Home Telemedicine in Heart Failure: A Pilot Study of Integrated Telemonitoring and Virtual Provider Appointments
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Running Head: Telemedicine in Heart Failure

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Abstract

Introduction: Congestive heart failure is an important cause of hospitalization, re-hospitalization, and death. Reducing hospital re-admission rates is a national priority. Various telemonitoring devices and programs have been developed to help meet this goal. The Health Connect system incorporates monitoring of physiologic data with regular virtual provider appointments.

Methods: Patients with NYHA II/III symptoms and left ventricular ejection fraction <35% were included. Patients were randomized into usual care and intervention groups. Usual care included standard medical therapy and regular office-based follow-up. The intervention group received standard care and a Health Connect telemedicine device for 3 months. The device allowed for daily monitoring of vital signs and weight and weekly virtual appointments. Primary outcome was all-cause and cardiac rehospitalization at 3, 6, and 12 months.

Results: 24 patients were enrolled; 12 usual care, 12 intervention. The control group was more likely to use tobacco, otherwise the groups were similar. There was no statistical difference in baseline clinical characteristics, laboratory characteristics, or heart failure medications. At one month the monitored group had 1 re-admission, usual care group had 7 (p=0.03). There was no difference at 3 or 6 months.

Discussion: The Health Connect system integrates traditional telemedicine with virtual provider appointments. Virtual appointments empower patients to advocate for their own health by providing numerous opportunities for education and feedback. In addition to early identification of impending decompensation virtual appointments allow providers to address noncompliance—a major factor driving poor outcomes. Further research is required to confirm the benefit of the Health Connect system.

Key words: Telemedicine, Heart failure, re-hospitalization
Introduction

Congestive heart failure (CHF) is one of the most common causes of hospitalization and readmission in the United States\(^1\). It has been singled out as an epidemic and is a staggering clinical and public health problem. CHF has been associated with significant mortality, morbidity, and healthcare expenditures, particularly among those aged ≥65 years. Despite progress in reducing CHF-related mortality, hospitalizations for CHF remain frequent and rates of readmissions continue to rise\(^2\).

Reducing hospital readmission rates is a national priority. There is currently a lack of evidence supporting strategies to effectively reduce readmission rates\(^3\). Some strategies include optimizing evidence-based drug and device therapies, addressing causes of CHF exacerbations, treating co-morbid conditions, and improving care management and coordination\(^4\). Basoor et al demonstrated that effective discharge instructions (i.e., appropriate dose up-titration, education regarding heart failure monitoring, and strict outpatient follow-up) can prevent CHF readmission\(^5\). All of these strategies are likely underutilized throughout the county. Ketterer et al identified the presence of psychiatric disorders and cognitive impairment as possible risk factors for early readmission\(^6\).

Interest in telemonitoring interventions to reduce readmissions in patients with CHF is growing\(^7\). The objective of this study was to determine the practicality and acceptability of a novel home telemonitoring system.

Methods

Patients with systolic heart failure, NYHA II/III symptoms, and left ventricular ejection fraction <35% were included (n = 24). The patients were randomized in a 1:1 ratio to the control or intervention group. The control group received standard care, consisting of optimal medical therapy with beta-adrenergic antagonist, angiotensin converting enzyme inhibitors (ACEI), aldosterone receptor
antagonists, vasodilators, and diuretics dosed to achieve a euvolemic state, resting heart rate <100 bpm, and blood pressure <140/90 mmHg. Medications were chosen and dosed at the discretion of the patient’s primary cardiologist. The intervention group received standard care in addition to daily remote monitoring of blood pressure, heart rate, oxygen saturation, and weight via the Health Connect telemonitoring system for 3 months. Furthermore, the intervention group received weekly video calls to discuss care issues, answer questions, and monitor compliance with medication regimens and office visits. Due to the nature of the study it was not possible to blind the caregivers or participants. Study participants were included if they met the following conditions (table 1):

1. CHF NYHA II or III;

2. LVEF <35%;

3. Hospital admission due to heart failure within 6 months of enrollment;

4. Optimal medical treatment (BB, ACEI/ARB, diuretics);

5. Age of 18 years or older; and

6. Ability to understand the study and willingness to provide informed consent.

Study participants were excluded from the study if they met one or more of the following conditions (table 1):

1. Inability or unwillingness to consent to the study;

2. Lack of English verbal skills needed to communicate with the study personnel, as assessed at the time of consenting;

3. Lack of computer skills necessary to operate the telemonitoring device;
4. Terminal illness other than CHF with a life expectancy of <1 year;

5. Severe cognitive impairment with inability to operate the telemonitoring equipment;

6. Primary valvular heart disease;

7. Unstable angina;

8. Hypertrophic or restrictive cardiomyopathy;

9. Liver cirrhosis;

10. Chronic renal failure with creatinine >2.5 mg/dL;

11. Alcohol or drug abuse;

12. Planned revascularization or CRT implantation;

13. Pregnancy; and

14. Concurrent participation in other trials.

Patient weight was charted and monitored for a change >10%. Patients were typically scheduled for office based follow-up at 2 weeks, 3 months, and 6 months after the initial consultation. Patient data was reviewed by a physician or nurse with expertise in cardiology. Any parameters outside of a normal range resulted in a consultation with a cardiologist for medication adjustments or recommendation for an office visit with a cardiologist. The intervention was performed for 3 months. The following parameters were considered abnormal for this study: heart rate >100 bpm; weight increase or decrease >10% over baseline; systolic blood pressure >140 mmHg and/or diastolic blood pressure >90 mmHg; O₂ saturation <92%; and development of new symptoms including angina, dyspnea, palpitations, orthopnea, dizziness, or lightheadedness (pre-syncope). At each visit (whether in-person or virtual), vital
signs, patient complaints/concerns, and changes to medications were recorded. Hospital readmissions were documented by interview and review of electronic medical records.

The primary study outcome measure was the frequency of all-cause and heart failure related to rehospitalization. Our secondary study outcome measures were cardiovascular and all-cause mortality. Follow-up meetings were conducted with all study patients at 3, 6, and 12 months.

Statistical Analysis

Descriptive statistics were generated to characterize the study populations according to demographic factors (i.e., age, gender, race, and known cardiovascular risk factors). Continuous variables were described using the mean, standard deviation, and range. Categorical variables were described using frequency distributions. Univariate analysis between groups was performed using Fisher’s exact test for binary variables, chi-squared tests for categorical variables, and t-tests for continuous variables. Linear regression analysis was used to model differences according to age, gender, other demographic factors, or cardiovascular risk factors, between study groups for the primary and secondary outcomes. A p-value of ≤0.05 was considered statistically significant.

Results

Table 2 summarizes participant demographics. Overall, 28 patients were enrolled. 14 were randomized to telemonitored arm and 14 to the control arm. As shown in table 2 there was no significant difference in co-morbid conditions between participants in both arms of the study. The majority were African American with 12 (86%) in monitored arm vs. 10 (71%) in the usual care arm (P-value 0.65). However, tobacco use was less common in monitored group vs. that of the usual care group (21% vs. 57% P-value 0.05).
Table 3 demonstrates the baseline clinical and laboratory characteristics along with discharge medications between participants in both arms of the study. Again there was no statistically significant difference between the two arms in regard to NT-proBNP (7094 Vs. 9994 P 0.33), ejection fraction (23.5 Vs. 22.1 P 0.4), ICD use (9 Vs. 7 P 0.45), and other parameters shown in table 2.

During the 12-months follow up period, the monitored arm received the weekly teleconferencing intervention for the first 3 months. Table 4 summarizes the primary and secondary study outcomes. Hospital readmission rates were statistically significant in the first 30 days between the arms (1 vs. 7 with P-value 0.03). There were no significant differences between readmission rates between the 2 arms at 3 or 6 months intervals. This was noted for both cardiac and non-cardiac causes of readmission. Furthermore, all-cause mortality was equal between the 2 arms during the 12 months study period with 7% in the monitored arm Vs. 14% in the control one (P >0.99).

Discussion

Telemedicine and telemonitoring technologies have been developed to include a wide range of possible patient-healthcare provider interactions. With advances in the field of information technology more sophisticated systems will continue to be developed. In the home setting, telemonitoring has been utilized for several chronic conditions (including diabetes mellitus, hypertension, chronic obstructive pulmonary disease, and cardiovascular disease)\(^8\). Among cardiovascular diseases heart failure in particular stands out as being suitable for the utilization of telemedicine technology. Patients with heart failure have a complicated disease and treatment course with frequent hospitalizations as well as high disease-related morbidity and mortality rates\(^9\).

Studies that have been conducted to examine the impact of telemonitoring on heart failure treatments have shown mixed results. An improvement in the overall survival of 17–47% over a 6–12 month follow-up and a decrease in the number and duration of hospitalizations after using
telemonitoring techniques has been demonstrated in 2 large meta-analyses\textsuperscript{10,11}. The validity of these findings has been questioned as many of the included trials utilized poor study designs (i.e., lack of randomization, no control group, relatively small sample size and vastly different telemonitoring techniques).

Two large randomized controlled trials failed to demonstrate a benefit in hospitalization or survival. In the TELE-HF study, patients who were recently admitted to the hospital were randomized to either the telemonitoring (n = 826) or usual care (n = 827) group\textsuperscript{12}. The telemonitoring group was instructed to call a toll-free number and follow voice prompted questions regarding symptoms and daily body weight. Certain responses triggered "variances," which were brought to the attention of a supervising physician who could take appropriate action. A significant difference in hospital readmission or death between the 2 groups was not detected in the trial. This telemonitoring strategy (i.e., entering data via automated telephone prompts) may not be ideal as the patients play a very passive role and typically do not receive immediate feedback on their clinical progress. In the TIM-HF study stable patients with chronic heart failure were randomly assigned to either the telemonitoring (n = 354) or usual care (n = 356) groups\textsuperscript{13}. A difference in all-cause mortality was not identified. The TIM-HF study used devices with wireless Bluetooth capabilities and a personal data assistant that automatically transmitted data to a telemonitoring center. This method also lacks direct contact between the patient and provider. The TIM-HF study population (i.e., patients with stable heart failure) may not be the population that would derive the most benefit from telemonitoring.

Prior applications of telemonitoring were designed around the principle that regular monitoring of physiologic parameters will enable early identification of clinical changes and consequently allow for intervention before decompensation. The Health Connect system provides the added benefit of virtual appointments with healthcare providers. Virtual appointments allow review of telemonitoring data,
assessment of symptoms, time for direct patient education, and monitoring of compliance with medications, diet, and office appointments. Most studies on the effects of telemonitoring report a high rate of patient satisfaction\textsuperscript{14}. An important benefit of telemonitoring appears to be related to patient empowerment. Patients gain insight and awareness into their disease when they are directly involved in the care process. Virtual appointments foster an environment that encourages patient empowerment by offering ideal opportunities for this type of interaction. The addition of virtual appointments truly transforms basic telemonitoring into telemedicine.

Despite the availability of evidence-based pharmacotherapies shown to improve survival and need for hospitalization, nonadherence to prescribed regimens remains a common problem in patients with heart failure. A recent study \((n = 557)\) demonstrated a rate of nonadherence to prescribed treatments of 39–65\% depending on the medication\textsuperscript{15}. Nonadherence was associated with a significantly higher risk of all-cause mortality and cardiovascular hospitalization. The investigators estimated that 23-31\% of hospital readmissions could have been prevented by improved adherence. It has been suggested that the level of adherence needs to be quite high (\textgreater{}88\%) in order to improve disease-free survival\textsuperscript{16}. Several factors appear to play a role in these high nonadherence rates. In one study \((n = 954)\), patients with depressive symptoms and poor knowledge of their condition experienced significant difficulties with adherence\textsuperscript{17}. The telemedicine system employed in the current study allows clinicians to not only monitor and encourage medication adherence, but also provides an ideal opportunity for patient education, which is a root cause of nonadherence.

A major limitation with traditional telemonitoring is the lack of clinical context for the collected physiological data. Virtual appointments provide this context and enable clinicians to better determine the most appropriate intervention. For example, a change in a previously stable vital sign may represent medication noncompliance, which may resolve with resumption of the missed medication. If necessary,
medication doses can be adjusted or the patients can be referred for an early appointment with their cardiologist. Patients should be taken directly to the emergency department if the clinical condition becomes serious or life-threatening.

Large randomized controlled trials that are adequately powered to detect effects on survival and hospitalization are needed to confirm the clinical benefits of this telemedicine system. If the benefits are found to be real the economic viability of telemedicine over usual care would need to be assessed prior to widespread implementation of this system.

Conclusion

The Health Connect telemedicine system appears to be acceptable and easy to use for both patients and healthcare providers. The integration of traditional telemonitoring technology with virtual provider appointments offers a powerful tool to improve outcomes in patients with chronic heart failure. Further research is required to confirm the clinical benefit and economic viability of the Health Connect system over standard medical therapy.

Tables

Table 1: Inclusion and Exclusion criteria.

<table>
<thead>
<tr>
<th>INCLUSION CRITERIA</th>
<th>EXCLUSION CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHF NYHA II or III</td>
<td>Inability or unwillingness to consent to the study</td>
</tr>
<tr>
<td>LVEF &lt; 35%</td>
<td>Lack of English verbal skills needed to communicate with the study personnel, as accessed at the time of consenting.</td>
</tr>
<tr>
<td>Hospital admission due heart failure within 6 months of enrollment</td>
<td>Lack of computer skills necessary to operate the telemonitoring device.</td>
</tr>
<tr>
<td>Optimal medical treatment (BB, ACEI/ARB, diuretics).</td>
<td>Terminal illness other than CHF with life expectancy less than 1 year</td>
</tr>
<tr>
<td>Age 18 and older</td>
<td>Severe cognitive impairment with inability to</td>
</tr>
</tbody>
</table>
Ability to understand the study and willingness to provide informed consent

Primary valvular heart disease

Unstable angina
Hypertrophic or restrictive cardiomyopathy
Liver cirrhosis
Chronic renal failure with creatinine > 2.5mg/dl
Alcohol or drug abuse
Planned revascularization or CRT implantation
Concurrent participation in other trials
Pregnancy

Table 2: Participant demographics; CAD= coronary artery disease, COPD= chronic obstructive pulmonary disease, CKD= chronic kidney disease.

<table>
<thead>
<tr>
<th></th>
<th>Monitored (n=14)</th>
<th>Usual Care (n=14)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58.5</td>
<td>66.5</td>
<td>0.07</td>
</tr>
<tr>
<td>African American</td>
<td>12 (86%)</td>
<td>10 (71%)</td>
<td>0.65</td>
</tr>
<tr>
<td>Male</td>
<td>5 (36%)</td>
<td>6 (43%)</td>
<td>0.70</td>
</tr>
<tr>
<td>Hypertension</td>
<td>14 (100%)</td>
<td>13 (93%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>6 (43%)</td>
<td>10 (71%)</td>
<td>0.13</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>3 (21%)</td>
<td>8 (57%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>10 (71%)</td>
<td>13 (93%)</td>
<td>0.33</td>
</tr>
<tr>
<td>CAD</td>
<td>6 (43%)</td>
<td>10 (71%)</td>
<td>0.13</td>
</tr>
<tr>
<td>COPD</td>
<td>2 (14%)</td>
<td>7 (50%)</td>
<td>0.10</td>
</tr>
<tr>
<td>CKD</td>
<td>7 (50%)</td>
<td>8 (57%)</td>
<td>0.71</td>
</tr>
</tbody>
</table>

Table 3: Baseline clinical and laboratory characteristics and discharge medications.

<table>
<thead>
<tr>
<th></th>
<th>Monitored (n=14)</th>
<th>Usual Care (n=14)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NT-proBNP (pg/mL)</td>
<td>7094</td>
<td>9994</td>
<td>0.33</td>
</tr>
<tr>
<td>NYHA class</td>
<td>2.6</td>
<td>2.4</td>
<td>0.60</td>
</tr>
<tr>
<td>Ejection Fraction</td>
<td>23.5</td>
<td>22.1</td>
<td>0.40</td>
</tr>
<tr>
<td>Baseline edema</td>
<td>7 (50%)</td>
<td>10 (71%)</td>
<td>0.09</td>
</tr>
<tr>
<td>ICD</td>
<td>9 (64%)</td>
<td>7 (50%)</td>
<td>0.45</td>
</tr>
<tr>
<td>Aspirin</td>
<td>10 (71%)</td>
<td>13 (93%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>11 (79%)</td>
<td>14 (100%)</td>
<td>0.22</td>
</tr>
<tr>
<td>ACEi/ARB</td>
<td>12 (86%)</td>
<td>10 (71%)</td>
<td>0.65</td>
</tr>
<tr>
<td>Statin</td>
<td>9 (64%)</td>
<td>12 (86%)</td>
<td>0.39</td>
</tr>
<tr>
<td>Loop diuretic</td>
<td>13 (93%)</td>
<td>13 (93%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Spironolactone</td>
<td>9 (64%)</td>
<td>5 (36%)</td>
<td>0.13</td>
</tr>
<tr>
<td>Digoxin</td>
<td>2 (14%)</td>
<td>5 (36%)</td>
<td>0.39</td>
</tr>
<tr>
<td>Hydralazine</td>
<td>4 (29%)</td>
<td>5 (36%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Nitrate</td>
<td>5 (36%)</td>
<td>5 (36%)</td>
<td>&gt;0.99</td>
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</tbody>
</table>
Table 4: Clinical outcomes, including death and hospital readmission at 1, 3 and 6 months. Readmissions were further classified as cardiac or noncardiac.

<table>
<thead>
<tr>
<th></th>
<th>Monitored (n=14)</th>
<th>Usual Care (n=14)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1 (7%)</td>
<td>2 (14%)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>1 month readmit</td>
<td>1</td>
<td>7</td>
<td>0.03</td>
</tr>
<tr>
<td>3 month readmit</td>
<td>6</td>
<td>9</td>
<td>0.27</td>
</tr>
<tr>
<td>3 month cardiac admit</td>
<td>5</td>
<td>6</td>
<td>0.62</td>
</tr>
<tr>
<td>6 month readmit</td>
<td>15</td>
<td>18</td>
<td>0.62</td>
</tr>
<tr>
<td>6 month cardiac admit</td>
<td>13</td>
<td>13</td>
<td>0.84</td>
</tr>
</tbody>
</table>

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4 Gheorghiade M, Braunwald E. Hospitalizations for heart failure in the United States – a sigh of hope. JAMA 2011; 306:1705


11 Inglis SC, Clark RA, McAlister FA, et al. Structured telephone support or telemonitoring programmes for patients with chronic heart failure. Cochrane Database Syst Rev 2010;8


