

Implanted pressure monitoring device improves heart-failure management and outcomes



The first implantable hemodynamic monitoring device for heart failure is now available to eligible patients at UCLA. The CardioMEMS HF System was approved by the Food and Drug Administration in 2014 as the first implantable heart failure monitoring device that has been shown to significantly reduce heart failure hospitalizations.

About 5.8 million people in the United States have heart failure, a condition that occurs when the heart is unable to pump enough blood to meet the body's demands. The pressure within the heart chambers becomes elevated and rapid worsening of symptoms (acute decompensation) can occur. Preventing hemodynamic decompensation is critical to avoid further heart damage, hospitalization and death. Despite best-management practices, however, more than one million hospitalizations due to heart failure occur each year and as many as 25 percent of those patients are rehospitalized within 30 days of discharge.

Traditionally, physicians watch for decompensation by monitoring body weight and symptoms, including fatigue and shortness of breath. However, changes in hemodynamics typically precede symptoms by days or weeks, offering the opportunity for early detection and treatment.

Device keeps patients out of the hospital

The CardioMEMS HF System addresses the critical need to detect hemodynamic congestion earlier and more precisely and adjust medications to better manage heart-failure patients and prevent hospitalization, says Gregg C. Fonarow, MD, professor of medicine and director of the Ahmanson-UCLA Cardiomyopathy Center.

“Relying on the classic signs and symptoms for evaluating pressures in the heart and lungs is very challenging, even in the hands of an expert cardiologist,” he says. “This is the first implantable, wireless, hemodynamic system that is approved by the FDA and available for reimbursement by Medicare. It provides highly useful clinical insights that allow clinicians to make personalized, precise recommendations regarding adjustments of medications.”

Clinical trials showed a 37 percent lower likelihood of hospitalization among patients with the device as compared to those monitored with best clinical practices.

“That additional information really allows the physician to detect presymptomatic congestion, before changes in body weight or symptoms or before the patient fully decompensates,” Dr. Fonarow says.

Careful monitoring of presymptomatic changes

The CardioMEMS sensor is designed to detect changes in pulmonary-artery pressure for earlier intervention and management. The system consists of an implantable pulmonary-artery sensor and a transmission system. The tiny, wireless monitoring sensor is permanently implanted during cardiac catheterization. The minimally invasive procedure takes about 30 minutes.

Patients transmit readings from a home bedside unit daily or as needed. The patient relaxes in bed, lying on a special pillow that collects data from the pulmonary-artery sensor during an 18-second reading.

Data is transmitted directly from the monitor to a healthcare provider via a secure website. Physicians can view the data to assess immediate pressure, trends or waveforms. A rise in pulmonary-artery pressure may signal the need to modify medications. Clinical-trial data suggests clinicians make more frequent and appropriate adjustments of medications in patients with the device.

Data from a 550-patient study showed a clinically and statistically significant reduction in hospitalizations linked to heart failure. The safety profile of the device is outstanding. Of the devices implanted, 100 percent were operational at six months, and there were no device explants or repeat implants during that time period.

Importantly, the benefits of the monitoring system extend to heart failure patients with preserved ejection fraction, a subgroup of patients who have not previously been found to benefit from traditional heart failure therapies without hemodynamic monitoring.

Approved for NYHA Class III patients

The device is approved for patients with heart failure categorized as New York Heart Association (NYHA) Class III. These patients experience marked limitation in physical activity, even during light activity such as walking short distances. Class III patients make up about 25 percent of U.S. patients with heart failure.

The device is contraindicated for patients who are unable to take two types of blood thinning medications for one month after the sensor is implanted.

Comprehensive follow-up monitoring

Implantation is only the first step toward optimal use of the CardioMEMS system. UCLA's comprehensive heart-failure management program is designed to provide meticulous monitoring and interpretation of data and timely communication of vital information to patients and primary-care physicians. A collaborative approach involving specialists, primary-care physicians and advanced-practice nurses provides a foundation for best practices and optimal outcomes. Clinical-trial data of patients with the CardioMEMS sensor shows not only enhanced symptom management but meaningful improvement in quality-of-life measures. Remote monitoring reduces the need for follow-up appointments in the physician's office.

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