Does Home Monitoring Heart Failure Care Improve Patient Outcomes?

Home Monitoring Heart Failure Care Does Not Improve Patient Outcomes

Looking Beyond Telephone-Based Disease Management

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Despite considerable advances in evidence-based medical therapy, heart failure continues to contribute a substantial burden of morbidity, mortality, and economic cost to the American healthcare system. After an admission for heart failure management, nearly 25% of patients are readmitted within 30 days, and by 6 months, this proportion reaches nearly 50%.\(^1,2\) Medicare payments for unplanned hospital readmissions totaling more than $17 billion account for nearly 15% to 20% of total Medicare expenditure on acute hospital care.\(^3\) Accordingly, in 2009, the US Center of Medicare and Medicaid Services began public reporting of all-cause readmission rates after heart failure hospitalization, and last year, the Patient Protection and Affordable Care Act (PPACA)\(^4\) was signed into law, establishing financial incentives for hospitals to reduce cardiovascular readmissions. These trends underscore the growing fiscal and medical imperative to develop better strategies to improve care delivery to heart failure patients and reduce rehospitalization rates.

Response by Konstam on p 836

Because nearly one half to two thirds of these readmissions appear to be triggered by potentially remediable factors, including poor discharge planning, nonadherence to recommendations regarding diet and medical treatment, inadequate follow-up, poor social supports, and delays in seeking medical attention,\(^5-7\) there is increasing interest in restructuring the care of ambulatory heart failure patients to reduce fragmentation, enhance patient self-efficacy, and improve cost-effectiveness, quality, and clinical outcomes while smoothing the transition from hospital to home. Initiatives focused on these goals are broadly categorized as “disease management programs” and are increasingly endorsed by congressional initiatives to overhaul the U.S. healthcare system, as exemplified by their inclusion as part of the essential health benefits enshrined in section 1302 of the PPACA.\(^4\)

Although heart failure disease management programs vary widely in their specific content and focus, most provide for some form of longitudinal patient surveillance to facilitate early detection of clinical deterioration and enable timely intervention. Automated electronic transfer of physiological data by use of telemedicine platforms has been embraced as a strategy to permit more intensive home monitoring heart failure care. In this review, we survey the range of current approaches to heart failure disease management, emphasizing the lack of a clear relationship between the intensity of home monitoring and improvement in patient outcomes. In the process, we highlight the data from recent trials of telemonitoring of weight and vital signs as an adjunct to routine heart failure care that suggest no significant incremental impact on morbidity and mortality. We conclude with a discussion of promising novel approaches to remote surveillance of hemodynamic parameters in heart failure patients using implantable devices, which underscores the looming challenges to effective deployment of these measures to facilitate disease management in clinical practice.
Heart Failure Disease Management in Theory and in Practice

Systematic evaluation of the clinical impact of disease management in heart failure dates to the publication in 1995 of a landmark study by Rich et al demonstrating simultaneous improvements in quality of life, readmission rates, and medical costs with a multidisciplinary, nursing-led heart failure disease management intervention. Since that time, several randomized clinical trials focused on the “vulnerable period” following heart failure hospitalization have suggested that comprehensive education, discharge planning, and multidisciplinary postdischarge support may be effective as a supplement to “usual” medical care. Pooling data from 18 prospective randomized trials of a variety of such postdischarge interventions with a mean observation period of 8 months, Phillips et al identified a 25% reduction in the rates of all-cause hospital readmission (relative risk 0.75, 95% confidence interval [CI], 0.65–0.88) and a statistically non-significant trend toward reduced mortality (relative risk 0.87; 95% CI, 0.73–1.03). Benefits were achieved without an increment in overall healthcare costs, and there was speculation regarding substantial potential cost savings.

The apparent success of heart failure disease management in clinical trials has inspired strong endorsement of this approach by treatment guidelines in both the United States and Europe and a proliferation of programs in the public and private sector. Despite the general consensus that disease management works, however, a number of questions remain about the best approach to operationalizing the concept for heart failure patients. The clinical trials that have been conducted suffer from a lack of standardization in the structure for disease management interventions, heterogeneity in their intensity and duration, variability in their target populations and the clinical environment in which they were conducted, and differences in the background care provided to the comparator groups. Few trials were individually powered to examine clinical outcomes, and as a result, the benefits have been largely inferred by aggregating data across trials, despite their differences, by use of meta-analytic techniques. As well, because many trials have been conducted at single sites (often academic medical centers), it is uncertain whether the results from clinical trials can be generalized to larger community-based populations. Most importantly, even if they are effective, it remains unclear which core components of these multidimensional, multidisciplinary interventions are essential to improvement in clinical outcomes.

More Intensive Disease Management Is Not Necessarily Better

Efforts at heart failure disease management typically take the form of nursing-intensive interventions focused on ensuring the delivery of guideline-based medical therapy (therapeutic modification), enhancing patient self-efficacy through education regarding adherence and self-management (education), and regular surveillance for early signs of clinical deterioration (monitoring). Although the educational and therapeutic content of disease management interventions is relatively consistent, programs vary widely with regard to the nature and intensity of contacts between healthcare providers and patients. It is tempting to speculate that programs with more intensive follow-up would yield the greatest improvement in patient outcomes; in general, however, this does not appear to be the case. In the meta-analysis by Phillips et al, the intensity of postdischarge surveillance was not a major determinant of benefit, with comparable outcomes observed in those receiving a single postdischarge home visit, more frequent home visits with or without frequent telephone follow-up, and extended home care services. Prospective trials of disease management have also failed to support the notion of a dose-response relationship; the Coordinated Study Evaluating Outcomes of Advising and Counseling in Heart Failure (COACH), which compared moderate and intensive nursing support after hospital discharge to standard care, identified no impact of either strategy with regard to death or all-cause hospitalization. Similarly, in the Trans-European Network Home Care Management System Study (TEN-HMS), mortality and readmission rates were comparable among patients randomized to follow-up with structured telephone support or a more intensive monitoring intervention. Moreover, although some attrition in the benefits of disease management would be expected after cessation of intensive follow-up, the Randomized Trial of Telephonic Intervention in Chronic Heart Failure (DIAL) suggested that the reduction in heart failure hospitalizations associated with a telephone-based nursing support and education intervention was sustained for up to 3 years after the completion of the trial, long after the telephone calls had stopped. Overall, these data collectively suggest that the real benefits of disease management may be related not to the intensity of home monitoring after discharge but to improvements in patient adherence to instructions regarding diet, weight control, and medications and greater use of evidenced-based medical therapies, including β-blockers, angiotensin-converting enzyme inhibitors, and spironolactone.

This conclusion, however, seems counterintuitive. It is now well understood that the vast majority of heart failure hospitalizations are related to acute congestive exacerbations of chronic heart failure. Patients at risk for heart failure hospitalization have chronically elevated filling pressures, and further accumulation of volume results in small but persistent increases in pressure that ultimately lead to hospitalization. Because changes in filling pressures are often apparent several weeks before symptoms worsen, it seems tautological that more frequent, and even automated, home monitoring should facilitate disease management by allowing providers to intervene early to prevent heart failure decompensation, largely by adjusting doses of diuretics. Furthermore, because specialized heart failure programs are out of reach of many patients with heart failure, and there has been limited support for training or reimbursement of the midlevel professionals necessary to provide comprehensive disease management, there has been increasing interest in focused study of remote patient monitoring as a stand-alone component of disease...
management. In particular, it has been suggested that remote monitoring might provide a more automated, centralized, cost-effective, and scalable approach to postdischarge support, focusing nursing attention on those patients with early evidence of clinical deterioration.\textsuperscript{14,22}

**Telemonitoring Is Not Enough**

Home monitoring of heart failure patients typically takes 1 of 2 forms: Structured telephone support, in which providers (typically specialized nurses) schedule routine telephone contacts with patients for ongoing assessment, and telemonitoring, in which physiological data (including weight, heart rate, blood pressure, and the like) are transferred automatically to a healthcare provider via a wireless or broadband connection, with targeted follow-up triggered by variances that exceed preset thresholds. Although several randomized trials have been conducted evaluating home monitoring approaches as adjuncts to routine care, the data regarding their efficacy are mixed (Table).\textsuperscript{17,19,23–28} In the most recent and comprehensive meta-analysis of this topic by Inglis et al.,\textsuperscript{14} which summarized data from 25 full, peer-reviewed studies comprising 8323 patients, telemonitoring, but not structured telephone support, was associated with statistically significant reductions in mortality (relative risk 0.66; 95% CI, 0.54–0.851, \(P=0.0001\)) and heart failure hospitalization (relative risk 0.79; 95% CI, 0.67–0.94, \(P=0.0088\)). However, of the 11 studies evaluating telemonitoring that were included in this review, most were conducted at a single site, only 1 met more than 5 of 9 Cochrane criteria for methodological quality, only 3 had independent outcome assessors and data analysts blinded to the group randomization, and only 4 enrolled more than 250 subjects.\textsuperscript{27}

Recent data from larger, prospective, multicenter clinical trials provides additional insight into the incremental value of home monitoring over standard heart failure care. In the Telemonitoring to Improve Heart Failure Outcomes (Tele-HF)\textsuperscript{27} Study, 1653 subjects within 30 days of a heart failure hospitalization were randomized to remote monitoring by a telephone-based interactive voice response system or usual care. Participants assigned to telemonitoring were instructed to call daily to answer automated questions about weight, symptoms, and general health. Responses signaling concern

### Table. Selected Large, Prospective, Randomized Controlled Trials of Telemonitoring in Heart Failure

<table>
<thead>
<tr>
<th>Study (Acronym)</th>
<th>Intervention</th>
<th>N</th>
<th>Duration, mo</th>
<th>Intervention</th>
<th>Control</th>
<th>RR (95% CI)</th>
<th>Intervention</th>
<th>Control</th>
<th>RR (95% CI)</th>
<th>Cost/QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleland 2005 (TEN-HMS)\textsuperscript{17}</td>
<td>Structured telephone support</td>
<td>258 (426 total)</td>
<td>8</td>
<td>27/173 (15.6%)</td>
<td>20/85 (23.5%)</td>
<td>0.66 (0.40–1.11)*</td>
<td>34/173 (19.7%)</td>
<td>24/85 (28.2%)</td>
<td>0.70 (0.44–1.10)*</td>
<td>N/A</td>
</tr>
<tr>
<td>Gesica 2005 (DIAL)\textsuperscript{19}</td>
<td>Structured telephone support</td>
<td>1518</td>
<td>16</td>
<td>118/760 (15.3%)</td>
<td>122/758 (16.1%)</td>
<td>0.95 (0.73–1.23)</td>
<td>126/760 (16.8%)</td>
<td>169/758 (22.2%)</td>
<td>0.71 (0.56–0.91)†</td>
<td>Improved MLHF Scores</td>
</tr>
<tr>
<td>Sisk 2006 (Tele-HF)\textsuperscript{23}</td>
<td>Structured telephone support</td>
<td>406</td>
<td>12</td>
<td>22/203 (10.8%)</td>
<td>22/203 (10.8%)</td>
<td>1.00 (0.57–1.75)*</td>
<td>18/203 (9.9%)</td>
<td>29/203 (14.3%)</td>
<td>0.62 (0.36–1.08)*</td>
<td>Improved MLHF Scores; costs offset by reduction in hospitalizations</td>
</tr>
<tr>
<td>Mortara 2009 (HHH)\textsuperscript{24}</td>
<td>Structured telephone support</td>
<td>266 (461 total)</td>
<td>12</td>
<td>9/106 (8.5%)</td>
<td>9/160 (5.6%)</td>
<td>1.51 (0.82–3.68)*</td>
<td>18/106 (17.0%)</td>
<td>28/160 (17.5%)</td>
<td>0.97 (0.57–1.66)*</td>
<td>N/A</td>
</tr>
<tr>
<td>Cleland 2005 (TEN-HMS)\textsuperscript{25}</td>
<td>Telemonitoring</td>
<td>253 (426 total)</td>
<td>8</td>
<td>28/168 (16.7%)</td>
<td>20/85 (23.5%)</td>
<td>0.71 (0.42–1.18)*</td>
<td>40/168 (21.6%)</td>
<td>24/85 (28.2%)</td>
<td>0.84 (0.55–1.30)*</td>
<td>N/A</td>
</tr>
<tr>
<td>Soran 2008 (HHFHC)\textsuperscript{26}</td>
<td>Telemonitoring</td>
<td>315</td>
<td>6</td>
<td>11/160 (6.9%)</td>
<td>17/155 (11.0%)</td>
<td>0.64 (0.30–1.38)</td>
<td>30/160 (18.8%)</td>
<td>37/155 (23.7%)</td>
<td>0.78 (0.49–1.27)</td>
<td>No difference in QOL</td>
</tr>
<tr>
<td>Giordano 2009 (HMC)\textsuperscript{27}</td>
<td>Telemonitoring</td>
<td>460</td>
<td>12</td>
<td>21/230 (9.1%)</td>
<td>32/230 (13.9%)</td>
<td>0.66 (0.39–1.10)*</td>
<td>43/230 (18.7%)</td>
<td>73/230 (31.7%)</td>
<td>0.49 (0.31–0.76)†</td>
<td>Costs per hospitalization reduced with intervention</td>
</tr>
<tr>
<td>Mortara 2009 (HHH)\textsuperscript{28}</td>
<td>Telemonitoring</td>
<td>355 (461 total)</td>
<td>12</td>
<td>15/195 (7.7%)</td>
<td>9/160 (5.6%)</td>
<td>1.37 (0.61–3.04)*</td>
<td>35/195 (17.9%)</td>
<td>28/160 (17.5%)</td>
<td>1.03 (0.65–1.61)*</td>
<td>N/A</td>
</tr>
<tr>
<td>Chaudhry 2010 (Tele-HF)\textsuperscript{29}</td>
<td>Telemonitoring</td>
<td>1653</td>
<td>6</td>
<td>92/826 (11.1%)</td>
<td>94/827 (11.4%)</td>
<td>0.97 (0.73–1.30)</td>
<td>227/826 (27.5%)</td>
<td>223/827 (27.0%)</td>
<td>1.02 (0.87–1.20)†</td>
<td>N/A</td>
</tr>
<tr>
<td>Koehler 2011 (TIM-HF)\textsuperscript{30}</td>
<td>Telemonitoring</td>
<td>710</td>
<td>26</td>
<td>54/354 (15.3%)</td>
<td>55/356 (15.4%)</td>
<td>0.97 (0.67–1.41)</td>
<td>64/354 (18.1%)</td>
<td>74/356 (20.8%)</td>
<td>0.84 (0.60–1.18)</td>
<td>No difference in QOL</td>
</tr>
</tbody>
</table>

HF indicates heart failure; RR (95% CI), relative risk (95% confidence interval); QOL, quality of life; TEN-HMS, Trans-European Network Home Care Management System Study; N/A, not available; Gesica, Grupo de Estudio de Sobrevivencia en la Insuficiencia Cardiaca en la Argentina; DIAL, Randomized Trial of Telephone Intervention in Chronic Heart Failure; MLHF, Minnesota Living with Heart Failure Questionnaire; HHH, Home or Hospital in Heart Failure; HFHC, Heart Failure Home Care; Tele-HF, Telemonitoring to Improve Heart Failure Outcomes; and TIM-HF, Telemeval Interventional Monitoring in Heart Failure. Trials listed are those from 2005 onward that enrolled >250 subjects. \*Risk ratios from Inglis et al.\textsuperscript{14} †Risk ratio calculated from reported event rates. ‡Statistically significant risk ratio (\(P<0.05\)).
for clinical deterioration were flagged as variances that required intervention by the site coordinator. After 6 months, no difference was seen between those assigned to usual care and those assigned to telemonitoring with regard to the primary composite end point of all-cause readmission or death (52.3% for telemonitoring versus 51.3% for usual care, difference 0.8%, 95% CI, −2.8% to 3.3%) or any of the prespecified secondary end points, including heart failure hospitalizations. None of the participant characteristics, including age, sex, race, ejection fraction, or New York Heart Association (NYHA) class, identified a group in which the intervention was effective.

Although the Tele-HF study has been criticized because of low rates of patient adherence to the intervention (14% never used the system, and only 55% used it more than 3 times per week by the end of the study), its results are broadly similar to those of a more intensive intervention conducted in Germany. In the Telemedical Interventional Monitoring in Heart Failure (TIM-HF)²⁸,²⁹ study, 710 patients with symptomatic (NYHA class II or III) heart failure and left ventricular ejection fraction ≤ 35% on optimal medical therapy were randomized to a strategy of remote monitoring or usual care. In this study, clinicians provided real-time responses to symptoms of heart failure and physiological data (weight, blood pressure, 3-lead ECG) provided through a wireless, Bluetooth-based system 24 hours a day, 7 days a week. In contrast to the system used in Tele-HF, adherence to the TIM-HF telemonitoring intervention was excellent, with 287 (81%) of 354 subjects completing more than 70% of daily transmissions. Nonetheless, over a median follow-up of 26 months, the incidence of the primary outcome of all-cause readmission or death (52.3% for telemonitoring versus 51.3% for usual care, hazard ratio 0.97; 95% CI, 0.67–1.41; \( P = 0.87 \)). There was also no discernible difference in the incidence of key secondary end points, including the composite of cardiovascular death or heart failure hospitalization, all-cause hospitalization, or heart failure hospitalizations.²¹² Recent data from the Specialized Primary and Networked Care in Heart Failure II (SPAN-CHF II)³⁰ trial, which evaluated a different platform for automated home monitoring as an adjunct to a more comprehensive disease management intervention, also revealed no incremental impact on health-related quality of life. In aggregate, the consistent message appears to be that in patients with heart failure who are well managed with evidence-based medical therapy, there is limited incremental impact of intensive home monitoring on clinical outcomes.

**Figure 1.** Feedback loops in home heart failure management. Home monitoring approaches rely on timely identification of deviations in physiological parameters that direct corrective interventions by physicians or specialized midlevel personnel, such as heart failure nurses. Instructions regarding appropriate therapeutic modifications must be transmitted to the patient and implemented efficiently to prevent further deterioration. The feedback loop can be effectively “short-circuited” if patients receive their own data and are empowered to act independently to manage deviations and may be lengthened if a delay is introduced by the need for supervised decision making. The circle of heart failure management may become disconnected at any step. Failure to efficiently collect, process, and act on the appropriate physiological data may introduce critical disruptions in the feedback loop that preclude successful intervention to prevent heart failure decompensation. This figure is adapted from one we have presented previously.³¹

**Toward a More Effective Home Monitoring Approach**

As we have argued previously,³¹ the success of home monitoring as an adjunct to heart failure care depends on the fundamental assumption that routine surveillance of heart failure symptoms and physiological data will facilitate early detection of clinical deterioration and direct corrective intervention to avert adverse clinical outcomes. An effective strategy must therefore accomplish several goals (Figure 1): The patient data collected must help to accurately anticipate decompensation with sufficient lead time to permit intervention; the data must be transmitted efficiently in a format that is easily interpretable and enables timely intervention; the personnel receiving the data must be qualified to interpret the data and respond appropriately; the patient must receive and implement the treatment recommendation; and finally, the system must provide timely feedback to confirm resolution of the perturbation or indicate the need for further intervention. Failure or delay in execution of any of these steps may fatally disrupt the feedback loop, preventing even an effective intervention from improving outcomes in practice.

Few existing ambulatory home monitoring approaches effectively close this loop in practice. Patient adherence and delays in provider recognition and response to detected variances in
measured parameters may be part of the problem; the requirement for decision making by midlevel providers to be supervised by physicians, in particular, may stall timely introduction of effective therapeutic changes.\textsuperscript{31} More importantly, however, whatever the mode of communication between providers and patients, the physiological data transmitted are typically limited to vital signs, weights, and symptoms. Because the primary corrective intervention available to providers of heart failure care is adjustment of diuretic therapy,\textsuperscript{32} the availability of an accurate and responsive measure of volume status is critical. When evaluating patients in person, healthcare providers typically have access to features of the physical examination (jugular venous pressure, pulmonary rales, S3 gallop, hepatomegaly, ascites, peripheral edema, blood pressure response to the Valsalva maneuver), cardiac biomarkers (eg, natriuretic peptides, serum sodium), and data regarding electrolytes and renal function that collectively feed a reasonably accurate estimation of cardiac filling pressures. By contrast, when monitoring patients at home, patient symptoms and weights must suffice. However, body weight and volume status diverge with increasing time from hospital discharge, with the target dry weight varying with changes in caloric intake. Although on average, patients do gain weight before hospitalization for decompenation, the quantity of weight gain is typically fairly modest, with fewer than 50% of patients gaining more than 2 lb (0.9 kg).\textsuperscript{33,34} As such, although rapid weight gain is a relatively specific predictor of heart failure decompensation, it is not a very sensitive marker.\textsuperscript{35} Data from trials of implantable hemodynamic monitors suggest that weight gain is a relatively poor surrogate for intracardiac filling pressures and may be inadequate to recognize impending decompensation in sufficient time to intervene to prevent hospitalization.\textsuperscript{21}

Alternatives to Transtelephonic Surveillance

Device-Based Heart Failure Diagnostics

If weights are an inadequate signal, what other options are available? Remote follow-up of implantable cardiac defibrillators and cardiac resynchronization therapy devices has been demonstrated to be safe and cost-effective and is rapidly becoming the standard of care for monitoring of rhythm device performance.\textsuperscript{36} As directed by their providers, patients wirelessly download diagnostic information and stored electrophysiological data from their devices to an external transmitter, which relays encrypted information to the manufacturer’s database. This information is then made available to the treating clinician through a Web-based interface. For the growing proportion of patients with heart failure (particularly those with reduced ejection fraction) who require implantable devices, there may be an opportunity to exploit this existing remote monitoring infrastructure to enhance heart failure management. Changes in certain routinely monitored parameters, such as the percentage of ventricular pacing, presence of arrhythmia, activity levels, and mean heart rates at rest or during exertion, may help clinicians to better anticipate impending decompensation, although they do not always illuminate a clear pathway to effective treatment. Proprietary heart failure diagnostics built into some devices may also provide additional data that may help to further discriminate the risk for future decompensation.

Heart rate variability, a parameter that can be estimated by most cardiac resynchronization therapy devices, appears to decrease in relation to progressive heart failure decompensation. In a study of 288 patients with NYHA class III to IV heart failure conducted by Adamson et al,\textsuperscript{37} an automated algorithm to detect decreases in heart rate variability had a sensitivity of 70% for detecting hospitalization but was associated with a high false-positive rate. In addition, because estimation of heart rate variability requires predominant sinus rhythm, it is impractical in patients with atrial fibrillation or substantial requirement for atrial pacing. Nonetheless, more refined prediction algorithms incorporating heart rate variability and other clinical parameters to anticipate heart failure decompensation events are under study.\textsuperscript{38}

Because most patients with heart failure decompensation exhibit pulmonary congestion caused by elevated left ventricular filling pressures, device-based diagnostics to estimate lung water content may provide an indirect indicator of volume status. Measurements of intrathoracic impedance can be evaluated in many commercially available devices by applying a subthreshold electric impulse between the tip of the right ventricular lead and the generator and correlate inversely with the left ventricular filling pressure in patients receiving treatment for heart failure. Although changes in impedance typically occur 10 to 14 days in advance of heart failure hospitalization,\textsuperscript{39} well before the onset of clinical symptoms,\textsuperscript{40,41} recent data suggest this may not be an accurate method for predicting clinically important heart failure events;\textsuperscript{42} in the only randomized prospective trial conducted to date (Diagnostic Outcome Trial in Heart Failure [DOT-HF]), treatment guided by routine monitoring of intrathoracic impedance did not improve clinical outcomes and actually increased the likelihood of heart failure hospitalizations.\textsuperscript{43}

Implantable Hemodynamic Monitors

If remote surveillance of these indirect correlates of volume retention does not improve patient outcomes, more direct estimation of cardiac filling pressures may offer a pathway forward. The first generation of implantable hemodynamic monitors used a programmable device similar to the pulse generator of a pacemaker and a modified unipolar pacemaker lead with a pressure sensor located at the tip (Chronicle; Medtronic, Minneapolis, MN). Passive fixation of the sensing lead within the right ventricular outflow tract permitted continuous measurement of hemodynamic parameters, including right ventricular systolic and diastolic pressures, maximal rate of change in right ventricular pressure, and estimated pulmonary artery diastolic pressure.\textsuperscript{44} In the Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure (COMPASS-HF) study, 274 patients with heart failure and NYHA class III to IV symptoms, independent of ejection fraction, underwent implantation of the Chronicle device. Subjects were then randomized to management with or without the hemodynamic
information from the monitor. Over 6-month follow-up, there was no statistically significant difference noted in the incidence of the primary end point of heart failure events (hospitalizations and emergency or urgent care visits requiring intravenous therapy) between management guided by hemodynamic data and standard care (event rate 0.67 per 6 patient-months versus 0.85 per 6 patient-months, intervention versus control, \( P = 0.33 \)).\(^{45}\) Given the failure to reach statistical significance for the primary end point, the Food and Drug Administration declined to approve the Chronicle device for use in the management of heart failure patients.

Newer-generation implantable hemodynamic monitor devices may be more effective. In The CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients (CHAMPION) trial,\(^{46}\) 550 patients with heart failure (independent of ejection fraction), NYHA class III symptoms, and a prior hospitalization for heart failure received a wireless implantable pulmonary artery pressure sensor (CardioMEMS; CardioMEMS, Inc, Atlanta, GA) and were randomized to treatment with or without the assistance of sensor data. Only the patients were masked as to their assigned group. At 6 months, management guided by the pressure sensor was associated with a statistically significant 30% reduction in the primary end point of heart failure hospitalizations (event rate, 0.31 versus 0.44; hazard ratio 0.70, 95% CI, 0.60–0.84, \( P < 0.0001 \)), with a low rate of system-related complications (1.4%). These results were seen despite high background use of evidence-based medical therapies in the population as a whole (78% treated with angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, 91% with \( \beta \)-blockers, and 42% with an aldosterone antagonist) and may have been related to the marked increase in the number of adjustments to heart failure medications by physicians who had access to the sensor data (2468; mean 9.1 adjustments per patient) relative to those without access to the data (1061; 3.8 per patient).\(^{46}\) These data suggest that for selected patients with advanced heart failure symptoms, continuous monitoring of intracardiac pressures may provide a reliable signal both for early detection of deterioration and for tracking effectiveness of early intervention that can facilitate improvements in clinical outcomes.

**Additional Challenges for Home Monitoring**

Although directly measured filling pressures may be the right signal to track, invasive hemodynamic monitoring is unlikely to be a realistic or scalable solution to address the burgeoning epidemic of heart failure, which increasingly includes a large proportion of elderly patients with heart failure and preserved ejection fraction.\(^{47}\) Moreover, even if impending heart failure decompensation can be detected efficiently through automated home monitoring, several steps remain to effectively connect the circle of home heart failure management and prevent a hospitalization event (Figure 1). Effective implementation of disease management relies on the creation of a framework for delivering an appropriate and timely response.

Filtering the relevant signals from the noise of physiological data provided by remote monitoring platforms is both challenging and time-consuming; even for the relatively rudimentary telephone-based system used in Tele-HF, an average of 25 monitored patients at each site generated 883 variances that required a response in a 6-month period.\(^{27}\) Because the data streams generated from next-generation systems and implantable hemodynamic monitors are likely to be even larger and more complex to handle, scaling remote management approaches to serve a growing population of heart failure patients will undoubtedly demand a larger workforce of midlevel personnel specialized in heart failure management. New benchmarks for the optimal ratio of nurses and physicians to patients in a remote monitoring framework need to be defined, as does the best structure for collating and integrating the data to formulate a timely response. Given evolving medicolegal concerns regarding the implications of a failure to respond quickly and appropriately to electronically transmitted data that require attention, it has been proposed that the most effective model may be the organization of dedicated telemedical centers that operate 24 hours a day, 7 days a week;\(^{45}\) however, it remains unclear how best to integrate such a framework with current care delivery models to most effectively support the nurse and physician primarily responsible for patient care. Moreover, a more elaborate infrastructure for remote management of heart failure patients may not be practical without improvements in standardization in the approach to interpretation of hemodynamic data, development of decision algorithms that guide the appropriate response to variances, and reformation of payment systems that currently do not provide reimbursement for telephone-based heart failure care. Finally, because a large proportion of hospitalizations among heart failure patients (in particular among the elderly and those with preserved ejection fraction) are not because of heart failure decompensation but rather because of exacerbations of noncardiovascular illness,\(^{45}\) a real impact on overall hospitalization rates and mortality may require disease management approaches that focus more comprehensively on the full range of medical comorbidities, not exclusively on heart failure management.

**Conclusion: Improving Patient Outcomes Requires a New Approach**

Despite widespread acceptance of the value of comprehensive disease management for heart failure patients, rates of heart failure rehospitalization remain high. In this context, home monitoring of heart failure patients has been broadly embraced as a focused, scalable, and practical approach to implementation of disease management. However, systematic study of the impact of currently available approaches for home monitoring in large, prospective, randomized clinical trials has to date provided little evidence that they improve key patient outcomes such as hospitalization or mortality. This lack of efficacy may be fed in part by excessive reliance on remote monitoring of weights and symptoms, which are likely insensitive and late markers of
incipient heart failure decompensation. High residual rates of readmission even in trials of successful home monitoring interventions underscore the need for more effective approaches to longitudinal disease management.

It is likely that no single approach to disease management will be effective for all heart failure patients; more personalization and a multitiered approach to heart failure management may be necessary. Tailoring the optimal disease management intervention for a given patient may require consideration of several factors, including the severity of disease, the setting in which care is being delivered (including the geographic distance between patients and their providers), and the patient’s capacity for self-management, as well as the specific metrics that are being used to evaluate efficacy (Figure 2). Telemonitoring approaches, although apparently ineffective for high-risk populations with advanced heart failure or recent heart failure hospitalization, may yet be suitable for patients at lower risk who still require intermittent surveillance. Higher-risk patients may require more intensive clinic-based follow-up, perhaps facilitated in selected cases by implantable hemodynamic monitors, either as stand-alone devices or as integrated modifications to implantable defibrillators and cardiac resynchronization devices. Leveraging technology to promote greater self-efficacy for patients may also be important. Mobile phone applications can be designed to enhance patient adherence to dietary recommendations and medical treatment. Next-generation remote monitoring approaches already suggest the potential to more efficiently close the heart failure management loop by enabling heart failure patients to self-adjust diuretic dosing according to daily intracardiac pressure measurements without routine need for remote supervision, much as diabetic patients self-adjust insulin dosing on the basis of readouts from home glucose monitors. Nesting heart failure care within novel healthcare delivery frameworks such as the patient-centered medical home might also help to improve the infrastructure for early detection and intervention to prevent hospital readmissions. Finally, systems-level changes, including payment reform to incentivize longitudinal follow-up and enhanced patient education for prevention of heart failure decompensation, are in order. Realizing the promise of disease management to improve patient outcomes requires creativity and a comprehensive, multidimensional approach. The telephone and a digital scale are simply not enough.

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The recent Cochrane analysis of all available trials documents improved heart failure outcomes with home-monitoring programs. Desai stresses variability in trial results and absence of a dose-response between monitoring intensity and outcome. However, just as no diagnostic procedure ever cured or prevented a disease, neither does knowledge of patients’ fluid status or hemodynamics, alone, prevent recurrent hospitalizations or death. Monitoring is necessary, although insufficient, for an effective disease management program.

In an editorial accompanying a recent neutral trial, Desai and Stevenson elegantly articulate the importance of effective interventional responses to monitored signals and subsequent reassessment of treatment goals. The amount of data collected is no more expected to correlate with heart failure outcomes than the number of electrocardiograms obtained before coronary intervention is expected to correlate with outcomes following ST-elevation myocardial infarction. But as the electrocardiogram is a necessary evaluative step, so is home monitoring essential to effective heart failure management.

We show the specific value of monitoring, demonstrating attrition of early benefit after weaning home monitoring in an otherwise well-managed population. Nevertheless, I agree that sustainability of benefit may be linked to enhancing patient adherence and self-efficacy. I also agree that we need improved monitoring techniques, more carefully tailored interventions, and global payment structures, aligning providers and patients and incentivizing investment in systems designed for continuity of care. As we become more sophisticated and enabled through these advances, ambulatory monitoring will remain a centerpiece of future systemic approaches to improving clinical outcomes for our patients with heart failure.
Home Monitoring Heart Failure Care Does Not Improve Patient Outcomes: Looking Beyond Telephone-Based Disease Management
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