

Review Article

Remote Patient Monitoring to Improve Outcomes in Heart Failure

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Abstract

In chronic medical conditions remote patient monitoring (RPM), is beneficial to empower both medical providers and patients. RPM supports medical care and early interventions to potentially promote patient's disease management and improve outcomes. In heart failure, although RPM holds significant promise, published trials provide evidence regarding historical success and failures that inform future efforts. Heart failure has increased in incidence and prevalence during the past years, leading to significant cost. We must find alternate ways to monitor daily disease progression and symptomatology to allow the patient and their health provider react to not only reduce cardiovascular outcomes but reduce hospitalizations and readmission rates. Here we display most up to date studies and analysis of our perspective on the role of RPM in heart failure.

ABBREVIATIONS

HF: Heart Failure; RPM: Remote Patient Monitoring; LVEF: Left Ventricular Ejection Fraction

INTRODUCTION

Heart Failure (HF), is a global problem with an incidence and prevalence that continue to increase exponentially. More than 6 million Americans suffer from HF, imposing an impressive economic and financial burden on the US healthcare system with an approximate annual cost of over \$30 billion US dollars [1]. By 2030, this economic burden is expected to increase by a 3-fold [2].

HF is one of the most frequent causes of hospitalization and remains the leading cause of 30-day hospital readmissions. Due to the high clinical and financial burden, reduction of costs, hospitalization, and mortality is a high priority for research investigation. Research of novel strategies for care coordination and the promotion of patient self-management, such as remote patient monitoring (RPM), and telemedicine, are of interest. Even though research on RPM and telemedicine began two decades ago, it is not currently standard of care. Early enthusiasm followed small studies that yielded positive results, but as the same strategies were applied in large multicenter, randomized controlled trials, the results were less impressive.

RPM is critical for telemedicine advancement. The reliance on telemedical alternatives for patient access and care have increased due to the COVID-19 pandemic [3]. These alternatives

allow patients to play a direct role in their medical care, leading to improve outcomes and reduction in healthcare expenditure [4]. The advantage of objective day to day data provided by RPM has been recognized by the updated medical coding system. The Medicare code "Chronic Care Remote Physiologic Monitoring" which is billed under CPT Code 99091, provides reimbursement for the collection and interpretation of physiologic data such as remote electrocardiogram, blood pressure and glucose monitoring [5]. These codes reimburse for patient's a direct role/access to health care and hold promise to reduce unnecessary medical visits and hospitalizations.

With these promising changes that support patient access for remote monitoring we are compelled to ask an important question. Why have RPM and telemedicine historically failed in benefiting HF outcomes? Where does the evidence fall short? Monitoring of hypertension, atrial fibrillation, coronary atherosclerosis and diabetes mellitus (strong contributors to incident HF) are valuable, where do we stand in monitoring HF?

The current guidelines from the Heart Failure Society of America do not recommend noninvasive RPM strategies for heart failure. Slightly stronger evidence comes from the European Society of Cardiology, which provides a weak yet positive recommendation that HF remote monitoring be considered. Financial pressure and the growing need for alternate low-risk, technologically efficient contactless strategies deem HF RPM and telemedicine a still relevant and essential area for further study. As a result, understanding the successes and failures in previous clinical investigations is crucial to inform the next steps forward.

In 2005, TEM-HMS [6], investigated potential benefits between RPM, nurse telephone support and usual care among 426 HF patients with recent HF admission and left ventricular ejection fraction (LVEF), less than 40%. Performed in Europe, the study showed decreased hospital length of stay among RPM and nurse telephone support groups when compared to usual care. TEM-HMS also showed increased one-year mortality among patients in the usual care group when compared to either RPM or nurse telephone support [6]. In 2007, Telemonitoring to Improve Heart Failure Outcomes (Tele-HF), was published in the US [7]. This randomized controlled trial included 1653 patients recently hospitalized for HF, which were then randomly assigned to either remote monitoring or usual care. Patients in the remote monitoring group received daily telephone-based interactive voice response contacts with symptoms and vital sign collection. Information was reviewed by clinicians, with intervention as necessary. The outcome at 180 days revealed no significant difference in death or hospitalization rate.

Telemedical Interventional Monitoring in Heart Failure (TIM-HF), a German study published in 2010, studied the impact of non-invasive remote monitoring on all-cause mortality, hospitalization rate, and composite cardiovascular mortality [8]. The study enrolled 710 patients with mildly symptomatic HF and either $LVEF \leq 25\%$ or $LVEF \leq 35\%$ and HF hospital admission within two years; and all on stable guideline-directed medical therapy. Selected patients were randomly assigned to either remote telemonitoring or usual care. In this study, remote monitoring included a 3-lead electrocardiogram, a blood pressure device, and a scale. The data generated by the remote-monitoring was transmitted daily to a physician-led telemedical center where strict communication and intervention protocols were followed. TIM-HF failed to demonstrate a significant impact on HF-related rehospitalization rates or mortality benefits [8].

Examining 10 trials published before 2012, a meta-analysis [9], revealed that remote monitoring or telemedicine interventions in HF patients did not produce significant differences in mortality rates, hospitalizations, readmissions, or quality of life [9]. Reflecting on disappointing outcomes, we seek to understand the obstacles encountered in these studies and lessons to be applied to future studies.

Most studies were challenged by patient adherence to the RPM strategies. For instance, in Tele-HF 14% of patients in the telemedicine group never used the system, and at the end of the study, only half used the system as instructed. Second, the patients experienced a high rate of events, for instance in TIM-HF hospitalization occurred in 44% and 39% of the intervention and control group respectively. Furthermore, mortality occurred in 8% of the recruited patients, suggesting perhaps patients were too ill, too far advanced in the disease process for successful intervention. Finally, success in single center trials that did not translate to large cohorts, illustrating the importance of individualized patient intervention. Solutions with scripted communications and protocolized treatment algorithms may need to yield to technology facilitated face to face interactions using video assisted home visits or the use of artificial intelligence.

The most recent trials include "Effectiveness of Remote Patient Monitoring after Discharge of Hospitalized Patients

with Heart Failure: The Better Effectiveness after Transition Heart Failure" (BEAT-HF), that was published in 2016. Here quality-of-life was improved with telemonitoring and nurse telephone health coaching. There was no significant mortality benefit or improved readmission rate [10]. Next, in 2018, the European "Efficacy of Telemedical Interventional Management in Patients with Heart Failure" (TIM-HF2) was published. TIM-HF2 stratified 1,571 patients based on their cardiovascular risk factor profile and provided individualized management [11], utilizing technology to facilitate patient adherence. The primary outcome was the percentage of days lost due to unplanned cardiovascular hospital admissions or all-cause death [11]. Compared to usual care, patients in the telemonitoring group experienced a significantly lower percentage of days lost due to unplanned cardiovascular admissions ($p=0.046$), decreased lost mean days, and decreased all-cause death rates ($p=0.028$). [6] The study nearly missed significance in cardiovascular mortality between the two groups ($p=0.056$) [11]. TIM-HF2 proved to be the first multicenter randomized controlled trial to benefit heart failure patients. Yet, the positive outcome of the intervention was sustained only during active remote management. A follow-up study published in 2020 [12], showed extinction of the benefit upon removal of remote monitoring intervention.

Charting the next steps in this field, we must acknowledge considerable disruption that occurred in 2020. The COVID pandemic created necessity for telemedicine across the United States. At the same time Americans examined how to provide better care to vulnerable populations. As mobile technology becomes more affordable and older populations become adept at using it, we are positioned to implement technology in new ways. Future solutions must provide efficiency for clinical providers, develop meaningful clinical interactions and produce patient centric end points. Providers have evolved, patients have evolved, and medicine has evolved. This research will investigate a new paradigm in telemedicine and remote monitoring in HF.

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