
- thrombosis or embolism,
- tamponade or perforation of the myocardium,
- hematoma or hemorrhage,
- lead fracture,
- pneumothorax, and
- infection.

Nursing care of patients after the procedure is the same as that for patients who have implantation of a permanent transvenous pacemaker. Antibiotics may be prescribed prophylactically. Restrictions in movement may be ordered to reduce the chance of lead displacement. Passive range-of-motion exercises help prevent frozen shoulder. The incision site should be observed for formation of pocket hematomas. For patients' comfort, the head of bed should be elevated 20° to 30° to minimize swelling. Pain medication may be given as needed.

Maintenance of the IHMS does not differ from that of a permanent pacemaker. Gradual resumption of activities according to each patient's tolerance is encouraged. Activities involving abrupt, forceful arm movement may result in lead fracture and may be limited for several weeks. Contact sports typically are not allowed. Certain procedures such as electrocautery and nuclear magnetic resonance imaging are contraindicated. Periodic checks help determine when a new battery is needed; currently, batteries last approximately 3 years. Although no direct health risk is associated with use of the IHM, potential risks include the following:
- tissue overgrowth of the lead,
- dislodgement of the lead,
interference with data collection by the sensor (may result in data loss), and

• malfunction of external components.

Hemodynamic Measurements

The pressure sensor uses a titanium diaphragm and a polyurethane window to detect various hemodynamic parameters and associated clinical data (Table 1). Estimated pulmonary artery diastolic pressure is calculated from the points in the cardiac cycle where the pressure in the right ventricle equals the pressure in the pulmonary artery, which occurs at the end of ventricular isovolumetric contraction. Changes in the systolic and diastolic pressure tracing reflect right ventricular contraction. During contraction of the right ventricle, the pulmonary valve opens when right ventricular pressure exceeds pulmonary pressure, and ejection begins. Because flow into the pulmonary artery begins at this point, the pulmonary artery pressure is at its end-diastolic level. Additionally, the maximum rate of contraction (dP/dt, change in pressure divided by change in time) occurs at the same time that isovolumetric contraction ends (ie, the pulmonic valve opens) and flow into the pulmonary artery begins. The IHM can detect the point of maximum dP/dt and record the simultaneous right ventricular pressure from the sensor of the right ventricular lead. Thus, on the basis of the relationship between the right ventricular pressure and the pulmonary artery diastolic pressure, estimated pulmonary artery diastolic pressure is measured.5-7 Figure 4 illustrates these events in relation to the cardiac cycle.

In patients without valvular insufficiency, mitral stenosis, or pulmonary vascular disease, the estimated pulmonary artery diastolic pressure serves as a measure of pulmonary artery diastolic pressure, which reflects left ventricular end-diastolic pressure or left ventricular preload6 (Figure 5). Figure 6 illustrates a real-time recording from the IHM with the programmer. Figure 7 shows trends in elevated hemodynamic pressure.

Research

The IHM has been under development for more than a decade.6,8-13 Earlier designs included sensors for right ventricular oxygen saturation and pulmonary artery sensors.9 But
because of long-term safety considerations such as thrombus formation associated with sensors for venous oxygen saturation, technical problems associated with these leads, and the accumulated experience with the safety of right ventricular pacemaker leads, these early designs were abandoned in favor of a single right ventricular sensor lead. Newer designs are safer, have greater long-term accuracy, and are more reliable than the earlier designs.

In the phase 1 multicenter clinical trial, 32 patients with heart failure had an IHM implanted. A total of 617 IHM recordings during a 1-year period were compared simultaneously with measurements obtained via pulmonary artery catheters while patients were at rest in the supine position, performing Valsalva maneuvers, and exercising (upright bicycle). Correlations between the 2 types of measurements were excellent: right ventricular systolic pressure, \( r = 0.95 \); right ventricular diastolic pressure, \( r = 0.87 \); and estimated pulmonary artery diastolic pressure, \( r = 0.87 \).

Device- and procedure-related adverse events included the following: pressure sensor failure (0.03%), complete heart block requiring a pacemaker (0.03%), pneumothorax (0.03%), hematoma of the device pocket (0.03%), and infection of the incision line (0.03%). No incidents of thrombus formation were evident in this study, which supported findings from earlier studies.

Table 2 summarizes IHM clinical trials to date. Figures 8 and 9 illustrates participants’ heart failure functional class and quality-of-life scores.

In a more recent multicenter study, 32 patients with heart failure had an IHM implanted. Baseline hemodynamic parameters were evaluated during a 9-month period and were unavailable for making decisions about patients’ therapy. Hemodynamic parameters, clinical events, and effect on hospitalizations were then studied during a 17-month period when the IHM data were available for making clinical decisions. Findings revealed increases and decreases in right ventricular pressures correlated with volume overload and depletion, respectively. A 20% increase occurred in at least 1 hemodynamic measurement (right ventricular systolic pressure, right ventricular diastolic pressure, estimated pulmonary artery diastolic pressure) in 75% of clinical events 2 to 4 days before exacerbation of heart failure. In all exacerbations, hemodynamic pressures increased 24 hours before clinical intervention was implemented. Mean hospitalizations were 1.08 per patient-year when the IHM data were unavailable for

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**Figure 5** From the RV pressure sensor, the ePAD is measured. ePAD = PA diastolic pressure = LA pressure, and LV end-diastolic pressure = LV preload.

**Figure 6** Real-time recording of the implantable hemodynamic monitor with the programmer.
making decisions about patients’ therapy and 0.47 per patient-year (a 57% reduction in hospitalization per patient-year, \( P < .01 \)) when the IHM data were available.

**Implications**

Although the cost of the IHMS has yet to be determined, the benefits to clinicians of having objective hemodynamic parameters and associated clinical data both in real time and during a specified period is clear. The ability to continuously monitor hemodynamic pressures during “one time snap shot” measurements is by far superior to current assessment methods in heart failure therapy. The IHMS can be used to evaluate a patient’s response to therapy or to optimize pharmacological agents used to treat heart failure. Treatment can be individualized according to each patient’s hemodynamic response.

In addition, the activity level feature, a formulated numerical scale, allows clinicians to evaluate hemodynamic pressures in everyday ambulatory conditions. Of particular importance is the ability to detect changes in right ventricular pressures 24 hours before physical deterioration. These “early warning profiles” (right ventricular pressures and estimated pulmonary artery diastolic pressure monitored in real time or

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**Figure 7** Elevated hemodynamic trends over a 1-month period downloaded by remote monitoring and reviewed by a clinician on a secured Internet site.

Abbreviations: ePAD, estimated pulmonary artery diastolic pressure; RV, right ventricle.

Illustration courtesy of Medtronic, Inc.
remotely) can prevent delays in treatment and prompt appropriate interventions before hemodynamic decompensation occurs.

The IHMS may also provide a means to objectively evaluate physiological effects of therapy in addition to specific events that may affect therapy. For example, a patient with heart failure celebrated a Super Bowl football game by indulging in nachos with cheese and beer. In a review of his hemodynamic data from the Internet Web site, this event was indicated by the IHMS within 24 hours by elevated pressures, although the patient had no symptoms. An extra dose of diuretics was prescribed for the next 3 days, and the patient’s hemodynamic pressures returned to baseline values (Figure 10). The additional benefit of being able to telephonically transmit data may result in improved quality of life, possibly resulting in fewer visits to a physician, clinic, or hospital, the elimination of right-sided heart catheterization, and a higher functional status due to optimization of hemodynamic status. Applications of the IHMS include the following:

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Abbreviations: IHMS, implantable hemodynamic monitoring system; NYHA, New York Heart Association.
ment companies, and home health-care agencies. The role of nurses in successfully incorporating this technology into practice is crucial. Educating healthcare providers about the physiological measurements, interpreting the importance of these measurements in each patient, and determining the trends of the data are the start of a shift in the management of patients with heart failure. Additionally, educating patients about this technology, promoting self-regulating behaviors, and addressing issues related to home physiological monitoring present a unique challenge to nurses. Nursing research initiatives can focus on these issues, in addition to quality of life.

**Conclusion**

The IHMS provides objective hemodynamic and associated clinical data both in real time via a programmer and telephonically to a central computer site where data can be viewed via the Internet. With the use of monitoring parameters, appropriate and timely interventions can be initiated to ensure optimal outcomes for patients. The impact of the IHMS, however, on mortality and morbidity of patients with heart failure remains unknown; further testing in larger clinical trials specifically designed to evaluate patients’ outcomes and quality of life is needed. Preliminary results are encouraging, and the IHMS may be a step in the management of patients with heart failure that moves beyond traditional care-delivery systems.

**Physiological monitoring of hemodynamic pressures is no longer confined to the critical care unit.**

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**References**


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**Figure 10** Evidence of elevated pressures with corresponding decline in pressures after treatment in a noncompliant patient with heart failure.

Abbreviations: ePAD, estimated pulmonary artery diastolic pressure; RV, right ventricle.

Illustration courtesy of Medtronic, Inc.


CE Test  Test ID C055: The Implantable Hemodynamic Monitoring System  

Learning objectives: 1. Identify nursing care for patients with implantable hemodynamic monitoring systems (IHMSs)  2. Describe the various implications for the use of IHMSs  3. Discuss the differences between indirect and direct hemodynamic monitoring and physiological parameters of IHMSs

1. What percentage of heart failure patients will die within 5 years of diagnosis despite pharmacologic advances?
   a. 25%
   b. 40%
   c. 50%
   d. 75%

2. Which of the following can be described as “considered” expenses in the overall economic burden of heart failure?
   a. Home healthcare, insurance premiums, and family living expenses
   b. Loss of work hours, family living expenses, and cost of durable medical equipment
   c. Insurance premiums, transportation costs, and cost of medications
   d. Cost of care delivered by healthcare providers, cost of medications, and hospital and nursing home expenses

3. Which of the following is not a potential cause of neurohormonal activation?
   a. Increased jugular venous pressure
   b. Increased pulmonary venous pressure
   c. Increased right and left atrial and ventricular pressures
   d. Increased pulmonary arterial pressure

4. Which of the following can provide indirect hemodynamic information on left ventricular ejection fraction as well as qualitative and quantitative measurements?
   a. 3-D cardiac computer-assisted tomography scanning
   b. Right-sided electrocardiogram
   c. Echocardiography
   d. Unipolar pressure sensors placed along the right chest wall

5. What is the best location for the placement of the implantable hemodynamic monitor?
   a. High-velocity blood flow region of the right ventricle
   b. High-velocity blood flow region of the right pulmonary artery
   c. Low-velocity blood flow region of the right atrium
   d. Low-velocity blood flow region of the superior vena cava

6. Which potential complications are associated with the placement of the implantable hemodynamic monitoring system (IHMS)?
   a. Esophageal perforation, bradycardia, and thromboembolism
   b. Hypotension, bradycardia, and cardiac tamponade
   c. Acute bifascicular or trifascicular atrioventricular blocks, hypotension, and pneumothorax
   d. Tamponade, lead fracture, pneumothorax, and infection

7. What is the nursing care for a patient with a newly placed IHMS?
   a. Elevate the head of bed 10° to 20°, observe for mottling of extremity, and take vital signs every 2 minutes
   b. Observe the site for pocket hematomas, elevate the head of bed 30° to 40°, and restrain extremity of the procedure site to prevent movement
   c. Observe the site for pocket hematomas, administer pain management as required, and elevate the head of bed 20° to 30° for comfort and to decrease swelling
   d. Administer pain management as required, leave the head of bed flat, and restrain extremity of the procedure site to prevent movement

8. Which of the following best identifies potential risks associated with IHMS placement?
   a. Increased mortality due to placement, failure to adequately diagnose complications, and poor patient compliance with treatment
   b. Dislodgement of the lead, pneumonia, and occlusion of the coronary artery
   c. Papillary muscle dysfunction, mitral valve regurgitation, and sensor failure
   d. Tissue overgrowth of the lead, dislodgement of the lead, and external component malfunction

9. How did the mean hospitalization rate decrease when IHM data were available?
   a. From 1.08 per patient year to 0.47 per patient year
   b. From 1.00 per patient year to 0.40 per patient year
   c. From 1.18 per patient year to 0.45 per patient year
   d. From 1.08 per patient year to 0.40 per patient year

10. How long before deterioration does the IHMS indicate changes in right ventricular pressure?
    a. 12 hours
    b. 36 hours
    c. 24 hours
    d. 72 hours

11. Which of the following is not a common application use of IHMS?
    a. Acute physiological monitoring of patients in the critical care unit
    b. A method for using chronic hemodynamic data for long-term management of patients
    c. Individualized and tailored therapy for patients with heart failure or pulmonary vascular disease
    d. Diagnosis of symptomatic events in the outpatient setting (home or clinic)

12. What are the identified physiologic parameters and associated clinical data collected from the IHMS?
    a. Heart rate, core temperature, pulse pressure, prejection interval and systolic time interval, and right ventricular systolic and diastolic pressures
    b. Core temperature, ejection fraction, pulmonary occlusion pressures, and left ventricular systolic and diastolic pressures
    c. Atrial ejection pressures, central venous pressures, and prejection interval and systolic time interval
    d. Estimated pulmonary artery diastolic pressure, left ventricular systolic and diastolic pressures, and activity level

Test answers: Mark only one box for your answer to each question. You may photocopy this form.

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