

Beyond the stethoscope: managing ambulatory heart failure during the COVID-19 pandemic

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Abstract

There have been nearly 70 million cases of COVID-19 worldwide, with over 1.5 million deaths at the time of this publication. This global pandemic has mandated dramatic changes in healthcare delivery with a particular focus on social distancing in order to reduce viral transmission. Heart failure patients are among the highest utilizers of health care and are at increased risk for COVID-related vulnerabilities. Effectively managing this complex and resource-intensive patient population from a distance presents new and unique challenges. Here, we review relevant data on telemedicine and remote monitoring strategies for heart failure patients and provide a framework to help providers treat this population during the COVID-19 pandemic. This includes (i) dedicated pre-visit contact and planning (i.e. confirm clinical appropriateness, presence of compatible technology, and patient comfort); (ii) utilization of virtual clinic visits (use of telehealth platforms, a video-assisted exam, self-reported vital signs, and weights); and (iii) use of existing remote heart failure monitoring sensors when applicable (CardioMEMS, Optivolt, and HeartLogic). While telemedicine and remote monitoring strategies are not new, these technologies are emerging as an important tool for the effective management of heart failure patients during the COVID-19 pandemic. In general, these strategies appear to be safe; however, additional data will be needed to determine their effectiveness with respect to both process and outcomes measures.

Keywords Heart failure; Ambulatory; Telemedicine; Telehealth; Remote monitoring

Received: 4 May 2020; Revised: 8 December 2020; Accepted: 2 January 2021

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Introduction

The COVID-19 pandemic has mandated dramatic changes in the delivery of healthcare over an extremely short period of time. There have been nearly 70 million cases of COVID-19 worldwide with over 1.5 million deaths at the time of this publication. In Europe alone, there have been nearly twenty million cases with the most cases being reported in Russia, France, Italy, the United Kingdom, and Spain.¹ During this time of crisis, policy makers, administrators, and front-line healthcare providers have shifted their focus towards one that emphasizes social distancing in an effort to reduce viral transmission.

Currently, patients with heart failure are among the highest utilizers of health care.² There are currently over 15 million adults living with heart failure in Europe, accounting for millions of hospitalizations, and over 1–2% of total health

care spending annually.^{3–5} Effectively managing this complex and resource-intensive patient population ‘from a distance’ presents new and unique challenges. The following provides a framework to help providers assess and treat heart failure patients during a time of social distancing with the ultimate hope of optimizing ambulatory heart failure care and improving access in the future.

Policy and care delivery changes in response to COVID-19

The COVID-19 pandemic has forced administrators and policy makers to balance a number of important and competing realities. These include the ongoing provision of appropriate and necessary medical care for all patients, safeguarding

healthcare personnel and non-COVID 19 patients from infection, and the strategic allocation of scarce resources such as personal protective equipment.⁶ To that end, there have been a number of changes to existing inpatient and outpatient care delivery models.

During the height of the pandemic, government organizations and cardiology professional societies recommended minimizing and delaying non-essential surgeries, procedures, and diagnostics.^{7–10} For the heart failure population, this included routine blood work, echocardiograms, right heart catheterizations, coronary angiograms, cardiac biopsies, and cardiopulmonary exercise testing.¹¹ As COVID-19 related restrictions evolve, providers will need to continue to incorporate the potential risk of COVID-19 exposure and transmission when determining the need for and timing of diagnostic tests.

Healthcare facilities have also been forced to reconfigure the day-to-day operations of routine ambulatory care. Many have turned to telehealth as a way to ensure patients have ongoing access to medical care in order to avoid unnecessary hospitalizations and reduce the risk of coronavirus transmission. In order to encourage the uptake of telehealth services in the United States, the Department of Health and Human Services and the Centers for Medicare & Medicaid Services enacted a series of policy changes, including relaxing licensure and patient privacy laws, reimbursing virtual visits at the in-person rate, expanding the eligible patient population, and limiting cost-sharing.^{12,13}

Recognizing the need for rapid changes in care delivery in response to the pandemic, a number of professional societies have released recommendations to guide ambulatory heart

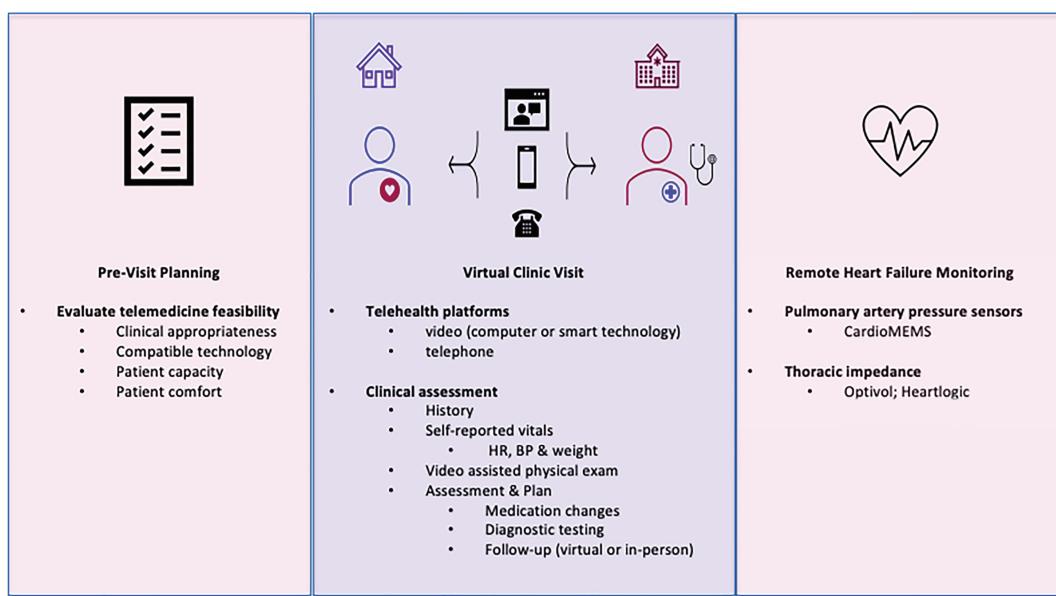
failure care. The European Society of Cardiology (ESC) has urged clinicians to transition routine elective care to virtual platforms and to contact patients prior to all face-to-face encounters to assess the need and urgency. Additionally, the ESC statement advocates for the use of remote vital sign monitoring and data from implantable devices when possible.¹⁴ Similarly, the Heart Failure Society of America released guidance on patient selection, work flow, and advanced care planning to ensure an effective virtual encounter.¹⁵ The ESC has also taken a vanguard approach in providing guidance for conducting clinical trials in heart failure during the COVID-19 pandemic.¹⁶

Telehealth in the heart failure population

Heart failure patients necessitate close and intensive outpatient monitoring, and there are a number of important considerations as cardiologists work to transition traditional clinical activities to a virtual platform. *Figure 1* provides a potential algorithm for providers to use in the remote care and monitoring of heart failure patients.

Providers must first identify patients appropriate for a virtual visit and re-triage those better served by traditional face-to-face evaluation. It is important that pathways exist to allow for the seamless transition between care mediums and locations (i.e. from virtual home-based care to in-person facility-based care).¹⁷ While there is little data evaluating the safety of virtual visits in the heart failure population, prior

Figure 1 COVID-19 ambulatory heart failure care via telehealth. BP, blood pressure; HR, heart rate.



studies have found other forms of telemedicine (including cardiology electronic consultation) to be safe without evidence for increased adverse events.^{18,19} In addition to basic safety concerns, there are more practical considerations such as evaluating a patient's ability to use and navigate the necessary technology and identifying other high-risk groups such as those who require interpreter services or who are hard of hearing.

As a frame of reference for feasibility, 70% of pre-COVID 19 ambulatory heart failure volume was preserved at our institution in the month following the government mandated shutdown. Of these encounters, 90% were successfully completed via either telephone or video, while only 10% required in-person evaluation due to clinical status.

There are a number of different platforms that can be used for telehealth encounters. Many physicians and patients are already comfortable interacting by telephone, and this will likely provide a fast and easy transition for most. While telephone encounters are appropriate for virtual check-ins, detailed verbal histories, and patient education or counselling, they do not allow for visual examination. There are also platforms with HIPAA-compliant video conferencing capacity including Zoom for Healthcare, VSee, Updox, Doxy.me, and others; and Centers for Medicare & Medicaid Services has recently relaxed the pre-existing requirements with respect to approved platforms.¹⁷ Many electronic medical records also have fully integrated video visit capabilities built into their patient portals. These strategies do require more technological know-how from both patient and provider. Ultimately, the optimal platform for the virtual visits will depend on the patient's clinical status, their technologic awareness, as well as specific institutional factors and volumes.

In fact, remote telemonitoring already has a presence in the management of ambulatory heart failure patients.²⁰ Table 1 highlights some of the key studies that have investigated the role of telemedicine in heart failure care. Each of these studies have demonstrated the feasibility of telemonitoring. While these strategies have not been shown to consistently effect clinical outcomes, they were conducted

in a non-pandemic environment in which access to in-person ambulatory care was unrestricted.^{21–25} Furthermore, a Cochrane meta-analysis found that both telemonitoring and telephone support reduced mortality and heart failure-related hospitalizations.²⁶

As health systems work to establish more robust telehealth operations, they should generate ideal workflows, procedures and operational guidance for providers, advanced practitioners, and support staff. These will need to be adjusted over time as the most appropriate and effective use of these technologies in the heart failure population is more clearly defined.

Virtual clinical assessment

Virtual visits should begin with a detailed history and assessment of any signs or symptoms suggestive of a decompensated state including, dyspnoea on exertion, orthopnoea, pedal oedema, or decrease in functional capacity (New York Heart Association class). Greater vigilance may be required during this time of social distancing given the lack of traditional mechanisms for heart failure monitoring and because of the potentiation of acute triggers for a decompensated state—including, dietary indiscretion, an increase in anxieties and stressors leading to poorly controlled blood pressure, and a decrease in baseline physical activity.

The virtual physical exam should focus on obtaining an accurate assessment of vital signs and fluid balance to allow for necessary medication titration. When possible, patients should be encouraged to monitor their blood pressure, heart rate, and heart rhythm (either with a pulse oximeter or smart watch) while at home. Patients should also record daily standing weights in accordance with the ACC/AHA/Heart Failure Society of America and the ESC guidelines.^{27,28} Finally, during visits with video capabilities, an evaluation of the jugular venous pressure and the presence of lower extremity

Table 1 Remote monitoring heart failure trials

| Study | N | Type | Primary endpoint | Result |
|--|------|--------|--|----------|
| Telemonitoring | | | | |
| GESICA Investigators, 2005 ⁴² | 1518 | RCT | All-cause mortality, heart failure hospitalization | Positive |
| Galbreath <i>et al.</i> , 2004 ⁴³ | 1069 | RCT | All-cause mortality | Positive |
| Galinier <i>et al.</i> , 2020 ²⁵ | 937 | RCT | All-cause mortality, heart failure hospitalization | Neutral |
| Ong <i>et al.</i> , 2016 ⁴⁴ | 1437 | RCT | 180-day readmission rates | Neutral |
| Koehler <i>et al.</i> , 2011 ⁴⁵ | 710 | RCT | All-cause mortality | Neutral |
| Chaudhry <i>et al.</i> , 2010 ²² | 1653 | RCT | All-cause mortality, all-cause readmission | Neutral |
| Pulmonary artery pressure monitoring | | | | |
| Abraham <i>et al.</i> , 2016 ³³ | 550 | RCT | Heart failure admission | Positive |
| Adamson <i>et al.</i> , 2014 ³⁴ | 119 | RCT | Heart failure admission | Positive |
| Thoracic impedance | | | | |
| Boehmer <i>et al.</i> , 2017 ⁴¹ | 900 | Cohort | Heart failure event (admission or unscheduled visit) | Positive |

RCT, randomized controlled trial.

Relevant telemonitoring studies based on size, randomization, and pertinent technologies.

oedema can be performed by having the patient appropriately positioned in front of the camera, *Figure 2*.

Patient compliance is critical during this period. A review of medications should be performed to ensure a complete and accurate list. Patients should be reminded to record daily standing weights, routine vital signs and to adhere to appropriate dietary and exercise regimens. Prior studies have shown non-compliance with these non-pharmacologic recommendations is associated with adverse outcomes.²⁹

Remote heart failure monitoring sensors

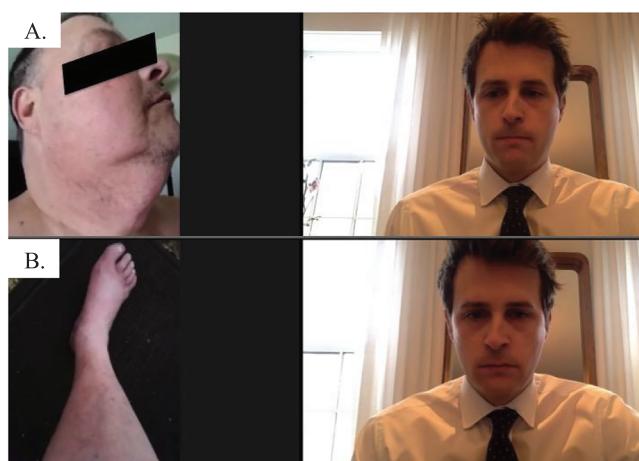
There is a growing armamentarium of remote sensor technology for heart failure patients that may be especially advantageous during this time of limited face-to-face clinical encounters.^{30,31} These technologies rely on the principle that subtle changes in cardiac physiology precede the overt signs and symptoms of heart failure and if used effectively can prevent hospitalizations. There are currently two types of monitoring systems: (i) de novo implanted sensors designed to monitor intracardiac filling pressures and (ii) cardiac implantable electronic devices (CIEDs), including defibrillators with and without biventricular pacing, that can measure other physiologic parameters relevant to the heart failure patient (*Table 2*). For those patients who have already been outfitted with these devices, the objective data from these sensors can enrich the virtual visit.³²

The CardioMEMS device is an implantable pulmonary artery (PA) pressure sensor that is FDA and CE Mark approved

to reduce hospitalizations and improve quality of life in heart failure patients. It is specifically indicated for patients with New York Heart Association class III functional capacity and at least one heart failure hospitalization within the previous 12 months. Derived from CHAMPION Trial data, the CardioMEMS device was shown to decrease hospitalizations in heart failure with reduced ejection fraction and heart failure with preserved ejection fraction.^{33,34} The technology works by monitoring PA pressure changes that are transmitted wirelessly to a website accessible to designated providers. This data can then direct the adjustment of diuretic and vasodilator therapies. Each patient will have a pre-set range of acceptable PA pressures, specifically with a target PA diastolic pressure. An advantage during this time of social distancing, the CardioMEMS system can herald patients at risk for heart failure decompensation. *Figure 3* illustrates a case in which the PA pressure tracing of a patient being managed remotely initially showed elevated filling pressures (i) that subsequently normalized after increasing diuretics (ii). To this end, a recent research letter further highlighted the clinical potential for PA pressure monitoring during the COVID-19 pandemic in which increases in PA pressures in 21 patients with CardioMEMS were effectively managed by correspondent increases in clinician–patient interactions and leading to fewer heart failure hospitalizations.³⁵

Certain CIEDs can function as heart failure sensors through the serial measurement of thoracic impedance. Intrathoracic impedance is inversely related to volume overload; specifically, as pulmonary fluid increases, intrathoracic impedance decreases (and vice versa). The Optivol system (Medtronic, Minneapolis, MN, USA) utilizes an algorithm derived from serial thoracic impedance measurements to derive an

Figure 2 Virtual visit physical examination. Examination of jugular venous pressure (A) and lower extremity oedema (B) during a virtual visit with video capabilities during COVID-19 social distancing.



Examination of jugular venous pressure (a) and lower extremity edema (b) during a virtual visit

with video capabilities during COVID-19 social distancing

Table 2 Available remote heart failure monitoring sensors

| Technology | Sensor | Company | Patient population | Data transmission |
|------------|--|-------------------|--------------------|--------------------|
| CardioMEMS | PA pressure | Abbott | Separate implant | Intermittent |
| CorVue | Thoracic impedance | Abbott | ICD, CRT-D, CRT-P | Automatic/wireless |
| OptiVol | Thoracic impedance | Medtronic | ICD, CRT-D, CRT-P | Automatic/wireless |
| HeartLogic | Heart sounds, thoracic impedance, respiratory rate, heart rate, activity | Boston Scientific | ICD or CRT-D | Automatic/wireless |

CRT-D, cardiac resynchronization therapy-defibrillator; CRT-P, cardiac resynchronization therapy-pacemaker; ICD, internal cardioverter defibrillator; PA, pulmonary artery.

Figure 3 CardioMEMS pulmonary artery (PA) pressure tracings during COVID-19 social distancing. A telemedicine visit revealed new onset shortness of breath on April 11, 2020. CardioMEMS pressure tracings, (A) revealed elevated PA pressures (PA diastolic 25 mmHg;), tachycardia (heart rate 117 bpm; above patient-specific thresholds (). Based on this data, the patient was directed to take additional diuretics with resulting symptom improvement. CardioMEMS pressure tracings from April 13, 2020, (B) reveal normalization of PA pressures (PA diastolic 12 mmHg; and heart rates (HR 63 bpm;) with a PA diastolic measuring 2 mmHg less than the patient's set target threshold ().



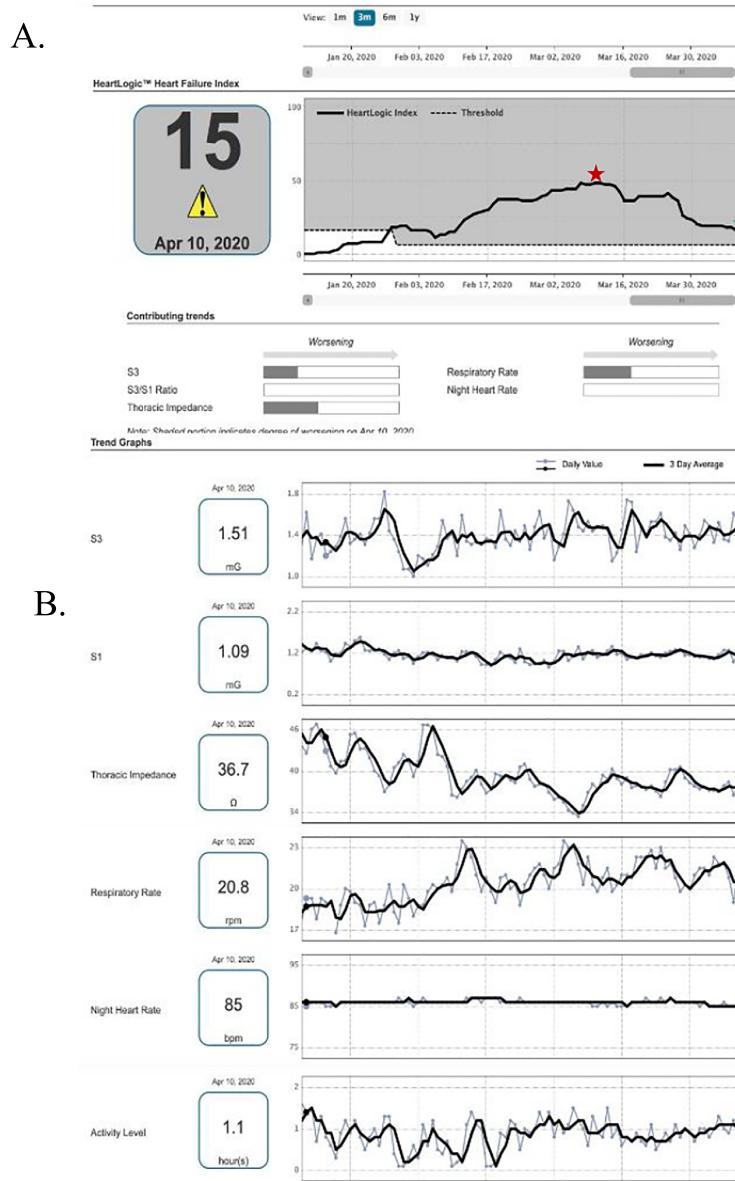
individualized 'Fluid Index' or impedance threshold at which a patient is at risk for clinical heart failure. This technology has been shown to be more sensitive than other clinical markers of heart failure.³⁶ While data showing a reduction in heart failure hospitalizations have been inconsistent, the objective data derived from this technology may serve as an important adjunct for providers and, in certain instances, may be able to presage a heart failure hospitalization at a time when face-to-face encounters are not possible and patient access is limited.^{36–39} Other devices measure heart rate variability to predict heart failure related events, although similarly have not been shown to have significant clinical utility in isolation.⁴⁰

Another device strategy, HeartLogic (Boston Scientific, St. Paul, MN), uses a proprietary multisensor algorithm collected by an implanted implantable cardioverter-defibrillator or cardiac resynchronization therapy-defibrillator device. With this algorithm, a HeartLogic index is derived from five metrics: intrathoracic impedance, nocturnal heart rate, the presence of a third heart sound, respiration rate, and patient activity. This index is a composite quantitative and objective assessment of a given patient's heart failure state. In the MULTI-SENSE trial, HeartLogic predicted heart failure events with 70%

sensitivity.⁴¹ Importantly, nearly 90% of patients enrolled in this study had a HeartLogic alert that preceded a true heart failure event by at least 2 weeks. This technology affords a provider advantage to intervene to further optimize heart failure management and potentially prevent a face-to-face visit or hospitalization. This index can be transmitted actively or on a routine schedule with the ultimate data and its interpretation to be derived from a collaborative effort between heart failure and cardiac electrophysiology providers. Figure 4 shows a representative example of a patient demonstrating a worsening trend in their HeartLogic index concerning for a decompensated heart failure state.

When one considers the CIED implantation volume in the heart failure population, it is more than plausible that available adjuvant heart failure sensors are being underutilized. This may be due in part to the opportunity for direct physical examination in traditional day-to-day practice. Another likely reason of underutilization of HF-CIED functionality is the perceived increased burden on resources and time that the set-up and maintenance of a robust remote monitoring platform and process requires. That being said, the potential utility of these technologies during this pandemic and time of social distancing cannot be underestimated and when used

Figure 4 HeartLogic Heart Failure Index report during COVID-19 social distancing. Elevated HeartLogic Heart Failure Index (HHFI) of 48 was noted on March 11, 2020 (★) significantly above the patient's threshold of 16. Subsequent improvement in HHFI trend to an index of 15 on April 10, 2020 (★) following dietary modification (A). Trends in multisensor parameters consisting of heart sounds (S1, S3), thoracic impedance, respiratory rate, night heart rate and activity level during this time period are illustrated in panel (B).



appropriately may be a powerful tool in the remote management of the heart failure patient.

Conclusion

In this era of social distancing, telemedicine and remote monitoring is emerging as an important tool for the management of heart failure patients. While many of these technologies are not new, their potential importance has been highlighted during the current COVID-19 pandemic. In general, these

strategies appear to be safe; however, additional data will be needed to determine their effectiveness with respect to both process and outcomes measures.

The management of heart failure patients during this time will ultimately be patient-specific and will undoubtedly lean on each individual provider's style of practice. However, providers should consider all available tools in order to empower the patient-provider experience, optimize management, and reduce the risk of heart failure hospitalizations at a time when access to hospitals is limited and patients are fearful to engage with medical centres. From this pandemic, we

should continue to aspire to learn lessons that will improve patient access to care and optimize management for heart failure patients using all available skillsets and technologies even when social distanced.

Conflict of interest

Andrew S. Oseran, Maxwell Eyram Afari, Conor D. Barrett, Gregory D. Lewis, and Sunu S. Thomas declare no conflicts of interest.

Funding

The authors have no sources of funding to declare.

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