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STATE-OF-THE-ART PAPER

Home Monitoring for Heart Failure Management

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With a prevalence of 5.8 million in the United States alone, heart failure (HF) is a common syndrome associated with substantial morbidity, mortality, and healthcare expenditures. Close to 1 million HF hospitalizations occur annually in the United States, with the majority of these resulting from worsening congestion in patients previously diagnosed with HF. An estimated $37.2 billion is spent each year on HF in the United States. These statistics emphasize the need to develop and implement more effective strategies to assess, monitor, and treat HF. It has also become increasingly apparent that interventions geared toward identifying and monitoring subclinical congestion would be of value in the home management of chronic HF. Earlier identification and treatment of congestion together with improved care coordination, management of comorbid conditions, and enhanced patient self-management may help to prevent hospitalizations in patients with chronic HF. Such home monitoring extends from the promotion of self-care and home visitations to telemedicine and remote monitoring of external or implantable devices. This paper discusses the challenges in monitoring patients with HF, reviews clinical trials testing different monitoring strategies in HF, and highlights ongoing investigations into the optimal approaches to home monitoring for HF. (J Am Coll Cardiol 2012; 59:97–104) © 2012 by the American College of Cardiology Foundation

Heart failure (HF) is a common clinical syndrome with frequent exacerbations requiring hospitalization. HF is challenging to manage because of the older patient population, often subtle onset of decompensation, and the complexities of the required lifestyle changes, medication regimen, laboratory monitoring, and interactions with comorbid conditions. Certain multidisciplinary HF disease management programs have been successful at reducing all-cause hospitalization rates (1,2). However, not all patients can participate in such programs because of geographic barriers, socioeconomic constraints, or other obstacles. Interventions have therefore evolved to better monitor the patient with HF at home. These interventions range from increasing self-care and structured telephone support to telemonitoring and remote monitoring of implantable devices. How these advances in monitoring will ultimately affect HF disease burden, progression, and health care expenditures is of great interest and under active investigation.

Challenges in HF Management

The difficulty in managing HF is manifest not only by a high rate of HF hospitalizations, currently estimated at approximately 1 million annually in the United States (3), but also by a 30-day readmission rate of 27%, the highest among all medical conditions necessitating hospitalization (4). Acute in-hospital care is responsible for up to 70% of the annual cost of HF in the United States and other developed countries (5). Given the aging population and growing economic burden, improved management of the patient with HF at home and prevention of hospital admissions have become national priorities. Rehospitalization rates for HF are now the target of publicly reported performance measures, national improvement initiatives, and government incentives (6).

Standard management of the ambulatory HF patient involves office-based follow-up 2 to 12 times a year, with physical examinations supplemented by laboratory tests and echocardiograms as needed. Patients are instructed to monitor their weight and symptoms. Therapy provided in this manner, however, is often adjusted in response to new complaints brought by the patient. Although routinely used in the outpatient setting to detect HF decompensation, there are limitations to the monitoring of symptoms, physical examination signs, and daily weight. Better strategies geared toward identifying subclinical congestion and anticipating severe episodes of decompensation would be of value. Instead of being episodic and reactive, care could then become proactive through continual home observation, education, and assistance to prevent deterioration (Fig. 1).

Self-Care and Self-Management

The American Heart Association defines self-care as the decision-making process patients use to maintain physiological stability (7). Self-care includes multiple components, such as adhering to medications, following diet and

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Abbreviations and Acronyms

HF = heart failure

ICD = implantable cardioverter-defibrillator

LVEF = left ventricular ejection fraction

NYHA = New York Heart Association

PPM = permanent pacemaker

RV = right ventricle

exercise recommendations, and actively monitoring for congestion. Self-management extends this concept to the self-adjustment of the treatment regimen. Self-management is therefore a complex process: patients have to recognize a change in themselves (e.g., increasing edema), evaluate the symptom, decide to take action, implement a treatment strategy (e.g., taking an extra diuretic dose), and evaluate the response to therapy (7). Self-care and self-management behaviors are ultimately the responsibilities of the patient, even if they are frequently seen in the office or telephoned at home.

However, there are multiple challenges with self-care for the patient. Although checking daily weight is an important part of HF self-management (8), fewer than one-half of patients with HF weigh themselves daily, even among those recently discharged for an HF exacerbation (9). But even if they did so, an increase of >2 kg over 24 to 72 h has only a 9% sensitivity for detecting clinical deterioration (10). Furthermore, patients may delay seeking care for HF symptoms for days or fail to bring new symptoms to the attention of their providers when they are seen (11).

Multiple comorbidities often compound the challenges in self-care. Other conditions may require additional, possibly conflicting, medications, and it is common for patients with HF to take 9 to 12 pills per day, without a good understanding of their treatment regimen (12). Symptom monitoring may also be more uncertain: patients with chronic obstructive pulmonary disease often cannot distinguish HF versus their lung disease as the cause of shortness of breath. Patients with diabetes may have fewer symptoms and more difficulty interpreting them (7). Patients with HF may also have lower health literacy levels as well as cognitive impairment. In a study of Medicare enrollees, 27% to 44% were found to have marginal or inadequate health literacy (13). Additional factors such as social isolation or concurrent depression also hamper self-care. Taken together, these obstacles frequently prevent HF patients from fully implementing self-management through medication taking, dietary and lifestyle adherence, symptom monitoring, and decision making.

Although self-care for HF has been strongly advocated, this approach has not been well tested in prospective randomized clinical trials. The HART (Heart Failure Adherence and Retention Trial) was a multiple-hospital, randomized controlled trial testing the value of self-management counseling in 902 patients with mild to moderate HF (14). This study found no impact of this intervention on reducing death or HF hospitalizations. Although there is a paucity of evidence that patients with HF benefit from self-management counseling on important clinical endpoints, it remains possible that if self-care were coupled with other interventions such as technology-assisted remote monitoring, benefits would emerge.

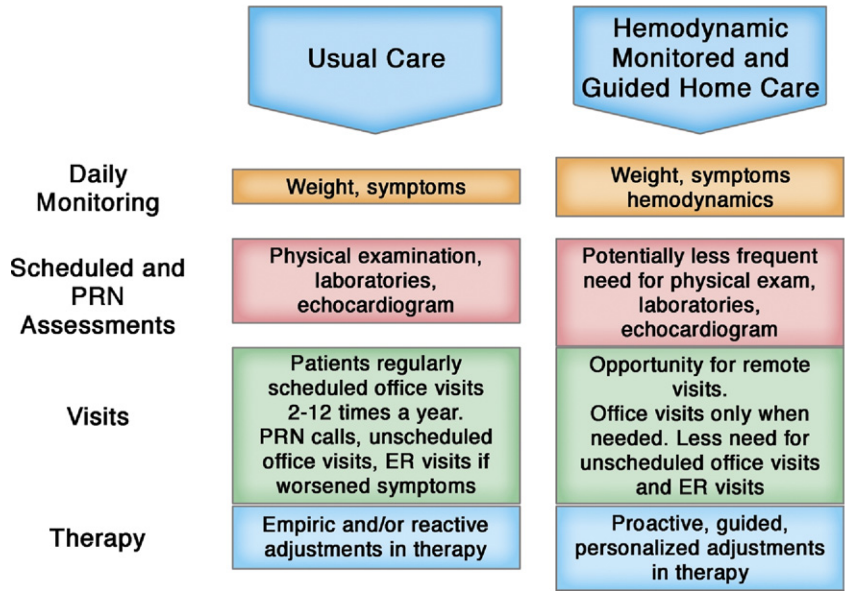

Figure 1 **Usual Care Versus Hemodynamic Monitoring and Guided Home Care for Patients With HF**

Comparison of monitoring, assessments, visits, and the approach to therapy with usual care compared with hemodynamic monitoring and guided home care for patients with heart failure (HF). ED = emergency department; PRN = as-needed.

Multidisciplinary Teams and Home Visitation

Guidelines by both European and U.S. scientific societies have recommended a multidisciplinary approach to HF (15,16). Rich et al. (17) explored this intervention, using an experienced cardiovascular research nurse to provide HF education, a dietician to provide nutritional assessment and guidance, social service personnel to facilitate discharge planning, a geriatric cardiologist to review and simplify the medications, and a study team to provide intensive follow-up with home care, individualized home visits, and telephone contact. This program reduced rehospitalization rates by 44%, with improvement in quality of life scores and a reduction in overall costs of care (Online Appendix). A subsequent meta-analysis has found that multidisciplinary teams reduce mortality by 25%, HF hospitalizations by 26%, and all-cause hospitalizations by 19% (18). Multidisciplinary disease management programs, however, have been unable to reach a wide spectrum of patients with HF because of the limited resources of healthcare systems to provide such intensive services and the limited resources of patients to actively participate (19).

Structured Telephone Support

One adaptation of the multidisciplinary disease management team model has been to use telephone calls. Information about the patient's condition would be gathered through a structured telephone conversation, and patients would be directed to follow up with their physician if there was evidence for deterioration. Structured telephone support can help with monitoring, self-care management, or both. Results, however, have been equivocal. Weinberger et al. (20) focused on 1,396 general medicine patients and found that a nurse-led telephone intervention, coupled with comprehensive discharge planning and primary-care physician follow-up within 7 days of discharge, led to an increase in hospitalization rates and more days of rehospitalization, despite the increase in contact (Online Appendix). Conversely, Riegel et al. (21) were able to demonstrate that a program of telephone contact with a computer decision support system reduced hospitalization rates by 47.8%, with lower inpatient costs and no evidence for cost shifting to the outpatient side.

Meta-analyses of structured telephone support programs suggest that telephone support may reduce HF rehospitalization by about 25% but has no significant impact on either all-cause readmission rates or all-cause mortality (18,19). The benefit of structured telephone support on HF readmissions may be attributable in part to appropriate nurse triage to immediate intervention in the face of clinical deterioration. However, increased contact may also lead to false alarms and pre-emptive admissions. Its true benefit may be in shortening length of stay, as patients are admitted earlier and can be discharged earlier if a high level of monitoring is available at home (22).

Telemonitoring or Remote Monitoring

With advances in information communication technology, monitoring can go beyond just telephone calls requesting patient information. Telemonitoring involves the transfer of physiological data such as blood pressure, weight, electrocardiographic signals, or oxygen saturation (Table 1) through technology such as telephone lines, broadband, satellite, or wireless networks. Similar to structured telephone support, this strategy may lift some of the burden of geographic or funding barriers limiting in-home visits (22). By incorporating more data, telemonitoring also promises to detect HF deterioration earlier, allowing for more prompt and effective intervention. Two recent meta-analyses have suggested that telemonitoring in ambulatory HF patients can improve mortality by 17% to 47% during 6 to 12 months of follow-up and reduce hospitalizations by 7% to 48% (19,23). However, 2 large subsequent randomized controlled trials suggest caution before widely using telemonitoring. In the TELE-HF (Telemonitoring to Improve Heart Failure Outcomes) study, a telephone-based interactive voice-response system that obtained symptom and weight information provided no significant benefit over usual care in terms of all-cause rehospitalization rates or

Table 1 Potential Measurements for HF Monitoring

Patient-reported data
Signs and symptoms of congestion
Signs: Jugular venous distension, peripheral edema, pulmonary congestion/rales, pleural effusions, S3 gallop
Symptoms: Dyspnea on exertion, orthopnea, paroxysmal nocturnal dyspnea, fatigue, abdominal fullness, anorexia, nausea, vomiting
Daily weight
Sodium intake
Medication adherence/persistence
Laboratory data
INR
Natriuretic peptides (BNP and NT-proBNP)
Other biomarkers
Directly recorded data
Heart rate
Blood pressure
Atrial/ventricular arrhythmias
Percentage pacing
Pressure sensor data
RV outflow
Left atrial
Pulmonary artery
Device parameters
Battery
Alerts
Leads
Calculated/derived data
Heart rate variability
Activity level
Intrathoracic impedance

BNP = B-type natriuretic peptide; INR = international normalized ratio; NT-proBNP = N-terminal pro–B-type natriuretic peptide; RV = right ventricular.

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death (Online Appendix) (24). Similarly, the TIM-HF (Telemedical Interventional Monitoring in Heart Failure) study was not able to demonstrate a significant impact of telemonitoring on HF-related rehospitalization rates or mortality (25).

The negative findings of TELE-HF and TIM-HF highlight the complexity of home monitoring interventions. In contrast to more successful implementations of telemonitoring (26), TELE-HF relied on patient-initiated communication: patients had to use a toll-free telephone system in which an automated voice asked a series of questions to which they had to respond by using a keypad. Fourteen percent of patients assigned to the telemonitoring arm never used the automated call-in system, and only 55% were still regularly using the system by the end of the study period (24). Also, nurses in TELE-HF were not empowered to change the medication regimen without physician consultation, thus adding a layer of communication and delay. Described by Desai and Stevenson as the "Circle of Home Management of HF" (27), HF home management involves multiple components of which monitoring is only one factor. There also needs to be timely transmission of data, receipt of the information by the appropriate staff who can analyze and act on it, a feedback loop to the patient with directions, and sufficient patient empowerment to understand and implement the instructions. Also, although telemonitoring promises to reduce the need for in-person follow-up, it may actually increase the workload involved. In the TELE-HF study, although there were only 25 patients per site on average, there were 884 incidents per site requiring responses.

Mobile phone–based remote monitoring systems along with application-based support of HF patient education and disease management could be relatively inexpensive and convenient tools to improve HF home management. Mobile phones are now widely available and have considerable computational power, while being relatively inexpensive compared with dedicated remote monitoring hardware. These systems are also portable, enabling patients to be monitored anywhere with mobile phone reception. Initial studies have shown the potential of this approach in HF home management (28), but further studies are needed. The U.S. Agency for Healthcare Research and Quality has recently provided substantial funding to support research into the use of wireless and telephone care management to reduce HF readmissions (29).

Implantable Devices

Because of the potential unreliability of patient-reported or patient-collected data, attention has turned to implantable devices that would automatically record data. Because conventional means of detecting changes in fluid status such as weight and symptom monitoring do not provide sufficient warning, additional metrics might also prove useful (Table 1). These implantable devices can take the form of permanent pacemakers (PPM), implantable cardioverter-defibrillators (ICD), or cardiac resynchronization therapy devices that have been placed for other indications. Or, they can be specially designed implantable hemodynamic sensors and monitors that can measure such parameters as intracardiac pressures.

PPMs and ICDs. When PPM, ICD, and cardiac resynchronization therapy devices are placed in patients with HF, it would make sense to use their potential capabilities to further evaluate the patient. Remote monitoring of these devices generally involves the transmission of recorded data through an external transmitter to the manufacturer's central database. Information is transferred on a regular basis, and alerts are forwarded to the physician (30). Some routinely monitored parameters may reflect a patient's clinical status and predict impending cardiac decompensation. For instance, atrial tachyarrhythmias (31), decreased heart rate variability (a measure of autonomic nervous tone) (32), and decreased patient activity level (as measured by integrated accelerometers) (32) can all predict clinical decompensation. Furthermore, an increase in the number of both appropriate and inappropriate shocks is associated with increased risk of HF hospitalization and mortality (33).

Another measure provided by some of these devices is intrathoracic impedance, which is the impedance measured between the right ventricular lead tip and the generator. An increase in pulmonary vascular congestion is reflected by decreased impedance, which can be recorded and reported by the device before symptom development (34). Although optimal lead configurations and thresholds are still under consideration, one such algorithm for impedance monitoring has a sensitivity of 76% in predicting clinical decompensation compared with 23% using weight change (Online Appendix) (35). By combining intrathoracic impedance measurements with other predictors, including atrial fibrillation episodes, patient activity level, and heart rate variability, Whellan et al. (36) were able to identify those with more than a 5-fold risk for HF decompensation and hospitalization.

Given these potential advantages, remote monitoring of implantable devices has been endorsed by recent expert consensus (37). Remote monitoring of PPM and ICD data may allow for the more timely recognition of serious arrhythmias, device problems, or worsening HF. With daily data transmissions, the number of in-home follow-up or clinic visits could be reduced without compromising safety, while also saving patient, staff, and physician time. Trials of PPM and ICD remote monitoring have found a reduction in time until event diagnosis and time from event to clinical decision (Online Appendix) (38–40), but the effects of this monitoring on outcomes such as hospitalizations and mortality are not yet available.

Implantable hemodynamic monitors. Elevations in left ventricular filling pressures and pulmonary artery pressures are closely correlated with clinical congestion, functional limitation, and prognosis in patients with HF (41). These intracardiac and pulmonary artery pressures increase several days to weeks before the onset of symptoms that typically trigger hospital admission (41–43). Thus, ambulatory hemodynamic monitoring could provide an early warning of potential decompensation as well as facilitate the day-to-day management of patients with HF by allowing for the titration of medications on the basis of reliable physiological data. Several systems are therefore currently under development that measure pressures directly in the right ventricle (RV), left atrium, and pulmonary artery.

The RV pressure sensor system is similar to a pacemaker generator with a modified unipolar pacemaker lead (Chronicle, Medtronic, Minneapolis, Minnesota). Information includes continuous heart rate, body temperature, and hemodynamics such RV systolic and diastolic pressures and ePAD (RV pressure at maximal RV dP/dT), which correlates with pulmonary artery diastolic pressures and thus approximates left-sided filling pressures (44). Evaluation of this device in the COMPASS-HF (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure) trial (46) in patients with New York Heart Association (NYHA) functional class III and IV HF, however, did not find a significant difference in HF events (e.g., hospitalizations, emergency or urgent care visits requiring intravenous therapy) between the intervention and control groups (Online Appendix). It is possible that the study was underpowered, that the event rate was lower than expected in the control group, that the intervention group did not have medications titrated aggressively enough, or that the standard of care in the control group, consisting of nearly weekly telephone contact, provided insufficient effect contrast. Subsequent analysis of the COMPASS-HF database found that HF patients with persistently high filling pressures were at higher risk of hospitalization, suggesting it may be more effective to use implantable hemodynamic monitoring data to adjust medications with the goal of reducing high filling pressures, irrespective of symptoms or weight (46).

A device to directly measure left atrial pressure has also been developed (HeartPOD, St. Jude Medical, Minneapolis, Minnesota). This device has a sensor lead placed intra-atrially through a transseptal puncture, which is then linked to a coil antenna placed subpectorally. Evaluation of this device among patients with NYHA functional class III and IV HF in the observational HOMEOSTASIS (Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients) study (43) found that those in the intervention group had a lower risk of acute decompensation or death (hazard ratio: 0.16 [95% confidence interval: 0.04 to 0.68]) (Online Appendix). Benefits may have been gained by the more aggressive titration of medications, as guided by left atrial pressure. This particular intervention notably included a "patient advisor module" that displayed the measured left atrial pressure and reminded patients of which medications were due based on the readings. This device therefore has the potential to support patient self-management by allowing for participation and control in patients' day-to-day HF care (30).

A pulmonary artery sensor (CardioMEMS Heart Sensor, CardioMEMS, Inc., Atlanta, Georgia) has also been under development. Unlike the other models, it is a silicone, pressure-sensitive capacitor that is implanted in the pulmonary artery via right heart catheterization. It is powered externally by an antenna that is placed on the back or side of the patient when readings are conducted, and it provides accurate pulmonary artery pressure assessment when compared with both Swan-Ganz catheterization and echocardiography (47). A study of its safety and efficacy, the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients) (48), demonstrated that the device can reduce HF hospitalizations by 30% (95% confidence interval: 0.60 to 0.84) among NYHA functional class III patients with a HF hospitalization in the previous 12 months (Online Appendix). Importantly, clinicians participating in the study were provided with specific recommendations and guidance on how to adjust HF therapies on the basis of the hemodynamic readings. Advantages of this device over other implantable hemodynamic monitors include its straightforward implantation through right heart catheterization, wireless nature of the sensor, and absence of an implanted battery requiring subsequent change-out (49). Notably, the benefits of sensor-guided treatment were similar in patients with preserved left ventricular ejection fraction (LVEF) as those with reduced LVEF, making this system one of the few management approaches ever demonstrated to improve outcomes in patients with HF and preserved LVEF.

Additional advantages of implantable devices include the ability to track measures longitudinally over time, average these values over the course of a day, and more accurately reflect a patient's clinical status. Changes could be compared with the patient's own baseline. Such devices also reduce the need for patient compliance, as measurements are obtained automatically. Similar to patients with diabetes who can self-regulate their prescribed therapy based on an objective daily measurement on their glucometer, the greater potential in this technology lies in empowering the patient with a tool to self-monitor and self-manage, particularly if customized alerts and instructions are given for each patient on the basis of readings (Fig. 2) (42).

Future Challenges and Opportunities

The field of HF home monitoring has many additional avenues to investigate (Table 2). Further studies to identify which patient population will derive the greatest benefit from home monitoring are needed. Also, identifying which variables are best to monitor requires further study, whether it be patient symptoms, directly recorded data such as heart rate, blood pressure, or pulmonary artery pressures, or calculated measurements such as intrathoracic impedance (Table 1). Alternately, monitoring patient behaviors such as medication adherence may be more important. There are

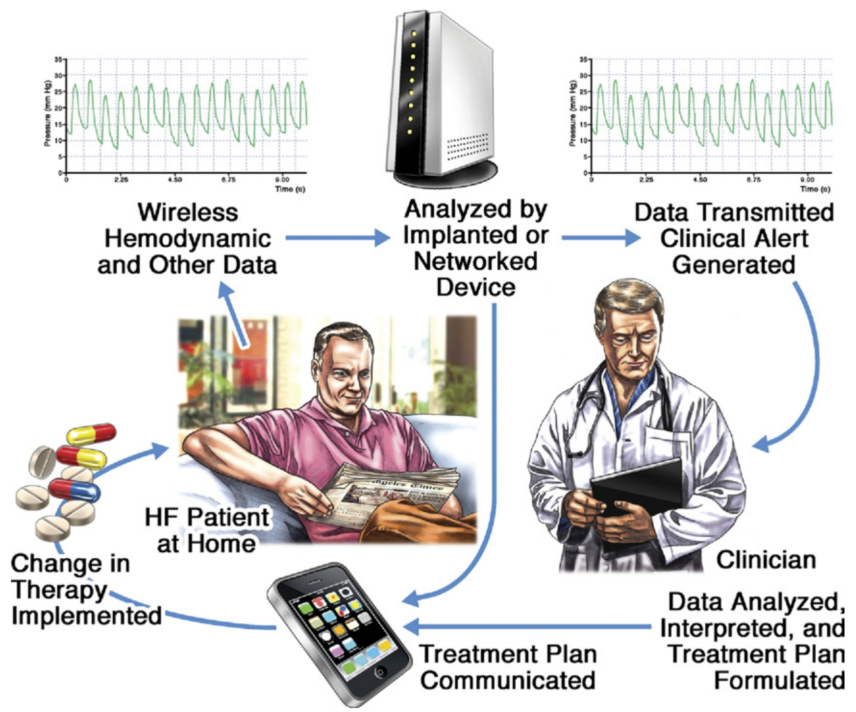

Figure 2 **Home Hemodynamic Monitoring of Chronic HF**

Changes in therapy can potentially be made more rapidly in response to wirelessly collected hemodynamic data. Even before symptoms develop, data are collected and alerts can be sent to a clinician for review or personalized treatment recommendations can be automatically generated on the basis of a prespecified algorithm. HF = heart failure.

automated pill boxes that record whether pills have been taken and even pills with an edible sensor that trigger a signal when digested (Raisin System, Proteus Biomedical, Inc., Redwood, California). Home testing and monitoring of biomarkers may also be of value. Use of serial natriuretic peptides has been found to be potentially useful in guiding care of HF patients in some but not all studies in the outpatient setting, with a meta-analysis of these trials suggesting that all-cause mortality may be reduced, particularly in patients younger than 75 years, without clear reduction in all-cause hospitalization (50). Home testing of these or other biomarkers should be further explored. As an increasing amount of information is gathered, however, one runs the risk of obtaining too much data to manage. Important alerts may get lost if an appropriate triage system is not in place.

Table 2 Future Challenges and Opportunities in Home Hemodynamic Monitoring
Evaluate in broader patient populations
Evaluate in more diverse clinical settings with more diverse clinicians managing patients
Better define optimal patient population for monitoring
Further define optimal sensor placement location
Further refine hemodynamic goals
Further study long-term reliability and safety
Evaluate direct patient use of hemodynamic data for self-management
Further analyze cost-effectiveness
Evolve reimbursement and professional liability standards

Any successful approach will likely need to be multipronged. Monitoring alone, without adequate follow-up and feedback to the patient, is unlikely to be the solution that prevents HF readmissions or decompensation. Importantly, as many of the interventions, particularly the implanted hemodynamic monitoring devices, were tested in a select cohort of patients being followed up by experienced centers, additional study will be needed to determine whether the benefits can be generalized to a broader cohort of patients and more diverse group of clinicians and clinical practice settings. Although these strategies are developed to reduce the HF burden for the patient and society, these interventions themselves may also be costly. The ability to reimburse not only for the devices, but also for the training and education of patients and staff, will dictate how these interventions develop. Although chronic care management programs are potentially cost saving, the benefits from improved disease control and reduced hospitalization rates often accrue to the insurers rather than the ambulatory care practices responsible for providing that care. How these home monitoring programs are incorporated into the patient–provider relationship is also a work in progress. This prospect will require methods to ensure more effective and efficient collection of data, reliable transmission of information, and integration into an already busy workflow.

Conclusions

Given the considerable, and largely unmitigated, burden of HF, the potential for home monitoring to improve the management of patients with HF is substantial. Home monitoring of the patient with HF can extend from home visitations and promotion of self-care to telemedicine and remote monitoring of external or implantable devices. The advancement of technology has allowed for the development of more advanced home-monitoring techniques, including implanted hemodynamic sensors, which are particularly promising. In patients with NYHA functional class III HF, a wireless implanted hemodynamic monitoring system has now been demonstrated to improve health status and reduce HF hospitalizations. Whether home-monitoring approaches for HF will live up to their full potential of improving quality of life, functional status, and HF outcomes while reducing healthcare expenditures in the broad population of patients with HF remains to be seen.

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APPENDIX

For a supplementary table listing the relevant studies of home monitoring, please see the online version of this article.