



Published in final edited form as:

N Engl J Med. 2010 December 9; 363(24): 2301–2309. doi:10.1056/NEJMoa1010029.

Telemonitoring in Patients with Heart Failure

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Abstract

BACKGROUND—Small studies suggest that telemonitoring may improve heart-failure outcomes, but its effect in a large trial has not been established.

METHODS—We randomly assigned 1653 patients who had recently been hospitalized for heart failure to undergo either telemonitoring (826 patients) or usual care (827 patients). Telemonitoring was accomplished by means of a telephone-based interactive voice-response system that collected daily information about symptoms and weight that was reviewed by the patients' clinicians. The primary end point was readmission for any reason or death from any cause within 180 days after enrollment. Secondary end points included hospitalization for heart failure, number of days in the hospital, and number of hospitalizations.

RESULTS—The median age of the patients was 61 years; 42.0% were female, and 39.0% were black. The telemonitoring group and the usual-care group did not differ significantly with respect to the primary end point, which occurred in 52.3% and 51.5% of patients, respectively (difference, 0.8 percentage points; 95% confidence interval [CI], -4.0 to 5.6 ; $P = 0.75$ by the chi-square test). Readmission for any reason occurred in 49.3% of patients in the telemonitoring group and 47.4% of patients in the usual-care group (difference, 1.9 percentage points; 95% CI, -3.0 to 6.7 ; $P = 0.45$ by the chi-square test). Death occurred in 11.1% of the telemonitoring group and 11.4% of the usual care group (difference, -0.2 percentage points; 95% CI, -3.3 to 2.8 ; $P = 0.88$ by the chi-square test). There were no significant differences between the two groups with respect to the secondary end points or the time to the primary end point or its components. No adverse events were reported.

CONCLUSIONS—Among patients recently hospitalized for heart failure, telemonitoring did not improve outcomes. The results indicate the importance of a thorough, independent evaluation of disease-management strategies before their adoption. (Funded by the National Heart, Lung, and Blood Institute; ClinicalTrials.gov number, NCT00303212.)

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

Despite advances in the care of patients with heart failure, outcomes after hospitalization are not improving.¹ Developing strategies to reduce readmissions of patients with heart failure is a national priority, as indicated by national improvement initiatives²; federal, publicly reported performance measures^{3,4}; and government incentives in the Patient Protection and Affordable Care Act.⁵

Telemonitoring is a promising strategy for improving heart-failure outcomes by making it possible to monitor patients remotely so that clinicians can intervene early if there is evidence of clinical deterioration. A recent Cochrane review concluded that telemonitoring of patients with heart failure reduced the rate of death from any cause by 44% and the rate of heart-failure–related hospitalizations by 21%.⁶ However, the quality of the methods used in the studies was variable, and many of the studies were small.

We conducted a multicenter, randomized, controlled trial, Telemonitoring to Improve Heart Failure Outcomes (Tele-HF), to determine whether telemonitoring would reduce the combined end point of readmission or death from any cause among patients recently hospitalized for heart failure.

METHODS

STUDY DESIGN AND OVERSIGHT

A description of the study design was published previously.⁷ The trial was conducted in accordance with the protocol (available with the full text of this article at NEJM.org), which was approved by the institutional review boards at Yale University School of Medicine and each participating site.

We appointed an independent data and safety monitoring board to monitor adherence to the protocol and to assess the recruitment and retention of patients and the quality of the data, as well as the safety and efficacy of the intervention. All study investigators and personnel (except for members of the data and safety monitoring board) were unaware of the treatment-group results until end-point data had been finalized for all the patients. All patients provided written informed consent before randomization.

The study was funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health. Pharos Innovations, the vendor of the telemonitoring system, was paid for its services and had no role in the study design, the collection or analysis of the data, or the writing of the manuscript. The study was designed by one of the authors, data were gathered by site coordinators and the Yale Coordinating Center, and the data were analyzed by two of the authors. Two of the authors drafted the manuscript; made the decision to submit it for publication, with all the authors contributing to subsequent revisions; and vouch for the accuracy and completeness of the data and analyses.

ELIGIBILITY AND ENROLLMENT OF PATIENTS

Patients were enrolled from 2006 through 2009 at 33 cardiology practices across the United States (see the Supplementary Appendix, available at NEJM.org). Practices were selected on the basis of their organizational capability and enthusiasm for participating in the study. At each practice, a site coordinator was assigned responsibility for overseeing implementation of and adherence to the protocol.

Site coordinators identified patients hospitalized for heart failure in the previous 30 days. Exclusion criteria were residence in a long-term nursing home; inability to participate in the study protocol for any reason, including a low expected probability of survival for the next 6

months owing to conditions other than heart failure; inability to stand on a scale; severe cognitive impairment⁸; and a planned hospitalization for a procedure.

Patients were randomly assigned to receive usual care or undergo telemonitoring, according to a sequence of computer-generated random numbers, with stratification on the basis of the study site. Clinicians were instructed to treat patients in accordance with national guidelines for the management of heart failure.⁹

USUAL CARE AND TELEMONITORING PROTOCOLS

At the time of enrollment, all patients received educational materials developed by the Heart Failure Society of America, and if needed, a scale. We also provided patients in the telemonitoring group with detailed instructions and a demonstration by site coordinators of how to use the telemonitoring system, as well as a touch-tone telephone, if needed.

Telemonitoring was performed with the use of a commercial system, Tel-Assurance (Pharos Innovations). We selected the system on the basis of its technical quality and established use in many clinical practices.

The telemonitoring group was instructed to make daily, toll-free calls to the system. During each call, patients heard a series of questions about general health and heart-failure symptoms, and they entered responses using the telephone keypad. Every 30 days, validated screening questions for symptoms of depression were also included.¹⁰ Information from the telemonitoring system was downloaded daily to a secure Internet site and was reviewed every weekday (except on holidays) by site coordinators. All questions had predetermined responses that triggered “variances” to flag clinicians’ attention (see the Supplementary Appendix). The protocol required the sites to contact any patient whose response generated variances and document their management of the variances.

To maximize adherence to telemonitoring, patients were told that their information would be reviewed by the clinicians responsible for managing their heart failure. If patients did not use the system for two consecutive days, they received a system-generated reminder call; after that, they were contacted by site staff to encourage participation.

Sites were made aware of the importance of timely review of telemonitoring information. Every 2 to 3 weeks, staff from the Yale Coordinating Center reviewed responses to variances and contacted the sites if there was no documentation of how the variance was managed, to ensure that the information had been reviewed.

The primary anticipated adverse event associated with telemonitoring was a delay in seeking care for urgent or emergency situations because of a belief that the telemonitoring data would immediately alert clinicians. To minimize this risk, patients were told to contact their clinicians directly with any urgent concerns.

DATA COLLECTION

At baseline, site coordinators collected the medical history and physical-examination data by means of direct interview, examination, and medical-record review. Patients were also interviewed with in 2 weeks after enrollment (which was considered to be the baseline), and 3 and 6 months after enrollment, by staff at the coordinating center who were unaware of the treatment assignments. During these telephone interviews, information was collected about the quality of life, satisfaction with care, and use of medications.

At 6 months, site coordinators at each clinical-practice site reviewed the office and hospital medical records to ascertain readmissions. They also contacted patients and their primary

care providers to inquire about readmissions. Discharge summaries, other chart documentation, or both were obtained for all readmissions.

During the follow-up interviews at 6 months, staff at the coordinating center also asked patients whether they had been rehospitalized during the study period. The Social Security Death Index, contact with family members, interviews with clinicians, and searches for obituaries were used to ascertain vital status.

END POINTS

The primary end point was a composite of readmission for any reason or death from any cause within 180 days after enrollment. Prespecified secondary end points included hospitalization for any reason or death from any cause, hospitalization for heart failure, number of days in the hospital, number of hospitalizations for any cause, and times to the primary end point and its components. A committee of physicians, all of whom were unaware of the treatment-group assignments, adjudicated each potential readmission to ensure that the event qualified as a readmission (and not another clinical encounter such as an emergency department visit) and to determine the primary cause of the readmission.

STATISTICAL ANALYSIS

We summarized patients' baseline characteristics according to treatment group. Adherence in telemonitoring group was defined as placement of at least three calls a week to the telemonitoring system (a cutoff point representing approximately half the expected usage). We summarized the end points on the basis of treatment group and tested the primary hypothesis using a chi-square test of independence. In secondary analyses, we calculated the Kaplan–Meier time-to-event function¹¹ for readmission or death from any cause. For each end point, we also estimated the corresponding hazard ratio and 95% confidence interval, using a Cox proportional-hazards model¹². The time to each event was calculated starting at the day of enrollment. We compared the numbers of readmissions and hospital days between the two groups using the Wilcoxon ranksum test.

Prespecified subgroup analyses included assessments of the primary end point within subgroups based on age (<65 years vs. ≥65 years), sex, race, left ventricular ejection fraction (<40% vs. ≥40%), and New York Heart Association class (I or II vs. III or IV), as well as the number of patients enrolled at each site (<100 vs. ≥100). We also tested for interactions between each pair of subgroups and the main treatment effect.

Our study was designed to have a power of 80% to detect a 15% relative reduction in the primary end point in the telemonitoring group as compared with the usual-care group. We calculated that 820 patients per treatment group would need to be enrolled, assuming a primary-end-point rate of 50% in the usual-care group, 10% loss to follow-up in the study population, use of an intention-to-treat analysis, and an alpha value of 0.05. All statistical analyses were performed with the use of Stata software, version 11.1, and SAS software, version 9.1.

RESULTS

PATIENTS

A total of 5069 potential participants were screened (Fig. 1). Of these, 2442 were ineligible and 974 declined to participate. The remaining 1653 patients were enrolled; 826 were randomly assigned to undergo telemonitoring and 827 to receive usual care. A total of 79% of the study patients completed the 6-month interview, with no between-group difference in

the rate of completion. Medical-record review for readmissions and vital-status verification were completed for 100% of patients.

Baseline characteristics of the patients were similar between the two groups (Table 1). The median age was 61 years; 42.0% of the patients were female, 39.0% were black, and 70.6% had a depressed left ventricular ejection fraction (<40%). Diabetes mellitus, hypertension, and coronary artery disease were the most common coexisting conditions, and 46.0% of patients had chronic kidney disease (defined as a glomerular filtration rate of <60 ml per minute).¹³ At enrollment, 66.9% of patients had received a prescription for either an angiotensin-converting-enzyme inhibitor or an angiotensin-receptor blocker, and 79.2% had received a prescription for a beta-blocker. Of the patients with a depressed ejection fraction who did not have chronic kidney disease, 82.9% had received a prescription for an angiotensin-converting-enzyme inhibitor or an angiotensin-receptor blocker. Of all the patients with a depressed ejection fraction, 82.9% had received a prescription for a beta-blocker.

PRIMARY END POINT

A total of 85.6% of patients in the telemonitoring group made at least one call; among these patients, adherence to the intervention was highest, 90.2%, during the first week of the study period and decreased to 55.1% by week 26. A total of 29,163 variances were generated during the study period, with a median of 21 (interquartile range, 5 to 54) per patient.

No significant difference was seen between the two groups in the rate of the primary end point, which occurred in 432 patients (52.3%) in the telemonitoring group and in 426 patients (51.5%) in the usual-care group (difference, 0.8 percentage points; 95% confidence interval [CI], -4.0 to 5.6; $P = 0.75$ by the chi-square test) (Table 2). The hazard ratio for the primary end point with telemonitoring versus usual care was 1.04 (95% CI, 0.91 to 1.19).

SECONDARY END POINTS

No significant differences were seen between the two groups with respect to the secondary end points (Table 2). Readmission for any cause occurred in 407 patients (49.3%) in the telemonitoring group and 392 patients (47.4%) in the usual-care group (difference, 1.9 percentage points; 95% CI, -3.0 to 6.7; $P = 0.45$ by the chi-square test). The hazard ratio for readmission for any cause with telemonitoring was 1.06 (95% CI, 0.93 to 1.22). A total of 92 patients (11.1%) in the telemonitoring group and 94 patients (11.4%) in the usual-care group died during the 180-day study period (difference, -0.2 percentage points; 95% CI, -3.3 to 2.8; $P = 0.88$ by the chi-square test). The hazard ratio for death was 0.97 (95% CI, 0.73 to 1.30). Readmissions for heart failure, the number of days in the hospital, and the number of readmissions were also similar in the two groups (Table 2). Kaplan-Meier time-to-event curves for the composite end point of readmission or death from any cause, as well as for each component separately, did not reveal a significant difference between the two groups (Fig. 2).

SUBGROUP ANALYSES

Subgroup analyses (Fig. 3) showed that none of the baseline characteristics of the patients — including age (<65 years vs. ≥ 65 years), sex, race, left ventricular ejection fraction (<40% vs. $\geq 40\%$), and New York Heart Association class (I or II vs. III or IV) — identified a group in which telemonitoring was effective. The intervention was no more effective at sites with greater experience using the telemonitoring system (i.e., ≥ 100 patients enrolled in the study). The only significant interaction found was for sex, but there was no indication that the intervention was beneficial in either men or women.

ADVERSE EVENTS

No adverse events were reported during the study period.

DISCUSSION

In our multicenter, randomized, controlled trial involving patients recently hospitalized with heart failure, we found no reduction in the risk of readmission or death from any cause with telemonitoring as compared with usual care. Moreover, there were no reductions in the risk of hospitalization for heart failure, the number of days in the hospital, or the time to readmission or death. Subgroup analyses failed to identify a group for which the intervention was effective, despite efforts to include sites and patients who demonstrated enthusiasm for participation in a daily telemonitoring program and screening of the patients for their ability to follow the protocol. These results contrast with the findings of a recent Cochrane review of telemonitoring for patients with heart failure⁶; however, our study was of higher methodologic quality and was larger than most of the studies included in the review.

The efficacy of complex interventions such as telemonitoring depends on the context in which they are applied.^{14,15} For our study, we chose a telemonitoring system that is currently in use, collected standardized clinical information, ensured that site personnel were thoroughly trained by the system vendor, paid sites for participation, and provided patients with ongoing support (including the provision of scales and telephones, as needed) in using the telemonitoring system. Only sites that were willing to make a strong commitment to integrating this system into their practices were included in the study, and we worked closely with them to ensure sustained adherence to the protocol. Moreover, each site was required to document its response to each variance, ensuring that an explicit clinical decision was made about each variance. These design features created a reasonable setting in which to determine the effect of telemonitoring, were it to be broadly used in an effort to reduce hospitalizations.

In interpreting our results, it is important to recognize that automated telemonitoring represents a single, focused approach to disease management. The American Heart Association developed a classification system for disease management, and several of the components of this system merit consideration.¹⁶ The intervention in our study consisted of providing physicians with increased information about their patients' clinical status; it is possible that including formal education, medication management, or peer support would have enhanced the effectiveness of the intervention. The method of communication used was an interactive voice-response system, with contact by clinicians driven by their assessment of patients' status; an intervention with more contact between clinicians and patients might have been more effective.

In a previous, small, single-site trial of remote monitoring of patients, our group found a 44-percentage-point reduction in the rate of readmission, which was associated with significant cost savings.¹⁷ However, we were concerned that, in that trial, reliance on a single, highly skilled and motivated nurse case-manager who deployed an intervention developed by the investigative team limited the generalizability and scalability of the findings. Moreover, the results prompted the question of whether an automated monitoring system with transmission of information to the clinicians responsible for the patients' care, precluding the need for one-to-one telephone calls with a clinician, could provide a similar benefit with the potential for widespread dissemination.

Our results underscore the need for rigorous, independent evaluation of disease-management systems before their adoption. In an environment in which vendors promote their products to

health systems that are under increasing pressure to reduce readmission rates, the knowledge that telemonitoring is ineffective suggests the need to consider alternative approaches to improving care. Our findings also raise questions about the value of findings that are based on a systematic review that includes many low-quality studies.

An important consideration is that 14% of our patients who were randomly assigned to undergo telemonitoring never used the system. Moreover, by the final week of the study period, only 55% of the patients were still using the system at least three times per week. This finding is important, given that considerable resources, which would be difficult to leverage outside a clinical trial, were directed toward optimizing patients' engagement with the system. Thus, the adherence rates in this trial most likely represent the best-case scenario and are in fact similar to previously documented 18 rates of medication adherence.¹⁸

It is also possible that the telemonitoring strategy would be more effective were it embedded in cardiology practices with greater organizational capacity to implement it. However, the sites in our study were selected on the basis of their ability to participate and their enthusiasm. Although sites were required to document their responses to variances, clinicians did not record these data in a systematic manner. We do know that variances were reviewed and purposeful decisions were made by the cardiologists responsible for clinical management of patients' heart failure, including medication adjustments, education about dietary indiscretions, and referrals for office visits.

A total of 21% of the study patients did not complete the final telephone interview at 6 months. This rate is not surprising, given the severity of illness in the study population. Missing data for these patients should have had minimal influence on our assessment of hospitalization and vital status, which were verified through medical-record review and electronic databases.

In summary, a telemonitoring strategy failed to provide a benefit over usual care in a setting optimized for its use. Previous claims of success of similar strategies, based on studies with small populations of patients and methodologic weaknesses, are not supported by the results of our large, multicenter trial. There remains a need for strategies to improve heart-failure outcomes, and our findings indicate the importance of a thorough, independent evaluation of disease-management strategies before their widespread adoption.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Supported by a grant (5 R01 HL080228) from the National Heart, Lung, and Blood Institute.

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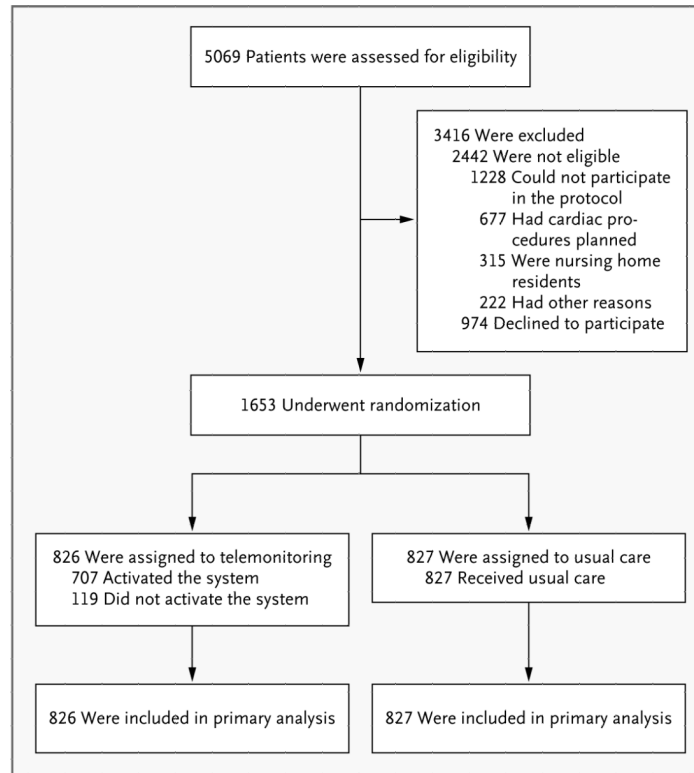


Figure 1.
Screening, Randomization, and Follow-up of the Study Patients.

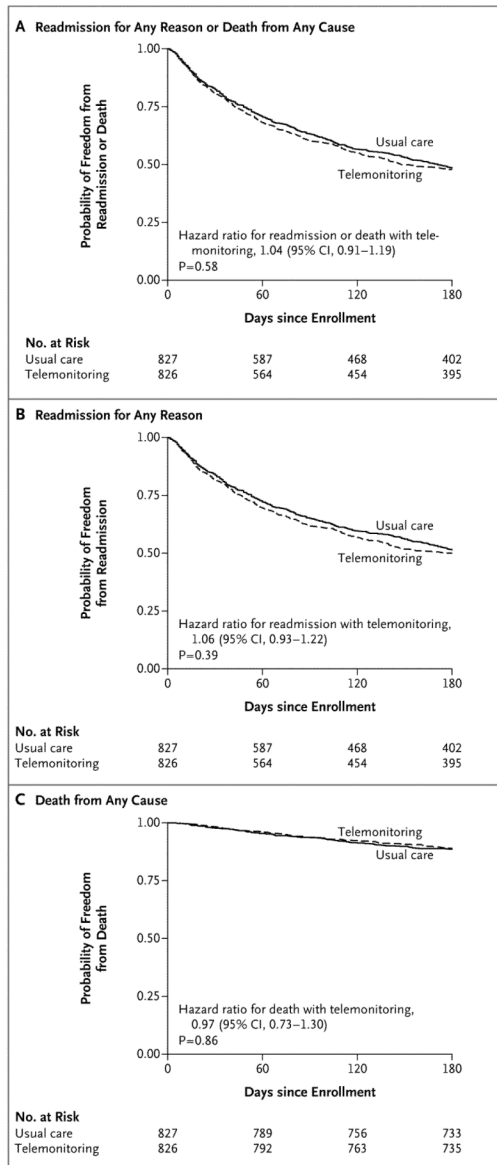


Figure 2. Kaplan–Meier Time-to-Event Estimates for the Primary End Point — Readmission for Any Reason or Death from Any Cause — and Each Component Separately, According to Treatment Group.

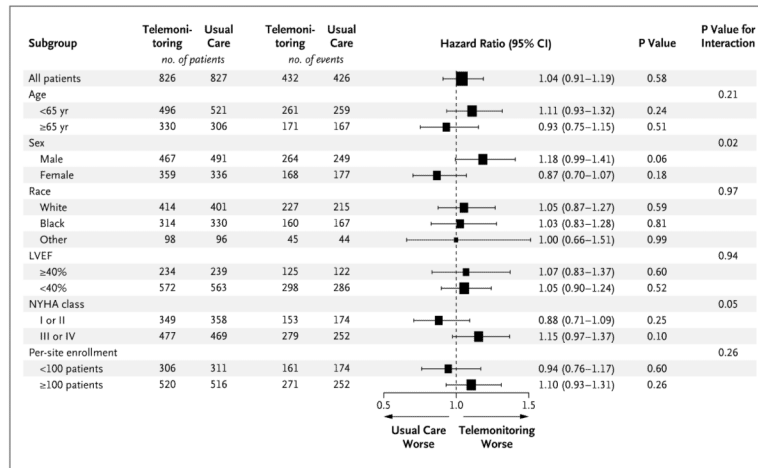


Figure 3. Subgroup Analyses of Readmission or Death from Any Cause

The size of the squares representing the hazard ratios ref the relative number of events. Data on left ventricular ejection fraction (LVEF) were missing for 45 patients. NYHA denotes New York Heart Association.

Table 1

Baseline Characteristics of the Study Population, According to Treatment Group.*

Characteristic	Telemonitoring (N = 826)	Usual Care (N = 827)	Total (N = 1653)
Age — yr			
Median	61	61	61
Interquartile range	51–73	51–73	51–73
Female sex — no. (%)	359 (43.5)	336 (40.6)	695 (42.0)
Race — no. (%) [†]			
White	413 (50.1)	402 (48.6)	815 (49.3)
Black	314 (38.0)	330 (39.9)	644 (39.0)
Other	98 (11.9)	96 (11.6)	194 (11.7)
Hispanic or Latino ethnic group — no. (%) [‡]	22 (2.7)	23 (2.8)	45 (2.7)
NYHA class — no. (%)			
I	48 (5.8)	52 (6.3)	100 (6.0)
II	301 (36.4)	306 (37.0)	607 (36.7)
III	416 (50.4)	423 (51.1)	839 (50.8)
IV	61 (7.4)	46 (5.6)	107 (6.5)
Left ventricular ejection fraction <40% — no./total no. (%)	572/806 (71.0)	563/802 (70.2)	1135/1608 (70.6)
Chronic kidney disease — no./total no. (%) [‡]	370/814 (45.5)	378/813 (46.5)	748/1627 (46.0)
COPD — no. (%)	169 (20.5)	177 (21.4)	346 (20.9)
Diabetes mellitus — no. (%)	394 (47.7)	378 (45.7)	772 (46.7)
Hypertension — no. (%)	632 (76.5)	639 (77.3)	1271 (76.9)
Coronary artery disease — no. (%)	432 (52.3)	403 (48.7)	835 (50.5)
Blood pressure — mm Hg			
Systolic	121.5±22.8	120.3±21.6	120.9±22.2
Diastolic	71.1±13.9	70.6±13.7	70.8±13.8
Serum potassium — mmol/liter	4.1±0.6	4.1±0.6	4.1±0.6
Blood urea nitrogen — mg/dl	27.8±18.0	26.8±17.2	27.3±17.6
Serum creatinine — mg/dl	1.5±0.8	1.4±0.7	1.5±0.7
Medications — no. (%)			

Characteristic	Telemonitoring (N = 826)	Usual Care (N = 827)	Total (N = 1653)
ACE inhibitor or ARB	549 (66.5)	557 (67.4)	1106 (66.9)
Beta-blocker	668 (80.9)	641 (77.5)	1309 (79.2)
Loop diuretic	646 (78.2)	646 (78.1)	1292 (78.2)
Digoxin	214 (25.9)	198 (23.9)	412 (24.9)
Aldosterone-receptor antagonist	266 (32.2)	277 (33.5)	543 (32.8)
Did not graduate from high school — no./total no. (%)	167/701 (23.8)	171/711 (24.1)	338/1412 (23.9)
Annual household income <\$10,000 — no./total no. (%)	168/571 (29.4)	152/585 (26.0)	320/1156 (27.7)

* All comparisons between the two groups were nonsignificant (P>0.05). To convert values for blood urea nitrogen to millimoles per liter, multiply by 0.357. To convert values for creatinine to micromoles per liter, multiply by 88.4. ACE denotes angiotensin-converting enzyme, ARB denotes angiotensin-receptor blocker, COPD chronic obstructive pulmonary disease, and NYHA New York Heart Association.

† Race and Hispanic or Latino ethnic group (which was considered a subcategory of white race) were self-reported.

‡ Chronic kidney disease was defined by a glomerular filtration rate of less than 60 ml per minute.¹³

Table 2

Clinical End Points, According to Treatment Group.*

End Point	Telemonitoring (N = 826)	Usual Care (N = 827)	P Value
Primary end point: death or readmission — no. (%)	432 (52.3)	426 (51.5)	0.75
Secondary end points			
Death — no. (%)	92 (11.1)	94 (11.4)	0.88
Readmission — no. (%)	407 (49.3)	392 (47.4)	0.45
Readmission for heart failure — no. (%)	227 (27.5)	223 (27.0)	0.81
No. of days in hospital	7.2±14.6	7.0±14.9	0.27
No. of readmissions — no. (%)			0.20
0	419 (50.7)	435 (52.6)	
1	199 (24.1)	212 (25.6)	
2	97 (11.7)	88 (10.6)	
3	53 (6.4)	52 (6.3)	
4	33 (4.0)	20 (2.4)	
≥5	25 (3.0)	20 (2.4)	

* Plus-minus values are means ±SD.