Issues in Emerging Health Technologies

Implantable Hemodynamic Monitoring (the Chronicle® IHM System): Remote Telemonitoring for Patients with Heart Failure

Summary

✓ Remote monitoring for ambulatory heart failure patients uses an implantable device to record hemodynamic data and transmit it to a central server for continuous assessment.

✓ Preliminary evidence from observational studies suggests a potential for reducing hospitalizations with the use of right ventricle implantable hemodynamic monitoring (IHM). However, although a multicentre, randomized controlled trial (COMPASS-HF) showed a reduction in hospitalizations in the IHM group the results were not statistically significant and the US Food and Drug Administration panel concluded the trial failed to meet its primary efficacy endpoint.

✓ In the COMPASS-HF study the most common device-related complication was lead dislodgement.

✓ Large randomized controlled trials are needed to demonstrate the clinical utility of IHM, particularly in terms of its impact on reducing hospitalization and improving patient outcomes.

Background

Heart failure (also called congestive heart failure) affects the heart’s ability to efficiently pump and circulate the blood. It usually results from other underlying conditions, such as ischemic or valvular heart disease, cardiomyopathy, or hypertension. The prevalence of heart failure is increasing as the population ages and new treatments for heart disease prolong survival. Heart failure is a leading cause of hospital admissions in Canada and a frequent reason for readmission.

The Technology

Successful management of heart failure is multifactorial, and the ability to recognize and assess the hemodynamic functioning of the heart is one of its components. Objective physiologic assessment tools are needed because of the limited reliability of physical symptoms, chest x-rays, and echocardiograms in monitoring the progression of heart failure. The filling pressures of the cardiac ventricles, especially the left ventricle, are particularly important indicators of the extent or progression of heart failure. The ability to transmit these data over the Internet may allow heart failure patients to be monitored remotely, on an outpatient basis. Ideally, this would improve patient management and reduce hospitalization and mortality.

Implantable devices have features that enable remote monitoring of hemodynamic data in patients with heart failure. The Chronicle® Implantable Hemodynamic Monitor (IHM) is about the size of a pacemaker. It consists of an implantable monitor and a transvenous lead carrying a pressure sensor. The device contains a lithium silver vanadium oxide power source, integrated circuitry, and a bi-directional telemetry transmission coil hermetically sealed in a titanium can.

Regulatory Status

The Chronicle® Implantable Hemodynamic Monitor (Medtronic, Inc., Minneapolis, MN) is not currently licensed in Canada. In the US, a March 2007 meeting of the Food and Drug Administration (FDA) Circulatory System Devices Panel reviewed trial data on the Chronicle IHM. Citing concerns regarding the lack of clinical efficacy, the panel members voted
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(nine to two) against recommending approval.\(^9\) The Chronicle IHM has an investigational device exemption in the US, which allows use of the device in clinical trials.

**Patient Group**

Heart failure is estimated to affect more than 400,000 Canadians, and over 50,000 new cases of heart failure occur in Canada each year.\(^1\),\(^3\),\(^10\) About 50% of patients with heart failure have diastolic heart failure. Medtronic estimates that perhaps 10% to 15% of these patients could benefit from the use of the Chronicle IHM.\(^11\) In Canada, this would translate to about 20,000 to 30,000 patients.

**Current Practice**

For out-patient monitoring of patients with heart failure, multidisciplinary heart failure clinics are considered the gold standard as indicated by recent meta-analyses and randomized controlled trials.\(^12\)\(^-\)\(^14\) Invasive heart catheterization is used frequently for hemodynamic assessment and monitoring of critically ill cardiac patients in the intensive care setting. However, the data, obtained in resting, supine, and often-sedated patients, may not reflect the hemodynamics in daily life. Other methods for diagnosing and monitoring heart failure include chest x-rays, echocardiograms, and laboratory tests, such as the use of B-type natriuretic peptide (BNP) or amino terminal pro-BNP.

**The Evidence**

Five prospective observational studies and one randomized controlled trial (RCT),\(^15\)\(^-\)\(^19\) all funded by Medtronic, were identified from searches that included various biomedical databases (2000 to present) as well as the Internet and through contacting Medtronic. Three of the above studies\(^15\)\(^-\)\(^17\) assessed the same group of patients and were conducted by the same group of investigators.

A study of 32 patients with heart failure who received a Chronicle IHM in the right ventricular (RV) outflow tract\(^15\) reported that resting RV pressures can be accurately estimated from 24-hour IHM data. (These pressures were consistently lower than the measurements found using fluid-filled catheters, which may be due to procedural anxiety associated with catheterization.) Studies on the same group of patients\(^16\),\(^17\) also found that the IHM and catheter values were not statistically significantly different at baseline or at one year (p>0.05), and long-term ambulatory pressure measurements from an IHM may favourably impact heart failure hospitalizations. Hospitalizations before using IHM data for clinical management averaged 1.08 per patient year and decreased to 0.47 per patient year (57% reduction, p<0.01) after hemodynamic data were used. Device and procedure-related adverse events included one pressure sensor failure noted at the time of implantation.\(^16\)

A study on 21 heart failure patients\(^18\) showed implantable sensors recorded hemodynamic values that correlated with those measured through catheterization. However, 12 of the 21 sensors failed to function. Success of data transmission by an IHM was examined during 7,791 data transmissions for 148 patients.\(^19\) Data transfer was successful in 87% of transmissions, while 10% had to be retransmitted at least once and 1.5% at least twice.

Data from the COMPASS-HF trial were presented to the US Food and Drug Administration (FDA) panel in March 2007.\(^20\) COMPASS-HF was a multicentre, randomized, single-blind controlled trial that included 277 patients with New York Heart Association (NYHA) Class III and Class IV heart failure. IHMs were successfully implanted in 274 patients; in three patients, implantation was attempted but was unsuccessful. The pre-specified primary efficacy endpoint for the trial was a lower rate of heart failure-related “hospital equivalents” (hospital admissions, emergency department, or urgent clinic visits) during a six-month follow-up period. In the Chronicle IHM group (n=133), 44 patients experienced 84 hospital equivalents, as compared with 60 patients in the control group (n=140) with 113 hospital equivalents. This 21% difference in hospital equivalents was not statistically significant (p=0.33), and the FDA panel concluded the trial had failed to meet its primary efficacy endpoint. It is possible, however, that the intensive patient-physician interaction in the control group, which was intended to better maintain the single-blind study design, may have had a positive effect on patient management in the control group.\(^21\)

**Adverse Effects**

In a Phase 1 study of 32 patients, complications during the first year of using the Chronicle IHM included pressure sensor failure, heart block requiring a pacemaker, pneumothorax, hematoma, and infection — all at a rate of 0.03%.\(^16\) The COMPASS-HF study reported a total of 24 device-related complications (most
commonly lead dislodgement) in 23 of the 274 patients implanted with the device.20

Potential adverse effects associated with IHMs include heart dysrhythmias, thrombosis, lead fracture or dislocation, perforation of the myocardium, hemorrhage, and infection.22 Other potential problems include electrical interference or data transmission failure. Contraindications for patients with IHMs are similar to those for patients with pacemakers and include biothermy, electrocautery, and magnetic resonance imaging (MRI).22

### Administration and Cost

The Chronicle IHM is implanted subcutaneously in the upper chest, just below the collarbone, with the lead in the RV outflow tract position. The patients do not receive anticoagulation unless this is required for other conditions. Antibiotics may be used to prevent infection from the implantation procedure, and pain medication may be administered as needed post-implantation. The batteries in the IHM last about three years. Battery replacement requires a second surgical procedure. The IHM continuously stores values of RV hemodynamic parameters, RV systolic and diastolic pressures, estimated pulmonary artery diastolic pressure, RV pulse pressure, maximum positive and negative change in pressure over time (dP/dt), and pre-ejection and systolic time intervals. High-resolution monitoring can be programmed by the physician (telemetry), activated by a magnet by the patient, or triggered by bradycardia or tachycardia events. The data files can be up linked from the implanted IHM via a telemetry link and automatically transmitted from the patient’s location to a central server using a simple remote monitoring box and standard telephone lines. The patient’s data are then available to health professionals via a web site.8

### Concurrent Developments

Impedance cardiography (ICG) is a non-invasive hemodynamic monitor that employs skin electrodes to measure thoracic electrical impedance changes for the evaluation of cardiac output, stroke volume, left ventricular contractility, and thoracic fluid volume status.23 This technology complements IHM in outpatient hemodynamic monitoring. Implantable cardioverter defibrillators that include telemetering functions are also under development.2 The HeartPOD™ (St. Jude Medical), a device inserted through a catheter into the heart wall to monitor left atrial pressure, is being investigated in the Homeostasis II (Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients) feasibility trial in the US.24

### Rate of Technology Diffusion

Technologies that allow out-of-hospital management of patients with chronic conditions have the potential to improve quality of life and reduce health care costs. The adoption of IHM will likely depend on the cost of the device and the availability of trained staff and specialized heart failure centres with the capacity to integrate this data into patient management. Should this technology follows similar trends to those seen with implantable cardioverter defibrillators, the potential patient population may be greater than health system resources can accommodate, which will likely limit diffusion.

### Implementation Issues

Implantable technology to measure hemodynamic variables in ambulatory heart failure patients has proved to be feasible. The Chronicle IHM monitors hemodynamic variables that reflect changes in RV performance. Technology capable of monitoring left ventricular performance is still needed.

Until further information on outcomes and the cost of the Chronicle IHM are available, the cost-effectiveness of this technology cannot be determined. Large randomized controlled trials are needed to identify potential complications associated with IHMs and to provide clear evidence of their ability to reduce hospitalizations and improve patient outcomes. These outcomes should be compared with those achieved with out-patient monitoring through multidisciplinary heart failure clinics. A recent systematic review of home telephone support and monitoring of patients with chronic heart failure found that hospital admissions were reduced by 21% and all cause mortality was reduced by 20%.25 Whether such improvements can be exceeded with implantable technologies is not yet known.

### References


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