Telemonitoring of Outpatients With Heart Failure
A Search for the Holy Grail?

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Heart failure (HF) remains a large medical problem, and prevention of decompensation and HF-related hospitalizations is important not only for the patient, but also from an economic point of view. Close monitoring is crucial and can be done through a whole spectrum of modalities. This monitoring ranges from a (nurse-based) disease management program, to structured telephone support, to remote or telemonitoring with or without the use of an implantable device.1–3 Disease management programs, usually with a specialized nurse and in the hospital, are implemented on a large scale, but the optimal level and intensity of care is still unclear.4 Structured telephone support may be useful, and a recent meta-analysis showed a reduction in HF hospitalization, but no effect on mortality.5 Remote, home, or telemonitoring using a number of (relatively simple) noninvasive variables such as heart rate, blood pressure, and body weight was also examined in a number of studies, and the same meta-analysis showed that this method reduced both hospitalizations and mortality.2 However, 2 recent large studies not included in that analysis did not show such a positive effect.5,6 In the American Telemonitoring to improve outcomes in HF (TELE-HF) study7 and in the German Telemedial Intervention Monitoring in HF (TIM-HF) study,6 which together randomly assigned 2362 HF patients, no effect on HF hospitalizations or mortality was observed.

In recent years, a number of studies in the field of telemonitoring have been published that measured invasive variables. In the Chronicle Offers Management to Patients with Advanced Signs and Symptoms of HF (COMPASS-HF) study,7 a strategy based on measurement of right-sided intracardiac pressures (with a special transvenous lead: Chronicle, Medtronic) was examined. The primary (composite) end point showed a nonsignificant 21% reduction, but there was a statistically significant 36% reduction in the time to first hospitalization in the 301 patients studied.7 More recently, the results from CardioMEMS Heart sensor Allows Monitoring of Pressure to Improve Outcomes in New York Heart Association Class III HF patients (CHAMPION) study have become available.8 The value of daily measurement of pulmonary artery pressure measurements was examined in 550 patients. The device used has a passive, wireless, radio-frequency sensor without batteries or leads, and results from the device were only available to the physician (through transmission), who could then change (increase) drug treatment. After 6 months, there was a significant 28% reduction in HF-related hospitalizations in the treatment group. Measurement of left-sided (atrial) pressures has only been examined in a small study,9 which showed potentially interesting findings, but this method may be more complicated, and large-scale data are awaited.

Some diagnostic variables can also be collected when built into an implantable cardioverter-defibrillator (ICD) or a cardiac resynchronization therapy device.1–3 The use of ICD and cardiac resynchronization therapy has markedly increased in recent years,10 and both have received a recommendation in HF patients with a decreased ejection fraction in current guidelines.11 The diagnostic variables that can be recorded by the use of ICD/cardiac resynchronization therapy devices include measurement of intrathoracic impedance to track changes in thoracic fluid content, heart rate variability, patients’ physical activity level, and (atrial and ventricular) arrhythmias.1 In the Program to Access and Review Trending Information and Evaluate Correlation to symptoms in patients with HF (PARTNERS) study,12 an increased fluid index (or drop in intrathoracic impedance) was the most sensitive parameter to detect HF hospitalizations. A number of smaller studies measuring intrathoracic impedance (with Optivol, Medtronic) had also shown promising results, but 2 recent, larger studies failed to confirm these favorable findings.13,14 In the Sensitivity of InSync Sentry Optivol feature for the prediction of HF (SENSE-HF) study13 in 501 patients, the sensitivity of intrathoracic fluid monitoring changed over time and was lower than earlier reported (up to 42% after 6 months), whereas the positive predictive value (and specificity) were also low.13 The Diagnostic Outcome Trial in HF (DOT-HF)14 was designed to examine whether ambulatory monitoring of intrathoracic fluid monitoring (with Optivol, Medtronic) could improve outcome in patients with HF. However, because of slow enrolment and changes in monitoring technology, the trial was stopped after only 345 of the planned 2400 patients were enrolled. Analysis of these 345 patients showed that there was an increase of borderline statistical significance of the primary end point of all-cause mortality and HF hospitalizations in the (Optivol) access arm that was mainly due to the HF hospitalizations.14 The number of outpatient visits ("health care utilizations") was also markedly (almost 3-fold) higher in the access arm.

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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Circulation is available at http://circ.ahajournals.org

DOI: 10.1161/CIRCULATIONAHA.112.118141

2965
In this issue of *Circulation*, Landolina et al. present results of the EVOLVO study. The authors enrolled 200 HF patients from 6 Italian sites in whom an ICD (90% cardiac resynchronization therapy device) had been implanted. The primary end point was the rate of emergency healthcare utilizations, defined as visits to the emergency department and urgent (unplanned) in-office visits, for HF, arrhythmias, or ICD-related events. Half of the patients were randomly assigned to the remote arm, in which all alerts regarding clinical management (intrathoracic impedance monitoring, atrial arrhythmias, and ICD shocks) were turned on for wireless notification through the CareLink (Medtronic). Participating clinics checked a special web site once daily for transmitted data. After 16 months follow-up, there was a 35% lower incidence of the primary end point in the remote arm than in the control arm (75 versus 117 events, incidence density: 0.59 versus 0.93 events/y; P = 0.005). There was also a 21% reduction in total healthcare utilizations (P < 0.001). No effect was observed regarding mortality (7 versus 8 deaths) or the number of hospitalizations (of which 76 of the 106 were for worsening of HF). The authors concluded that remote monitoring reduced emergency department/urgent in-office visits and apparently not recognized by the patients, or the clinician did not consider them relevant. Fourth and last, in the present study, Optivol alerts (intrathoracic impedance changes) were again the most common alert condition (in 274/315 cases [87%] in the remote arm, and in 231/256 cases [90%] in the control arm), which agrees with earlier reports. In the remote arm, after the data were analyzed in more detail with the use of the CareLink information, many patients could, however, be reassured and alerts were (most likely) false positives. This brings into attention again sensitivity but, more importantly, specificity issues regarding the use of intrathoracic impedance monitoring.

What can be concluded from the EVOLVO study, and what do these data add to the current thinking regarding home or telemonitoring in HF? Although there is a lively and ongoing debate with regard to the value of home monitoring in HF patients, most people would probably agree that many of the measured variables may have some value in detecting early changes leading to a cardiac decompensation, and that these variables could potentially have a place in the management of HF patients. However, not all abnormal values lead to clinical problems and these variables often fluctuate, and, in particular, the specificity of abnormalities may be low. Indeed, knowing too much may be a problem, and including the patient in the information loop may not always be wise. In case of audible alerts, this may be hard to ignore, particularly for the patient, who may require treatment or even an urgent hospital visit or overnight stay. The search for an optimal HF disease management program, which will include a home-monitoring component in many patients, will continue in the future, and may become a search for the Holy Grail. The EVOLVO study adds an important piece to this puzzle and shows that with remote monitoring many of these unnecessary healthcare utilizations can be avoided.

**Disclosures**

Dr Van Veldhuisen was the Principal Investigator of the DOT-HF study, for which he has received Board Membership fees in the past. Dr Maas reports having received lecture fees from Medtronic, Biotronik, Boston Scientific, and Sorin. The Department of Cardiology, UMC Groningen, has received unrestricted research grants from Biotronik and Medtronic.

**References**


KEY WORDS: Editorials devices for heart failure heart failure telemonitoring
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Circulation. 2012;125:2965-2967; originally published online May 24, 2012; doi: 10.1161/CIRCULATIONAHA.112.118141
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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