A Randomized Controlled Trial of Telemonitoring in Older Adults With Multiple Health Issues to Prevent Hospitalizations and Emergency Department Visits

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Background: Efficiently caring for frail older adults will become an increasingly important part of health care reform; telemonitoring within homes may be an answer to improve outcomes. This study sought to assess differences in hospitalizations and emergency department (ED) visits among older adults using telemonitoring vs usual care.

Methods: A randomized controlled trial was performed among adults older than 60 years at high risk for rehospitalization. Participants were randomized to telemonitoring (with daily input) or to patient-driven usual care. Telemonitoring was accomplished by daily biometrics, symptom reporting, and videoconference. The primary outcome was a composite end point of hospitalizations and ED visits in the 12 months following enrollment. Secondary end points included hospitalizations, ED visits, and total hospital days. Intent-to-treat analysis was performed.

Results: Two hundred five participants were enrolled, with a mean age of 80.3 years. The primary outcome of hospitalizations and ED visits did not differ between the telemonitoring group (63.7%) and the usual care group (57.3%) (P = .35). No differences were observed in secondary end points, including hospitalizations, ED visits, and total hospital days. No significant group differences in hospitalizations and ED visits were found between the preenrollment period vs the postenrollment period. Mortality was higher in the telemonitoring group (14.7%) than in the usual care group (3.9%) (P = .008).

Conclusions: Among older patients, telemonitoring did not result in fewer hospitalizations or ED visits. Secondary outcomes demonstrated no significant differences between the telemonitoring group and the usual care group. The cause of greater mortality in the telemonitoring group is unknown.

Trial Registration: clinicaltrials.gov Identifier: NCT01056640


INCREASED LIFE EXPECTANCY IN DEVELOPED COUNTRIES HAS BEEN A REMARKABLE FEAT.1,2 Longer life expectancy challenges the health care system to optimally manage older patients at high risk for hospitalization.3 Caring for patients in their homes could provide a cost-effective approach using telemonitoring of clinical symptoms and biometrics. Telemonitoring systems offer biometrics tracking and videoconferencing asynchronously and in real time and allow data to be transmitted easily from patient to physician. Many care organizations will focus on high-risk older adults with multiple chronic illnesses as a part of medical home initiatives. Home telemonitoring may reduce hospitalizations and emergency department (ED) visits in this population. This is important because hospitalizations and ED visits may portend functional decline in older adults4 or mortality.5 Home telemonitoring has been shown to reduce hospital admissions, ED visits, and hospital length of stay in various chronic illnesses.6,8 Results of a systematic review suggest a 20% reduction in hospitalizations among patients with cardiovascular disease (primarily heart failure) using telemonitoring.9 However, the Tele–Heart Failure study10 showed no reductions in hospitalizations associated with telemonitoring.
ing. In patients with multiple chronic conditions, insufficient evidence supports the efficacy of telemonitoring to prevent hospitalizations or ED visits. To fill this gap, we conducted a randomized controlled trial comparing daily home telemonitoring (with biometrics, symptom reporting, and videoconference) vs usual care in older adults at high risk for hospitalization. We hypothesized that telemonitoring would reduce hospitalizations and ED visits compared with usual care.

METHODS

STUDY DESIGN

We conducted a multisite randomized controlled trial at 4 sites within Mayo Clinic’s Employee and Community Health program. Three sites are in Rochester, Minnesota, and the fourth is in rural Kasson, Minnesota. Patients were randomized to telemonitoring or to usual care. We obtained study approval from the Mayo Clinic Institutional Review Board on October 30, 2009. All patients provided written informed consent before enrollment and randomization.

There was no change in the study protocol or group allocation after the initiation of the trial. Specifically, no variation occurred at the sites of care or in the study eligibility criteria.

PARTICIPANTS

Inclusion Criteria

Eligible patients were older than 60 years who were enrolled in the Employee and Community Health program primary care panel and whose Elder Risk Assessment Index (ERA) exceeded 15. The ERA is an electronic database to assess patient risk for hospitalizations or ED visits based on administrative data for age, sex, previous hospitalizations, and comorbid conditions (stroke, dementia, heart disease, diabetes mellitus, and chronic obstructive pulmonary disease). Previous hospitalizations are weighted heavily in a standard fashion but are not required for a high ERA. Patients in the top 10% of ERAs in the Employee and Community Health program were identified as eligible for enrollment.

Exclusion Criteria

Patients who lived in a nursing home, had a clinical diagnosis of dementia, or scored 29 or less on the short test of mental status by Kokmen et al13 were excluded from the study. Patients who believed they could not use the telemonitoring system (ie, because of visual impairment or inability to use the device) were excluded from the study.

Settings

According to census data for the study period, most residents older than 60 years in Olmsted County, Minnesota, were female (55%) and of white race/ethnicity (>90%). The Employee and Community Health program has a combined population of about 21,000 patients older than 60 years. Collection of study data occurred within the participant’s home or in the clinical setting, depending on the comfort level of the patient. Survey instruments were administered in a standard fashion.

INTERVENTIONS

Telemonitoring

Details of the telemonitoring intervention protocol were previously described. A Food and Drug Administration–approved telemonitoring device (Intel Health Guide; Intel-GE) was used in the patient’s home. The device had real-time videoconferencing capability and peripheral measures (scales, blood pressure cuff, glucometer, pulse oximeter, and peak flow data). Telemonitoring patients performed daily sessions (5–10 minutes) for assessment of symptoms and biometrics. The device worked asynchronously, and data were downloaded to a health website, which was then reviewed by the health care team daily (J.L.P., G.J.H. and others), including weekends and holidays. A registered nurse oversaw approximately 100 patients and communicated with the individuals via phone or videoconference if alerts arose. The nurse assessed symptoms and communicated with the primary physician about treatment options if needed. The decisions for triage were made clinically by the nurse with decision support assistance from the electronic medical record as needed. Participants were advised to call 911 for emergencies because the telemonitor is not a lifesaving device.14

Usual Care

Usual care patients had access to primary and specialty office visits. Individuals routinely had posthospitalization outpatient visits in a timely fashion and received a nurse-generated phone call within 1 business day of hospital discharge. Usual care patients also had access to phone nursing, urgent clinic visits, and the ED.

DATA COLLECTION

Data were collected by the research team (P.Y.T., N.D.S., H.V.H., I.C., and J.M.N.) and were maintained electronically. The investigators (P.Y.T. and I.C.) also maintained paper records of all information. To ensure uniform application, the investigators and research team members were formally educated on the survey and examination instruments.

OUTCOMES

The primary outcome was a composite end point of hospitalizations and ED visits in the 12 months following enrollment, as prespecified in the original protocol. Data on hospitalizations and ED visits were obtained using administrative billing resources. Secondary end points included hospitalizations and ED visits as individual outcomes, along with total hospital days. Mortality was calculated from 12 months following enrollment; patients who dropped out of the study were included in the mortality evaluation. There were no changes in the methods of outcomes determination after the initiation of the trial.

Baseline data for all participants included age, sex, mood, functional status, cognitive status, and quality of life. Each individual was administered the Patient Health Questionnaire 9 to screen for depression19 and a short test of mental status by Kokmen et al10 to assess memory loss. The 12-Item Short Form Health Survey (SF-12), which measures quality of life and psychosocial factors,19 was administered to all participants. Functional status was assessed by measuring grip strength using tonometry,11 the timed Up & Go test,16 and gait speed in meters per second.19 Activities of daily living were measured by the Barthel ADL Index,20 which uses a self-reported questionnaire.
SAMPLE SIZE

Based on an α value of .05 and 80% power, the power calculations were derived from an estimated 76% event rate of hospitalizations and ED visits during 2 years in a high-risk group using the ERA. With 100 patients in each study group and a yearly hospitalization and ED visit rate of 38.2%, we were powered to detect a 36.1% decrease (from 38.2% to 24.4%) in combined outcomes.

RANDOMIZATION AND BLINDING

Block randomization was used at each site. Block size of 2 to 4 individuals was randomly determined using computer-generated allocation. Allocated randomization decisions (telemonitoring vs usual care) were placed in sequentially numbered envelopes at each site. Randomization was performed by statistical services, and study coordinators presented a randomization envelope to each participant after consent.

Given the requirements for participants to use the telemonitoring equipment, it was not possible to blind the patients or the study staff (P.Y.T., J.L.P., B.U., N.D.S., H.V.H., S.C., I.C., J.M.N., and G.J.H.) to the intervention. Analysis of the final results was performed in a blinded fashion.

DATA ANALYSIS

All analyses were performed according to original group assignment using an intent-to-treat method. Wilcoxon rank sum test, 2-sample t test, or χ² analysis was used to compare baseline characteristics between the 2 groups. The primary end points of combined and individual percentages of hospitalizations and ED visits were compared between the 2 groups using χ² test. Statistical adjustment was planned only if there were statistical differences in clinical variables between the groups. As a secondary method of analysis, the mean numbers of hospitalizations and ED visits were compared using Wilcoxon rank sum test. Kaplan-Meier time-to-event analysis was conducted, with a combined end point for mortality, hospitalizations, and ED visits. All tests for significance used a 2-sided P value of .05. Analyses were performed using commercially available software (SAS version 9.1 for Windows; SAS Institute, Inc).

RESULTS

Five hundred thirteen eligible individuals were phoned, with 234 visits scheduled to discuss the study. Two hundred five patients gave consent and were randomized. One hundred two were assigned to the telemonitoring group, and 103 were assigned to the usual care group. Recruitment started on November 25, 2009, and ended on July 26, 2011. Twenty-six telemonitoring patients (25.5%, representing 15 deaths and 11 withdrawals) did not complete the trial compared with 12 usual care patients (11.7%, representing 4 deaths and 8 withdrawals). The trial was stopped after achieving recruitment and time goals (Figure 1).

Baseline characteristics did not differ statistically between the groups except for a slightly lower SF-12 mental health composite score in the telemonitoring group (Table 1). The mean (SD) ages were 80.3 (8.9) years in the telemonitoring group and 80.2 (7.6) years in the usual care group. The SF-12 physical quality-of-life composite scores were similar, with mean (SD) scores of 35.5 (10.7) in the telemonitoring group and 34.7 (11.3) in the usual care group. The SF-12 mental health composite scores of 54.8 (8.7) in the telemonitoring group and 57.1 (7.1) in the usual care group were not statistically different (P = .03), with a slightly better score in the usual care group. Self-reported health was similar in both groups. The ERA results were also similar; however, they were lower than expected. With no clinical differences between groups, we made no statistical adjustments.

The primary outcome of the percentage of patients with hospitalizations and ED visits was 63.7% in the telemonitoring group compared with 57.3% in the usual care group, resulting in a 6.4% increased risk for the combined outcome among telemonitoring patients (P = .35) (Table 2). Considering each outcome separately did not reveal significant differences between the groups for hospitalizations, ED visits, and total hospital days. Mortality differed between the groups, with 15 deaths (14.7%) in the telemonitoring group and 4 deaths (3.9%) in the usual care group (P = .008). The ERA results at the end of study did not differ, with mean (SD) ERAs of 17.3 (6.1) in the telemonitoring group and 16.3 (5.5) in usual care group (P = .23). In total, 9938 of 11 212 scheduled telemonitoring visits (88.6%) were completed. In total, 3942 phone calls were made to participants using a telemonitor. No direct harms or unanticipated problems involving risk to participants or others were reported.

The study groups did not differ in preenrollment hospitalizations and ED visits compared with postenrollment hospitalizations and ED visits. Table 3 gives the total numbers of hospitalizations and ED visits for the telemonitoring group and for the usual care group. Table 4 compares the preenrollment and postenrollment numbers of hospitalizations and ED visits.
Telemonitoring is a potential method of home care management to reduce hospitalizations and ED visits. We found no difference herein between the telemonitoring group (63.7%) and the usual care group (57.3%) in hospital admissions and ED visits (P = .35). Previous telemonitoring investigations among patients with mixed chronic diseases have been promising but showed no improvement in outcomes. In a trial of 53 patients with congestive heart failure (CHF), chronic obstructive pulmonary disease, or a chronic wound, a trend toward fewer rehospitalizations approached statistical significance in the telemonitoring group vs the usual care group (15% vs 42%, P = .06).22 A randomized controlled trial of 104 patients with CHF, chronic obstructive pulmonary disease, or diabetes demonstrated a reduction in bed-days of care in a telemonitoring group vs a control group (1.88 vs 5.11 bed-days per 6 months, P < .001).23 However, in a trial of the same telemonitor as that used in our study, no difference was found in hospital admissions or ED visits among patients with heart failure using telemonitoring (44.5%) vs case management (40.1%).24 In the present study, there was a small increase in events, with potentially greater costs for support and equipment. This implies that investments in telemedicine may not provide better outcomes in its current delivery of case management.

Secondary end points of our study were also not significant, with no differences in hospitalizations between the telemonitoring group (52.0%) and the usual care group (43.7%) (P = .24). The ED was used at least once by 35.3%
in the telemonitoring group compared with 28.2% in the usual care group \( (P = .27) \). In previous studies, there were borderline nonsignificant differences between home telehealth and usual care in acute visits\(^2\) and rehospitalizations as individual outcomes.\(^2\) Consequently, the lack of significance for the primary and secondary end point herein may reflect a lack of clinical infrastructure to process the information. It may be that frequent contact with the nurse resulted in greater awareness of symptoms, which generated increased hospitalizations or ED visits. Protocols can help guide specific illnesses but may be more challenging in patients with multiple illnesses. Further work in care management of these adults with complex illnesses will be required for success in telemonitoring.

Telemonitoring in individual diseases has had mixed results in various trials. Although there are limitations in generalizing the results of single-disease trials (eg, CHF), they add valuable information to the existing evidence base for telemonitoring. The use of home telemonitoring in the Home–Heart Failure study\(^2\) resulted in fewer unexpected admissions for CHF. In a meta-analysis\(^2\) of CHF telemonitoring vs usual care, no difference was found in all-cause hospitalizations, but a reduction in CHF hospitalizations was observed. The Tele–Heart Failure study\(^1\) among 1653 participants revealed difference in hospitalization rates between telemonitoring vs usual care, although nonsignificantly higher rates of admission and readmission were seen in the telemonitoring group. In the study\(^3\) of telemonitoring vs case management among seniors with heart failure, no differences were observed in ED visits or hospitalizations. Our study extends the knowledge base because we apply telemonitoring to a group of patients with complex medical problems that will likely be part of medical home initiatives. Our results provide further evidence of a lack of efficacy of telemonitoring on hospitalizations and ED visits. Given the potential costs of telemonitoring and the lack of efficacy, it may be important for physicians and funding organizations to evaluate which patient groups might be most responsive and which implementation strategies will be most useful.

Mortality was increased in our telemonitoring group compared with the usual care group. Using the ERA stratification strategy, one would expect 22% mortality at 2 years, with an extrapolated 13% mortality at 1 year.\(^2\) The 14.7% mortality among the telemonitoring group herein is consistent with this. Mortality in the usual care group was 3.9%, which was lower than expected. The difference in mortality between the 2 groups could be due to the lower-than-

Table 3. Preenrollment and Postenrollment Emergency Department (ED) Visits, Hospitalizations, and Total Hospital Days

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (N = 205)</th>
<th>Telemonitoring (n = 102)</th>
<th>Usual Care (n = 103)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED visits</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preenrollment</td>
<td>115</td>
<td>74</td>
<td>41</td>
</tr>
<tr>
<td>Postenrollment</td>
<td>118</td>
<td>72</td>
<td>46</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preenrollment</td>
<td>211</td>
<td>102</td>
<td>109</td>
</tr>
<tr>
<td>Postenrollment</td>
<td>195</td>
<td>110</td>
<td>85</td>
</tr>
<tr>
<td>Total hospital days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preenrollment</td>
<td>840</td>
<td>397</td>
<td>443</td>
</tr>
<tr>
<td>Postenrollment</td>
<td>1051</td>
<td>420</td>
<td>631</td>
</tr>
</tbody>
</table>

Figure 2. Combined end point for time-to-event analysis of mortality, hospitalizations, and emergency department (ED) visits.
expected mortality among the usual care group or could represent higher mortality among the telemonitoring group because of increased access to health care that occurred with telemonitoring. For example, the performance of unnecessary tests could have resulted in increased mortality among the telemonitoring group. It is possible that the 2 groups differed by chance or by another unrecorded predictor; however, recorded variables were similar between the groups at baseline except for the SF-12 mental health composite score. The ERA results at study entry were similar in the 2 groups. Access to ED and hospital care remained the same in both groups.

This novel study represents the largest randomized controlled trial to date of telemonitoring focusing on older adults with multiple illnesses. The application of risk stratification reflects real-world practice and will likely be used in medical home initiatives. The model used mimics a clinical practice using communication between a telemonitoring team and the primary care physician. 34 In addition, the trial reflects an effort to change clinical practices for primary care physicians. However, our study has some limitations. It was not practical to blind the physicians or the patients receiving home equipment and monitoring. This could have led to the Hawthorne effect that states that the act of being monitored changes behavior. Within the telemonitoring group, the Hawthorne effect should favor an improved effect in that group. The clinical outcomes were derived from Mayo Clinic billing records; therefore, patients receiving care outside of Mayo Clinic may not be recorded. It is also possible that the groups differed by an unmeasured quality, such as socioeconomic status, education, transportation, and caregiver or social support, which might have changed use.

Other limitations of the study involve generalizability. The population of Olmsted County is primarily of Northern European descent, which limits the application of our results. Patients in the usual care group had access to a tertiary care hospital and to some case management for treatment of heart failure and diabetes. These services may have biased the results to show no difference between the groups. The study was powered at the upper end of the clinically reasonable range at 38.2%, but we saw the results go in a different direction from what we had hypothesized.

In conclusion, in this unique study of 205 patients with multiple comorbid illnesses, there was no difference in combined hospitalizations and ED visits between patients receiving telemonitoring vs usual care. The lack of efficacy of telemonitoring may reflect the number of patients in the trial or may indicate a lack of effective infrastructure needed to fully optimize case management.

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In this issue of the Archives, Takahashi et al2 report on the results of a rigorous randomized controlled trial of telemonitoring in older adults at high risk for hospitalization. They found that in-home monitoring of biometrics (eg, blood pressure and weight) and symptoms failed to reduce hospital readmissions or the need for emergency department (ED) visits compared with usual care. The results of this study are important and sobering and warrant careful consideration. It might be tempting to discount the lack of benefit of the telehealth intervention for any number of reasons. For example, it might be possible that the lack of effect in the telehealth intervention compared with usual care was a consequence of the fact that usual care was already outstanding because the comparator group was already receiving care from a top-tier integrated delivery system (Mayo Clinic, Rochester, Minnesota). Alternatively, it is possible that telehealth is not beneficial among the (presumed) highly educated and affluent residents of Olmsted County, Minnesota, because such patients already are highly activated and engaged in their own health care at baseline.

We would caution against such discounting of this study and its negative findings. In contrast, we would argue that this study joins a growing body of literature suggesting that home telehealth does not reduce readmissions or ED visits. Most, but not all, of these studies have focused on patients with congestive heart failure, which adds to the importance of the study by Takahashi et al. In a 2010 study in The New England Journal of Medicine, Chaudhry et al11 found that telemonitoring failed to reduce mortality or hospital readmission for patients with congestive heart failure. A 2011 study published in Circulation by Koehler and colleagues12 reached similar conclusions. Studies13,14 focusing on other applications of telehealth (eg, disease management for other conditions) have similarly shown the value of this approach.

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