

Care Management for Low-Risk Patients with Heart Failure

A Randomized, Controlled Trial

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Background: Nurse care management programs for patients with chronic illness have been shown to be safe and effective.

Objective: To determine whether a telephone-mediated nurse care management program for heart failure reduced the rate of rehospitalization for heart failure and for all causes over a 1-year period.

Design: Randomized, controlled trial of usual care with nurse management versus usual care alone in patients hospitalized for heart failure from May 1998 through October 2001.

Setting: 5 northern California hospitals in a large health maintenance organization.

Patients: Of 2786 patients screened, 462 met clinical criteria for heart failure and were randomly assigned (228 to intervention and 234 to usual care).

Intervention: Nurse care management provided structured telephone surveillance and treatment for heart failure and coordination of patients' care with primary care physicians.

Measurements: Time to first rehospitalization for heart failure

or for any cause and time to a combined end point of first rehospitalization, emergency department visit, or death.

Results: At 1 year, half of the patients had been rehospitalized at least once and 11% had died. Only one third of rehospitalizations were for heart failure. The rate of first rehospitalization for heart failure was similar in both groups (proportional hazard, 0.85 [95% CI, 0.46 to 1.57]). The rate of all-cause rehospitalization was similar (proportional hazard, 0.98 [CI, 0.76 to 1.27]).

Limitations: The findings of this study, conducted in a single health care system, may not be generalizable to other health care systems. The overall effect of the intervention was minor.

Conclusions: Among patients with heart failure at low risk on the basis of sociodemographic and medical attributes, nurse care management did not statistically significantly reduce rehospitalizations for heart failure or for any cause. Such programs may be less effective for patients at low risk than those at high risk.

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The societal and personal burden of heart failure is large and is growing apace with the aging of the population (1). Heart failure is the largest Medicare expenditure and is the leading cause of hospitalization for persons 65 years of age or older (2). Rates of hospital readmission within 6 months range from 25% to 50% (3). Moreover, behavioral factors, such as nonadherence to diet and medications, and social factors, such as social isolation and indigence, frequently contribute to early rehospitalizations (3-4). Previous studies of specialized treatment programs for heart failure have targeted clinically high-risk, medically underserved populations. These studies demonstrated reductions in rehospitalization for heart failure and, to a lesser extent, rehospitalization for all causes (4-6). In a pilot study conducted at a single Kaiser Permanente medical center in 1994 to 1995, we found a statistically significant reduction in rehospitalization rates during a 3-month period among low-risk patients with heart failure who received nurse care management over a 6-month period (7). The present study evaluated nurse care management for heart failure in a low-risk population of patients selected from several medical centers in the same large health maintenance organization (HMO).

METHODS

Design

This was a randomized, controlled trial of a nurse care management system for heart failure.

Patient Sample

We selected patients who were hospitalized with a provisional diagnosis of heart failure from Kaiser Permanente medical centers located in San Francisco, Vallejo, Walnut Creek, Sacramento, and Roseville, California, between May 1998 and October 2000.

Hospital-based project nurses reviewed hospital charts to screen for patients with new-onset or worsening heart failure on the basis of 1) shortness of breath (dyspnea at rest, including orthopnea or paroxysmal nocturnal dyspnea) and 2) at least 1 corroborating clinical sign (pulmonary congestion on examination, including rales, crackles, or wheezes) or radiologic abnormality (pulmonary congestion on chest radiograph) consistent with heart failure. We excluded patients who were scheduled for coronary artery bypass or valvular surgery; had undergone cardiac surgery in the preceding 8 weeks; had a serum creatinine value of 13.26 $\mu\text{mol/L}$ (5 mg/dL) or greater; were receiving dialysis or awaiting renal transplantation; had a history of severe pulmonary disease requiring home oxygen; had 1 or more

additional diseases that were expected to result in death within 1 year; had cognitive mental deficits, substance abuse, or severe psychiatric disorders; or were expected to move from the area within 1 year.

We did not use measurements of left ventricular function by echocardiography, radionuclide angiography, or contrast angiography as selection criteria. Among the 59% of patients who had left ventricular ejection fraction measured, 28% had an ejection fraction less than 0.40 and 31% had an ejection fraction of 0.40 or greater.

Study nurses interviewed patients during hospitalization or by telephone within 2 weeks after discharge, explained the purpose of the study, and obtained written informed consent. Research staff who were not associated with delivering the intervention randomly assigned patients to treatment conditions by using sealed assignments. Equal numbers of patients were allocated to the 2 groups in each medical center by using the Efron procedure (8). Physicians were notified of randomization assignment by letter. The institutional review boards at Stanford University and Kaiser Permanente approved the study.

Baseline Data Collection

Baseline data, recorded by staff nurses on standardized forms, included sociodemographic characteristics, self-reported illnesses, medications, and results of standard diagnostic studies and laboratory tests.

Treatment Environment

Before the study, the investigators met with the medical staffs of the 5 participating hospitals to present and discuss the research protocol, including detailed descriptions of the planned interactions between the nurse care managers and the medical staff. The medical staffs were multispecialty groups of 20 to 60 physicians—approximately 480 physicians total. After randomization, all patients continued to receive usual care, including instruction on diet, drug adherence, physical activity, and response to changing symptoms.

Intervention

In addition to usual care, patients in the intervention group received a physician-directed, nurse-managed, home-based program for heart failure developed by the investigators (9). Originally designed for coronary risk factor management, this program was expanded to encompass heart failure. It incorporated the features of “best practice” designated by Rich (10): coordination of care across disciplines, patient and caregiver education, enhancement of self-management skills, effective follow-up, and guidelines-based medications for heart failure. Our system also incorporated the principles of heart failure management developed by the Cardiovascular Nursing Council of the American Heart Association (11).

The standardized, telephone-mediated intervention included the following elements: initial educational session, including a videotape; baseline telephone counseling session; nurse-initiated follow-up telephone contacts; phar-

Context

Case management by nurses improves outcomes for patients with heart failure, but studies have targeted patients at high risk for poor outcomes because of sociodemographic or clinical factors. Whether such programs benefit low-risk patients with heart failure is unknown.

Contribution

Among 462 patients in 1 staff-model health maintenance organization who were hospitalized with heart failure, those randomly assigned to nurse care management had rates of rehospitalization and death similar to rates in those who received usual care.

Implications

Care management for heart failure may offer limited benefit for patients with clinical and sociodemographic characteristics that put them at low risk for hospitalization or death.

—The Editors

macologic management; and nurse-initiated communication with physicians. The initial 1-hour educational session with a nurse occurred in the patient’s medical center. Patients received printed educational materials, including methods for self-monitoring of symptoms, body weight, and medications; a dietary management workbook; food-frequency questionnaires; and instructions on how to access emergency care in case symptoms abruptly worsened. Patients viewed a videotape portraying the treatment process. Two experienced Stanford-based nurse care managers provided a 45-minute baseline telephone counseling session within 1 week of randomization; subsequent nurse contacts were tailored to the needs of the individual patients. Nurse-initiated follow-up telephone contacts with patients during daytime weekday hours were scheduled at weekly intervals for 6 weeks; biweekly for 8 weeks; monthly for 3 months; bimonthly for 6 months; and as needed to monitor patients’ medications, laboratory assessments, symptoms, and other medical problems. We based pharmacologic management for heart failure on published treatment guidelines (12, 13). The nurse care managers obtained permission from physicians to initiate and regulate pharmacologic therapy for heart failure according to study protocol. Nurse-initiated communication with physicians about patients’ current medical status was maintained and specific management problems were addressed. Nurse care managers spent an average of 9 hours per patient coordinating the treatment plan with patients and physicians during the first year. The intervention did not include consultation with social services to facilitate discharge planning or home visits after discharge.

Measurement

Research staff who were not associated with, and were blinded to, the intervention conditions measured health outcomes at 12 months. On the basis of review of the Kaiser Permanente medical records, project nurses used standardized forms to record the cause, number, and duration of hospitalizations and emergency department visits during the 12-month follow-up period. Kaiser Permanente provided more than 90% of all care. Two cardiologists who were not associated with implementing the intervention reviewed medical records on deaths, rehospitalizations, and emergency department visits to determine whether these events were primarily due to heart failure or due to other causes. They did not use discharge diagnoses recorded in the medical record to make these judgments. Rehospitalizations and emergency department visits were classified as either due to heart failure or due to other causes; the latter were classified as cardiac or noncardiac.

Outcomes

The primary outcome of the study was the time to first rehospitalization for heart failure or for any cause. In our analysis, we treated deaths occurring before rehospitalization as censored data. However, analysis in which we classified deaths occurring before rehospitalization as outcome events resulted in similar conclusions, primarily because most observed deaths occurred after a rehospitalization. Secondary outcomes were the time to a composite outcome of death, rehospitalization, or emergency department visits for cardiac cause or for any cause, the proportion of patients receiving recommended pharmacotherapy, and the rate of outpatient clinic and emergency department visits. We based the study's power on a proposed reduction in the risk for rehospitalization for heart failure from 21% to 13%, corresponding to a number needed to treat for benefit of 12.5. We expected that the actual number needed to treat for benefit would be less than 12.5.

Statistical Analysis

We evaluated the effect of care management on rehospitalization rates by using Kaplan–Meier survival curves and Cox proportional hazards regression models. We compared nominal variables by using chi-square tests, ordered variables by using trend tests, and continuous variables by using *t*-tests. The analysis was by intention-to-treat.

Role of the Funding Sources

The National Heart, Lung, and Blood Institute reviewed and financially supported the project but did not participate in the design, conduct, or reporting of the study or in the decision to submit the manuscript for publication.

RESULTS

We screened 2786 patients from 5 northern California hospitals between May 1998 and October 2000. Of these, 70% (1951 patients) were excluded for 1 of the following

reasons: 1) clinically significant comorbid condition complicating the interpretation of symptoms of heart failure during nurses' periodic telephone contacts, 2) psychosocial disorders limiting patients' participation in treatment, or 3) logistic limitations precluding patients' participation in a telephone-mediated intervention. The **Appendix Table** (available at www.annals.org) contains further details on study exclusions. Among the 835 medically eligible patients, 55% (462 patients) were randomly assigned to either usual care or nurse-based case management. Thus, we randomly assigned 16.6% of screened patients: 228 patients to the treatment group and 234 patients to the usual care group (**Figure 1**).

No demographic or clinical characteristic statistically significantly differed by enrollment group (**Table 1**). The mean age (\pm SD) of patients was 72 ± 11 years, 62% of patients were married, and approximately 60% of patients in both groups received a diagnosis of heart failure before the index hospitalization. Heart failure severity at baseline was New York Heart Association (NYHA) class I or II for 215 patients (49%) and NYHA class III or IV for 227 patients (51%). More than half of all patients had hypertension (63%) or coronary artery disease (51%).

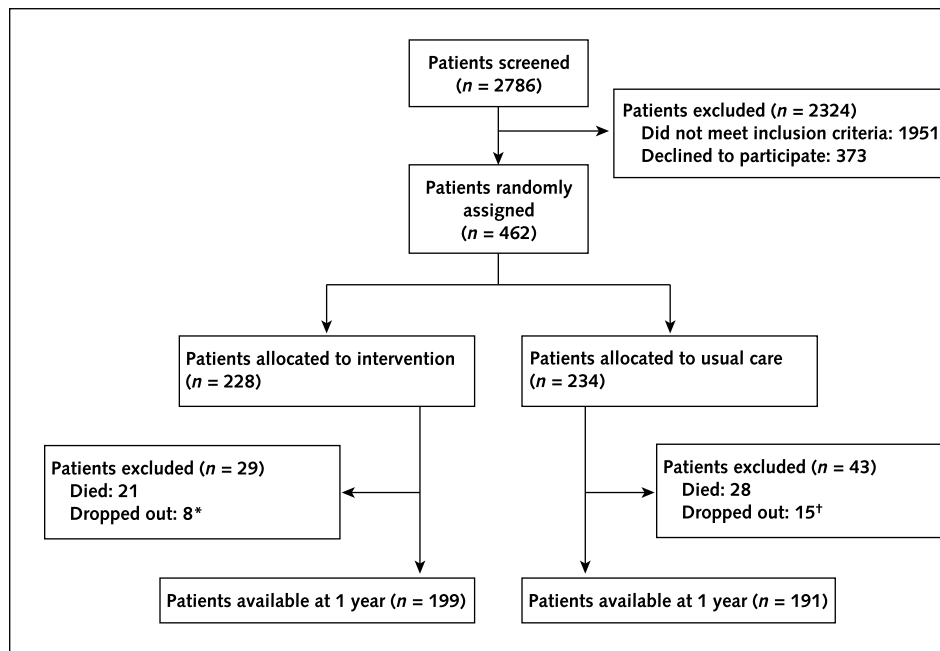
During the first year of follow-up, 23 patients (3%) dropped out of the trial (8 in the treatment group and 15 in the usual care group). Fifty patients (11%) died: 21 (9%) in the treatment group and 29 (12%) in the usual care group. Of these deaths, 13 of the 21 (62%) in the treatment group and 23 of 29 (79%) in the usual care group were due to cardiac causes.

At the end of the first year, half of all patients had been rehospitalized at least once. A total of 116 of the 228 patients (51%) in the treatment group were rehospitalized, for a total of 237 rehospitalizations (mean, 1.04; median, 1.0). During the same period, 117 of the 234 patients (50%) in the usual care group were rehospitalized for a total of 232 rehospitalizations (mean, 0.99; median, 1.0) per person per year. **Table 2** shows the reasons for all rehospitalizations and for first rehospitalizations in the first year. Heart failure was present in 37% of all rehospitalizations in the usual care group and 32% of all rehospitalizations in the intervention group.

In a Cox proportional hazards model, time to first rehospitalization for heart failure did not statistically significantly differ between patients receiving care management and patients receiving only usual care (proportional hazard, 0.84 [CI, 0.56 to 1.25]). The number needed to treat for benefit to prevent 1 hospitalization for heart failure by 1 year was 34.4 (CI, 9.7 to ∞). The rate of first rehospitalization for any cause was also similar for the 2 groups (proportional hazard, 0.98 [CI, 0.76 to 1.27]) (**Figure 2** and **Table 3**).

We also used the Cox proportional hazards model to evaluate the combined end point of rehospitalization, emergency department visit, or death. One hundred twenty-six of 228 patients (55%) in the care management group made 1 or

Figure 1. Patient flow.



*Four patients declined to participate and 4 dropped out for medical reasons. †Eight patients declined to participate and 7 dropped out for medical reasons.

more emergency department visits for any cause compared with 132 of the 234 patients (56%) in the usual care group. The mean number of emergency department visits in the treatment and usual care groups during the first year of follow-up was 3.2 (median, 2.0) and 3.5 (median, 2.0), respectively. The rates of combined cardiac end points (proportional hazard, 0.85 [CI, 0.64 to 1.14]) and combined end points for any cause were similar for the 2 groups (Figure 3 and Table 3). The site by treatment interactions were not statistically significant for any study outcome ($P > 0.2$ for first rehospitalization for heart failure, first rehospitalization for any cause, first combined cardiac end point, and first combined end point for any cause).

In the first year, patients in both groups had an average of 3 cardiology outpatient visits, 6 internal medicine visits, and 4 non-internal medicine visits.

A high proportion of patients in both groups received recommended pharmacotherapy (12, 13) for systolic dysfunction, defined as a left ventricular ejection fraction less than 0.40. Among such patients, the proportion receiving angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers was slightly higher in the treatment group than in the usual care group (90% vs. 75%; difference not statistically significant). At 12 months, the proportion of patients receiving angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers was 90% in the treatment group and 88% in the usual care group. Among patients with systolic dysfunction in the treatment and usual care groups, a similar pattern of drug administration was found for β -blockers: At baseline, the rate was

38% and 32%, respectively, and at 12 months, the rate was 50% and 46%, respectively. No statistically significant between-group differences in the use of angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers, β -blockers, diuretics, or digitalis were noted at any time.

DISCUSSION

To our knowledge, our study is the largest randomized clinical trial to date that has evaluated specialized care management for patients discharged after hospitalization for heart failure. We found no statistically significant differences between usual care alone and usual care supplemented with nurse care management in the rate of rehospitalizations or in the combined outcome of rehospitalization, emergency department visit, or death. In contrast, other studies of nurse care management have shown large differences in rehospitalization rates (6, 13–16). The discrepancy in findings probably reflects the sociodemographic and medical attributes of the study sample and the scope and quality of the health care services in which the supplemental nurse care management was embedded.

Clinical trials designed to evaluate the efficacy of nurse care management for heart failure usually target high-risk patients who are most likely to benefit from the intervention (6, 14–18). We designed our trial to evaluate the effectiveness of a similar intervention in a sample of HMO enrollees who were eligible to participate in a telephone-mediated intervention. Kaiser Permanente provides medical care to nearly one third of insured northern California

Table 1. Demographic and Medical Characteristics of Participants*

Characteristic	Treatment Group, n (%)	Usual Care Group, n (%)	All Patients, n
Age			
<60 y	35 (15)	32 (14)	67
60–70 y	52 (22)	55 (24)	107
70–80 y	92 (40)	86 (37)	178
>80 y	49 (21)	61 (26)	110
Sex			
Female	119 (52)	107 (45)	226
Male	109 (48)	127 (54)	236
Race or ethnicity			
American Indian	1 (0)	3 (1)	4
Asian	9 (4)	18 (8)	27
Black	4 (2)	4 (2)	8
White	13 (5)	14 (6)	27
Hispanic	195 (86)	191 (82)	386
	7 (3)	7 (3)	14
Marital status			
Separated, divorced, or single	36 (16)	32 (14)	68
Married	141 (62)	151 (64)	292
Widowed	51 (22)	51 (22)	102
Education level			
College graduate or more	123 (54)	144 (62)	267
High school or less	81 (36)	75 (32)	156
Unknown	24 (11)	15 (6)	39
Heart failure history			
Previous diagnosis of heart failure	136 (60)	135 (58)	271
Baseline NYHA class I–II	103 (50)	112 (50)	215
Baseline NYHA class III–IV	103 (50)	113 (50)	216
Cause of heart failure			
Coronary disease	118 (52)	117 (50)	235
Hypertension	147 (64)	143 (61)	290
Valvular disease	36 (16)	45 (19)	81
Unknown	47 (21)	38 (17)	85
Symptoms before hospitalization			
Angina	43 (19)	47 (20)	90
Atypical chest pain	54 (24)	54 (23)	108
Exertional shortness of breath	200 (88)	214 (91)	414
Cough	129 (57)	131 (56)	260
Paroxysmal nocturnal dyspnea	126 (55)	131 (56)	257
Peripheral edema	154 (68)	146 (62)	300
Orthopnea	152 (67)	157 (67)	309
Other medical conditions			
COPD	38 (17)	42 (18)	80
Stroke	44 (19)	49 (21)	93
Type 1 diabetes	16 (7)	15 (6)	31
Type 2 diabetes	58 (25)	65 (28)	123
Hypertension	154 (68)	148 (63)	302
Renal insufficiency (serum creatinine level >13.26 μmol/L [>1.5 mg/dL])	35 (15)	35 (15)	70
All	228 (100)	234 (100)	462

* COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association.

residents, and the 5 medical centers participating in our study are generally representative of the 18 Kaiser Permanente facilities in the northern California region.

We included patients who were hospitalized for treatment of new-onset heart failure and those hospitalized for exacerbation of preexisting heart failure. We designed our clinical definition of heart failure to identify not only pa-

tients with depressed left ventricular systolic function but also those with preserved left ventricular systolic function. The latter group, which has been underrepresented in clinical trials of heart failure, included more than half of all patients in our study in whom left ventricular function was measured. Other community-based studies of heart failure have also found a high proportion of patients with pre-

Table 2. Reasons for Rehospitalization

Reason	Intervention		Usual Care	
	All Hospitalizations, n (%)	First Hospitalization, n (%)	All Hospitalizations, n (%)	First Hospitalization, n (%)
Cardiac				
Heart failure	76 (32)	38 (33)	86 (37)	43 (37)
Ischemic heart disease*	48 (20)	22 (19)	42 (18)	19 (16)
Other cardiac disease	29 (12)	18 (16)	27 (12)	14 (12)
Cardiac arrhythmia	26 (11)	15 (13)	22 (9)	14 (12)
Noncardiac				
Other diseases	77 (32)	32 (28)	97 (42)	48 (41)
Renal or metabolic disorder	29 (12)	18 (16)	31 (13)	13 (11)
Infectious disease	29 (12)	13 (11)	31 (13)	15 (13)
Vascular disease†	24 (10)	11 (9)	8 (3)	2 (2)
Total, n‡	237	116	232	117

* Myocardial infarction, unstable angina, and coronary revascularization.

† Peripheral or cerebrovascular.

‡ Totals do not sum to 100% since patients could have more than 1 cause of hospitalization.

served left ventricular function (19). Recent studies have demonstrated that the prognosis for patients with the clinical syndrome of heart failure is similar for both of these patient subgroups (20). Management guidelines for heart failure have only recently begun to address the needs of patients with preserved left ventricular function (21).

We did not select patients on the basis of factors known to influence the risk for rehospitalization for heart failure, such as older age, history of hospitalization for heart failure, or the NYHA class of heart failure at baseline. Most previous studies of care management have selected patients with a high risk for readmission for heart failure, including 1 or more previous hospitalizations for heart failure. The study by Kasper and colleagues (22) included patients with adverse hemodynamic status, as well as adverse clinical characteristics, and the study by Rich and colleagues (6) included patients with 4 or more hospitalizations for any reason in the preceding 5 years, representing the sickest segment of the screened population. In contrast, patients enrolled in our study represent a substantially healthier segment of the screened population.

The degree of heart failure in our patients was less than that of other studies of specialized management. Only 49% of patients in our study were classified as NYHA class III or IV at baseline compared with 97% in the study by Riegel and colleagues (18). In our study, the proportion of patients with a history of heart failure before the index

hospitalization was smaller than in Rich and colleagues' study (60% vs. 77%). The 1-year mortality of 11% in our study contrasts with the 30% 1-year mortality reported by Stuart and colleagues (15), and values of 1-year mortality in previous studies of specialized management for heart failure range from 25% to 60% (23, 24).

Patients with heart failure are often elderly, indigent, and socially isolated; these factors may limit their access to health care and leave them underserved (25). These conditions leave much room for supplemental health care management to produce an incremental health benefit. In contrast, the patients in our study had ready access to high-quality health care, and they used it extensively. Therefore, they had less need for supplemental medical management. The results of our study are consistent with the view of Riegel and colleagues (26) that a specialized program for patients with mild heart failure may increase health costs without substantially improving clinical outcomes, such as rehospitalization. The health care management system used in our study has been shown to improve health outcomes in populations exhibiting more severe health problems (9). This evidence lends further support that severity of health status is the primary differentiating factor in our study.

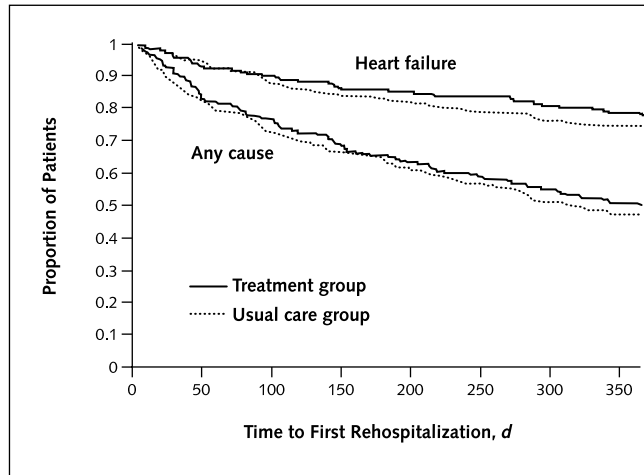
Clinical trials of disease management for heart failure have often considered only rehospitalizations due to heart failure (16) rather than all-cause rehospitalizations or death. In the study by Rich and colleagues (6), readmis-

Table 3. Survival Free of Rehospitalization or Combined End Point of Death, Rehospitalization, or Emergency Department Visit

Analysis	Outcome	Proportional Hazard (95% CI)*	P Value
Rehospitalization	Time to first rehospitalization for heart failure	0.84 (0.56–1.25)	>0.2
	Time to first rehospitalization for any cause	0.98 (0.76–1.27)	>0.2
Combined end point	Time to first cardiac combined end point	0.85 (0.64–1.14)	>0.2
	Time to first combined end point for any cause	0.87 (0.69–1.08)	>0.2

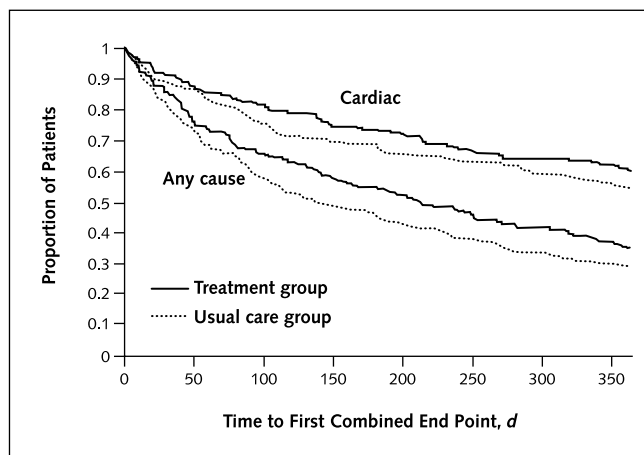
*All proportional hazards were adjusted for site and site by treatment interaction by using variable-centered Cox proportional hazards regression.

Figure 2. Proportion of patients free from rehospitalization for heart failure or for any cause by treatment group.



sions for heart failure were statistically significantly less frequent in the treatment group than in the control group. In contrast, readmissions for reasons other than heart failure were not statistically significantly different between the 2 groups, in accord with our results. A unique feature of our study was the use of a composite outcome measure that consisted of death, rehospitalizations, and emergency department visits due to any cause. In most studies, more than half of patients are rehospitalized for heart failure alone in the 6 months after hospital discharge (24). We found that only half of the patients were rehospitalized for all causes, including heart failure in the 12 months after enrollment. Moreover, only 35% of all rehospitalizations in our study were for heart failure. Krumholz and colleagues (3) found that heart failure accounted for only 18% of rehospitalizations for heart failure. The Digitalis Study

Figure 3. Proportion of patients free from the combined end point of death, rehospitalization, or emergency department visit for cardiac causes or for any cause by treatment group.



(27) showed that most rehospitalizations were for acute vascular events, including acute myocardial infarction, unstable angina, coronary revascularization, and stroke, rather than for heart failure exacerbation. Thus, as in our study, patients with heart failure are often hospitalized for reasons other than heart failure. Moreover, treatments for heart failure may weakly influence acute vascular events, such as acute myocardial infarction and stroke resulting from progressive atherosclerotic disease.

The factors that influence emergency department visits and rehospitalizations are often complex and reflect the adequacy of social support, communication with the primary physician, and arrangements for transportation (28). Most emergency department visits and rehospitalizations in our study were for treatment of comorbid conditions, such as acute coronary syndromes, pulmonary infections, and other intercurrent illnesses. Many decisions on these emergency department visits were made at night and on weekends, when the nurse care managers were not available.

Although nurse care management did not statistically significantly reduce the rate of rehospitalization compared with the Kaiser Permanente HMO-treated group, its potential value in non-HMO settings should not be diminished. Organizations such as Kaiser Permanente that successfully implement evidence-based medicine are likely to achieve superior medical outcomes for various chronic medical conditions (29). Resources required to enhance the management of chronic diseases include a clinical information system, a supportive clinical and administrative leadership, and a group culture that promotes quality improvement (30, 31). In our study, a high proportion of patients receiving usual care achieved benchmarks for pharmacotherapy established by national experts (12, 13), leaving little room for improvement by specialized management. The high frequency of all kinds of follow-up clinic visits, 13 visits in the 12 months after hospitalization, also attests to the intensity of usual care provided in the participating Kaiser Permanente medical centers. The usual care provided by other health care organizations may be far less standardized or intensive than that provided by Kaiser Permanente.

The results of our study suggest that the benefits of specialized health care programs for heart failure that target the elderly, the underserved, and those with advanced heart failure may not be generalizable to low-risk patients, especially in medical settings, such as HMOs, that promote systematic care for heart failure.

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References

- Havranek EP, Masoudi FA, Westfall KA, Wolfe P, Ordin DL, Krumholz HM. Spectrum of heart failure in older patients: results from the National Heart Failure project. *Am Heart J*. 2002;143:412-7. [PMID: 11868045]
- Massie BM, Shah NB. Evolving trends in the epidemiologic factors of heart failure: rationale for preventive strategies and comprehensive disease management. *Am Heart J*. 1997;133:703-12. [PMID: 9200399]
- Krumholz HM, Parent EM, Tu N, Vaccarino V, Wang Y, Radford MJ, et al. Readmission after hospitalization for congestive heart failure among Medicare beneficiaries. *Arch Intern Med*. 1997;157:99-104. [PMID: 8996046]
- Chin MH, Goldman L. Factors contributing to the hospitalization of patients with congestive heart failure. *Am J Public Health*. 1997;87:643-8. [PMID: 9146445]
- Stewart S, Marley JE, Horowitz JD. Effects of a multidisciplinary, home-based intervention on unplanned readmissions and survival among patients with chronic congestive heart failure: a randomised controlled study. *Lancet*. 1999;354:1077-83. [PMID: 10509499]
- Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. *N Engl J Med*. 1995;333:1190-5. [PMID: 7565975]
- West JA, Miller NH, Parker KM, Senneca D, Ghandour G, Clark M, et al. A comprehensive management system for heart failure improves clinical outcomes and reduces medical resource utilization. *Am J Cardiol*. 1997;79:58-63. [PMID: 9024737]
- Efron B. Forcing a sequential experiment to be balanced. *Biometrika*. 1971;58:403-17.
- DeBusk RF, Miller NH, Superko HR, Dennis CA, Thomas RJ, Lew HT, et al. A case-management system for coronary risk factor modification after acute myocardial infarction. *Ann Intern Med*. 1994;120:721-9. [PMID: 8147544]
- Rich MW. Heart failure disease management programs: efficacy and limitations [Editorial]. *Am J Med*. 2001;110:410-2. [PMID: 11286961]
- Grady KL, Dracup K, Kennedy G, Moser DK, Piano M, Stevenson LW, et al. Team management of patients with heart failure: A statement for healthcare professionals from The Cardiovascular Nursing Council of the American Heart Association. *Circulation*. 2000;102:2443-56. [PMID: 11067802]
- Guidelines for the evaluation and management of heart failure. Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Evaluation and Management of Heart Failure). *J Am Coll Cardiol*. 1995;26:1376-98. [PMID: 7594057]
- Consensus recommendations for the management of chronic heart failure. On behalf of the membership of the advisory council to improve outcomes nationwide in heart failure. *Am J Cardiol*. 1999;83:1A-38A. [PMID: 10072251]
- Konstam MA, Dracup K, Baker DW, Bortoff MB, Brooks NH, Dacey RA, et al. Heart Failure: Evaluation and Care of Patients with Left-Ventricular Systolic Dysfunction. Clinical Practice Guideline no. 11. Rockville, MD: Agency for Health Care Policy and Research; 1994. AHCPR publication no. 94-0612.
- Stewart S, Pearson S, Horowitz JD. Effects of a home-based intervention among patients with congestive heart failure discharged from acute hospital care. *Arch Intern Med*. 1998;158:1067-72. [PMID: 9605777]
- Stewart S, Horowitz JD. Home-based intervention in congestive heart failure: long-term implications on readmission and survival. *Circulation*. 2002;105:2861-6. [PMID: 12070114]
- Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. *JAMA*. 1999;281:613-20. [PMID: 10029122]
- Riegel B, Carlson B, Kopp Z, LePetri B, Glaser D, Unger A. Effect of a standardized nurse case-management telephone intervention on resource use in patients with chronic heart failure. *Arch Intern Med*. 2002;162:705-12. [PMID: 11911726]
- Dauterman KW, Go AS, Rowell R, Gebretsadik T, Gettner S, Massie BM. Congestive heart failure with preserved systolic function in a statewide sample of community hospitals. *J Card Fail*. 2001;7:221-8. [PMID: 11561221]
- Gottdiener JS, McClelland RL, Marshall R, Shemanski L, Furberg CD, Kitzman DW, et al. Outcome of congestive heart failure in elderly persons: influence of left ventricular systolic function. The Cardiovascular Health Study. *Ann Intern Med*. 2002;137:631-9. [PMID: 12379062]
- Hunt SA, Baker DW, Chin MH, Cinquegrani MP, Feldman AM, Francis GS, et al. ACC/AHA Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult: Executive Summary A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1995 Guidelines for the Evaluation and Management of Heart Failure): Developed in Collaboration With the International Society for Heart and Lung Transplantation; Endorsed by the Heart Failure Society of America. *Circulation*. 2001;104:2996-3007. [PMID: 11739319]
- Kasper EK, Gerstenblith G, Hefter G, Van Anden E, Brinker JA, Thiemann DR, et al. A randomized trial of the efficacy of multidisciplinary care in heart failure outpatients at high risk of hospital readmission. *J Am Coll Cardiol*. 2002;39:471-80. [PMID: 11823086]
- McAlister FA, Lawson FM, Teo KK, Armstrong PW. A systematic review of randomized trials of disease management programs in heart failure. *Am J Med*. 2001;110:378-84. [PMID: 11286953]
- Burns RB, McCarthy EP, Moskowitz MA, Ash A, Kane RL, Finch M. Outcomes for older men and women with congestive heart failure. *J Am Geriatr Soc*. 1997;45:276-80. [PMID: 9063271]
- Masoudi FA, Havranek EP, Krumholz HM. The burden of chronic congestive heart failure in older persons: magnitude and implications for policy and research. *Heart Fail Rev*. 2002;7:9-16. [PMID: 11790919]
- Riegel B, Carlson B, Glaser D, Hoagland P. Which patients with heart failure respond best to multidisciplinary disease management? *J Card Fail*. 2000;6:290-9. [PMID: 11145753]
- The effect of digoxin on mortality and morbidity in patients with heart failure. The Digitalis Investigation Group. *N Engl J Med*. 1997;336:525-33. [PMID: 9036306]
- Mion LC, Palmer RM, Meldon SW, Bass DM, Singer ME, Payne SM, et al. Case finding and referral model for emergency department elders: a randomized clinical trial. *Ann Emerg Med*. 2003;41:57-68. [PMID: 12514683]
- Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. *JAMA*. 2002;288:1775-9. [PMID: 12365965]
- Shortell SM, Gillies RR, Anderson DA, Mitchell JB, Morgan KL. Creating organized delivery systems: the barriers and facilitators. *Hosp Health Serv Adm*. 1993;38:447-66. [PMID: 10130607]
- Rundall TG, Shortell SM, Wang MC, Casalino L, Bodenheimer T, Gillies RR, et al. As good as it gets? Chronic care management in nine leading US physician organizations. *BMJ*. 2002;325:958-61. [PMID: 12399351]

Appendix Table. Reasons for Exclusion

Category	Patients, n (%)
Medical comorbid condition	795 (41)
Renal failure	245 (31)
Severe pulmonary disease	173 (22)
Valve disease	138 (17)
Other comorbid condition	124 (16)
Myocardial obstructive disease	64 (8)
Cardiac surgery scheduled	51 (6)
Total	795 (100)
Psychosocial disorders	635 (32)
Cognitive disorders	287 (45)
Other psychosocial problems	231 (37)
Substance abuse	91 (14)
Psychiatric problems	26 (4)
Total	635 (100)
Logistic limitations	521 (27)
Discharge to skilled-nursing facility	267 (51)
Language barrier	145 (28)
Participating in existing heart failure program	81 (16)
Leaving area or no telephone available	28 (5)
Total	521 (100)
Total	1951 (100)

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