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Randomized Trial of an Education and Support Intervention to Prevent Readmission of Patients With Heart Failure

Harlan M. Krumholz, MD, FACC,*†‡§ Joan Amatruda, RN,† Grace L. Smith, MPH,† Jennifer A. Mattera, MPH,† Sarah A. Roumanis, RN,† Martha J. Radford, MD, FACC,*†‡ Paula Crombie, LCSW,‖ Viola Vaccarino, MD, PHD¶

New Haven and Middletown, Connecticut; and Atlanta, Georgia

OBJECTIVES We determined the effect of a targeted education and support intervention on the rate of readmission or death and hospital costs in patients with heart failure (HF).

BACKGROUND Disease management programs for patients with HF including medical components may reduce readmissions by 40% or more, but the value of an intervention focused on education and support is not known.

METHODS We conducted a prospective, randomized trial of a formal education and support intervention on one-year readmission or mortality and costs of care for patients hospitalized with HF.

RESULTS Among the 88 patients (44 intervention and 44 control) in the study, 25 patients (56.8%) in the intervention group and 36 patients (81.8%) in the control group had at least one readmission or died during one-year follow-up (relative risk = 0.69, 95% confidence interval [CI]: 0.52, 0.92; p = 0.01). The intervention was associated with a 39% decrease in the total number of readmissions (intervention group: 49 readmissions; control group: 80 readmissions, p = 0.06). After adjusting for clinical and demographic characteristics, the intervention group had a significantly lower risk of readmission compared with the control group (hazard ratio = 0.56, 95% CI: 0.32, 0.96; p = 0.03) and hospital readmission costs of $7,515 less per patient.

CONCLUSIONS A formal education and support intervention substantially reduced adverse clinical outcomes and costs for patients with HF. (J Am Coll Cardiol 2002;39:83–9) © 2002 by the American College of Cardiology

Heart failure (HF) has an extremely high rate of readmission after index hospitalization, with up to 44% of patients rehospitalized within six months of discharge (1). Recent studies have suggested that multidisciplinary disease management programs can substantially reduce the risk of readmission, with as much as a 56% reduction in HF readmissions and a 44% reduction for all-cause readmissions (2). These interventions, however, have generally included medical management components and, consequently, it is difficult to identify the critical factors responsible for their success.

Behavioral factors such as noncompliance with medications and diet and delay in seeking preventive care may contribute to readmissions and premature mortality (3,4). Thus, we hypothesized that an education and support intervention intended to increase compliance and empower patients to manage their disease would significantly reduce the rate of readmission and death for patients with HF. We conducted a prospective, randomized trial of 88 patients to assess the effect of the intervention on the rate of readmission and death and cost of hospital readmissions.

From the *Section of Cardiovascular Medicine, Department of Medicine, Yale University School of Medicine, New Haven, Connecticut; †Yale-New Haven Hospital Center for Outcomes Research and Evaluation, New Haven, Connecticut; ‡Qualidigm®, Middletown, Connecticut; §Section of Health Policy and Administration, Department of Epidemiology and Public Health, Yale University School of Medicine, New Haven, Connecticut; ‖Yale-New Haven Hospital, New Haven, Connecticut; and the ¶Division of Cardiology, Department of Medicine, Emory University School of Medicine, Atlanta, Georgia. At the time this work was conducted, Dr. Vaccarino was affiliated with the Section of Chronic Disease Epidemiology, Department of Epidemiology and Public Health, Yale University School of Medicine, New Haven, Connecticut.

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METHODS

Patients. We studied patients aged ≥50 years who met clinical criteria for presence of HF on admission to Yale-New Haven Hospital (YNHH) between October 1997 and September 1998. Consecutive admissions were screened daily to identify eligible patients, who were required to have either an admission diagnosis of HF or radiologic signs of HF on the admission chest X-ray. These patients' medical records were reviewed within three days of admission to verify a set of additional symptom and sign criteria, based on a modification of the National Health and Nutrition Examination Survey I study and criteria by Schocken et al. (5) and Harlan et al. (6). Excluded from the study were patients transferred from other hospitals, patients admitted from nursing homes, patients with HF secondary to high-output states or noncardiac diseases and patients with terminal illness in addition to HF (e.g., cancer with <6-month expected survival). The Institutional Review Board of the Yale University School of Medicine approved the study, and all patients provided informed consent.

Study intervention. The study intervention was based on five sequential care domains for chronic illness, including

Abbreviations and Acronyms

CI = confidence interval
CVD = cardiovascular disease
HF = heart failure
HR = hazard ratio
RR = relative risk
YNHH = Yale-New Haven Hospital

patient knowledge of the illness, the relation between medications and illness, the relation between health behaviors and illness, knowledge of early signs and symptoms of decompensation and where and when to obtain assistance. In the teaching module, each sequential domain supplemented knowledge acquired in previous domains. Operationalizing the intervention occurred in two phases. Initially, the patients' understanding of the domains was assessed and reviewed in order to provide information about patient gaps in knowledge for the nurse to address. Subsequent follow-up sessions reviewed knowledge of care domains and provided support for patients to apply their knowledge, participate in managing these domains and effectively seek and access care. This support was designed to reinforce the initial educational foundation theoretically by empowering patients and offering strategies to improve patients' compliance.

For the initial phase, an experienced cardiac nurse educated patients during an hour-long face-to-face in-depth session within two weeks of hospital discharge using a teaching booklet. Home visits were performed for 45% of intervention patients unable to travel to the hospital, but the visits were not intended to provide additional assessments that were more detailed than clinic sessions. Neither clinical assessment of HF nor modification of current medical regimen was a component of the baseline meeting.

During the subsequent telemonitoring phase, the nurse contacted the patient by phone on a weekly basis for four weeks, then biweekly for eight weeks and then monthly for a total intervention period of one year. These calls reinforced care domains but did not modify current regimens or provide recommendations about treatment. However, the nurse could recommend that the patient consult his or her physician when the patient's status deteriorated abruptly or the patient experienced a significant problem with medical therapy requiring prompt attention, and, in doing so, the nurse helped patients understand when and how to seek and access care. Patients assigned to the control group received all usual care treatments and services ordered by their physicians.

Data collection and follow-up. A face-to-face baseline enrollment interview provided demographic information. Clinical information abstracted from patient medical records included medical history, physical examination, laboratory evaluation, results of cardiac tests and hospital course.

One-year outcomes included deaths, ascertained through next-of-kin, hospital records, active monitoring of obituaries and information about readmissions obtained from patients, their families, discharge summaries and hospital records to confirm the event and classify the cause, based on the assessment of a clinician blinded to the patients' intervention allocation.

Cost analysis. For the readmissions that occurred at YNHH (91%), the Transition Accounting System (Transition Systems, Inc., Boston, Massachusetts) was used to calculate costs. For each admission, the quantity of each resource used was multiplied by the unit cost of the resource, and the individual resource costs were totaled. For rehospitalizations outside of YNHH, costs were based on an equation derived from a prospective cohort of patients with HF at YNHH (G. Smith, unpublished data, 2000), lengths of stay and cost-to-charge ratios from billing information. A similar percentage of the readmissions for both groups occurred at YNHH (88% of the control group and 98% of the intervention group).

The calculated cost of the intervention included an hourly rate of $50 estimated for nursing and social work time. Costs of in-hospital follow-up medical care included the sum of costs of readmission for all patients in each group; outpatient costs were not included. Costs associated with start-up, research and monitoring (i.e., screening, randomization, data collection and follow-up) were also not included.

Study end points and statistical analysis. Analyses were conducted according to the intention-to-treat approach, with readmission or death as the primary outcome measure. Secondary end points included number of all-cause, HF and HF-related or other cardiovascular disease (CVD)-related readmissions, cumulative number of days of hospitalization during follow-up and the cost of readmissions. Other analyses adjusted for the effect of early mortality on outcomes. The study was powered to detect a 40% relative reduction in the total rate of readmission or death among patients in the intervention group, based on the assumption of a 75% rate of death or readmission for the control group.

Characteristics of the two study groups were compared by the chi-square test for categorical variables and by the Wilcoxon rank-sum test for continuous variables. The primary outcome (rate of readmission or death) was compared using the Mantel-Haenszel chi-square, and relative risks (RR) were calculated. Time to first readmission or death was compared using the log-rank test. Subgroup analyses stratified by cause of readmission, as well as all outcomes adjusted for early mortality, were also conducted.

A Cox proportional-hazards model assessed readmission-free survival, with data on patients who died without readmission to the hospital censored at the time of death. Based on the bivariate analysis and previous work identifying predictors of readmission within one year of discharge from the hospital, we adjusted for age, gender, history of HF and admission creatinine (1). An additional analysis was performed adjusting for prior coronary artery disease, use of

calcium channel blockers and use of beta-blockers. All analyses were conducted using SAS 6.12 (SAS Institute, Cary, North Carolina).

RESULTS

Study sample. A total of 390 patients was screened from October 1997 through September 1998. Among them, 248 (63.6%) were not eligible due to at least one exclusion criterion: admission from a nursing home (46 patients); transfer from another acute-care facility (45 patients); conditions severely interfering with interview (45 patients); admission for elective procedure (29 patients); already enrolled in study (23 patients); HF due to high output states (15 patients); other terminal disease (11 patients); terminal or skilled nursing care (10 patients); enrolled in other studies (8 patients); no signs/symptoms of HF (8 patients); other impairing conditions (4 patients); HF due to toxic cardiomyopathy (3 patients); patient <50 years old (3 patients); or followed by another facility (2 patients). An additional 54 patients (13.6%) were eligible but not enrolled, due to no interview because of death, discharge or other medical reasons (22 patients), patient, physician or family refusal (20 patients) or having no telephone or residing in another state (12 patients).

Baseline characteristics. The median age of the patients was 74 years; 57% were men and 74% were Caucasian. The two groups were well balanced with respect to most characteristics, although the intervention group was slightly older, had a lower rate of prior coronary artery bypass graft surgery, percutaneous transluminal coronary angioplasty and acute myocardial infarction and a lower use of calcium channel blockers and beta-blockers (Table 1).

Table 1. Comparison of Intervention and Control Baseline Characteristics

Characteristics	Intervention (n = 44)	Control (n = 44)	p Value
Age	75.9 ± 8.7	71.6 ± 10.3	0.050
Male gender	21 (48)	29 (66)	NS
White race	31 (70)	34 (77)	NS
Prior myocardial infarction	24 (55)	29 (66)	NS
Prior congestive heart failure	31 (70)	35 (80)	NS
Prior CABG	7 (16)	16 (36)	0.029
Prior PTCA	5 (11)	9 (20)	NS
Diabetes	23 (52)	23 (52)	NS
Systolic blood pressure (mm Hg)	162 ± 38	157 ± 35	NS
Sodium (mmol/l)	138 ± 4	137 ± 5	NS
Blood urea nitrogen (mmol/l)	11.1 ± 6.4	12.5 ± 8.2	NS
Creatinine (μmol/l)	141.4 ± 61.9	150.3 ± 79.6	NS
Ejection fraction (%)*	38 ± 17	37 ± 16	NS
Activities of daily living score	5.6 ± 1.1	5.5 ± 1.2	NS
Procedures during admission			
Cardiac catheterization	8 (18)	6 (14)	NS
PTCA	1 (2)	0 (0)	NS
Discharge medications			NS
Aspirin	19 (43)	19 (43)	NS
Beta-blockers	14 (32)	22 (50)	NS
Calcium channel blockers	8 (18)	17 (39)	0.033
ACE inhibitors	28 (64)	24 (55)	NS
Digoxin	22 (50)	17 (39)	NS

*Ejection fraction values were available for 87 (99%) patients.
ACE = angiotensin-converting enzyme; CABG = coronary artery bypass graft surgery; PTCA = percutaneous transluminal coronary angioplasty.

Readmissions. Among the 88 patients (44 intervention and 44 control) in the study, 25 patients (56.8%) in the intervention group and 36 patients (81.8%) in the control group had at least one readmission or died during follow-up (RR = 0.69, 95% confidence interval [CI]: 0.52, 0.92; p = 0.01). Only 12 patients (27.3%) in the intervention group compared with 21 patients (47.7%) in the control group experienced more than one readmission (RR = 0.57, 95% CI: 0.33, 0.99; p = 0.05). Overall, there were 49 all-cause readmissions in the intervention group and 80 in the control group in the one year after discharge (p = 0.06), indicating a 39% reduction in readmissions. In the intervention group, 9 patients (20.4%) died, compared with 13 patients (29.5%) in the control group (RR = 0.69, 95% CI: 0.33, 1.45; p = 0.33).

The number of patients experiencing HF or other CVD readmissions or death was 22 (50.0%) in the intervention group and 35 (79.6%) in the control group (RR = 0.63, 95% CI: 0.46, 0.86; p = 0.004). These patients accounted for 35 readmissions in the intervention group and 66 in the control group (p = 0.03), for a 47% decrease in the total number of HF or other CVD readmissions.

In the intervention group, 18 patients (40.9%) had at least one HF readmission compared with 30 patients (68.2%) in the control group (RR = 0.60, 95% CI: 0.41, 0.89; p = 0.01). These patients accounted for 22 total readmissions for HF in the intervention group and 42 in the control group (p = 0.07), for a 48% decrease in these readmissions (Table 2). All primary analyses and subgroup analyses excluding patients with early mortality yielded comparable results (not shown).

Median time from discharge to all-cause readmission or death was 193 days in the intervention group, compared with 126 days in the control group (Figs. 1 to 3). In multivariate Cox proportional hazards models, after adjusting for age, gender, history of HF and admission serum creatinine, the intervention group had a significantly lower risk of all-cause readmission or death (hazard ratio [HR] = 0.56, 95% CI: 0.32, 0.96; p = 0.03), lower risk of HF or other CVD readmission or death (HR = 0.51, 95% CI: 0.29, 0.90; p = 0.02) and lower risk of HF readmission or death (HR = 0.52, 95% CI: 0.28, 0.98; p = 0.04) compared with the control group (Table 3). Subsidiary analyses adjusting for calcium channel blockers at discharge, beta-blockers at discharge or presence of coronary artery disease (history of myocardial infarction, angioplasty or bypass surgery) did not significantly change hazard estimates (not shown).

Cost of care. The average cost of the study intervention included an average of 5 h per patient with the nurse and 2 h per patient with the social worker for the 30% of patients needing a social worker for the educational sessions during

Table 2. Readmission and Death Within One Year of Initial Discharge*

	Intervention (n = 44)	Control (n = 44)	Reduction (%)	RR (95% CI)	p Value
Patients readmitted or died					
All-cause readmission or death	25 (56.8)	36 (81.8)	−30.6%	0.69 (0.52, 0.92)	0.01
HF or other CVD readmission or death	22 (50.0)	35 (79.6)	−37.2%	0.63 (0.46, 0.86)	0.004
HF readmission or death	18 (40.9)	30 (68.2)	−40.0%	0.60 (0.41, 0.89)	0.01
More than 1 readmission	12 (27.3)	21 (47.7)	−42.8%	0.57 (0.33, 0.99)	0.05
More than 2 readmissions	6 (13.6)	11 (25.0)	−45.6%	0.55 (0.23, 1.32)	0.18
Deaths	9 (20.4)	13 (29.5)	−30.8%	0.69 (0.33, 1.45)	0.33
Number of readmissions					
All-cause readmission	49	80	−38.8%	—	0.06
HF or other CVD readmission	35	66	−47.0%	—	0.03
HF readmission	22	42	−47.6%	—	0.07
Hospital days					
All-cause readmission	10.2 ± 16.8	15.2 ± 17.5	—	—	0.09
HF or other CVD readmission	6.3 ± 9.2	12.3 ± 14.3	—	—	0.03
HF readmission	4.1 ± 6.4	7.6 ± 12.1	—	—	0.1

*Values followed by parentheses indicate number of patients and percentages of the group. Continuous values are expressed as mean ± SD. Percent reduction calculated by dividing the absolute percent difference between groups by the control group percentage.

CI = confidence interval; CVD = cardiovascular disease; HF = heart failure; RR = relative risk.

the one-year follow-up period. The total estimated cost was $530 per patient.

Hospital readmission costs were higher in the control group by an average of $7,515 per patient ($21,935 in the control group and $14,420 in the intervention group, p = 0.02). After taking into consideration the average cost of $530 per patient with intervention, the overall cost of care was $6,985 less per patient in the intervention group. For HF or other CVD readmissions, costs per patient were $18,421 in the control group and $8,888 in the

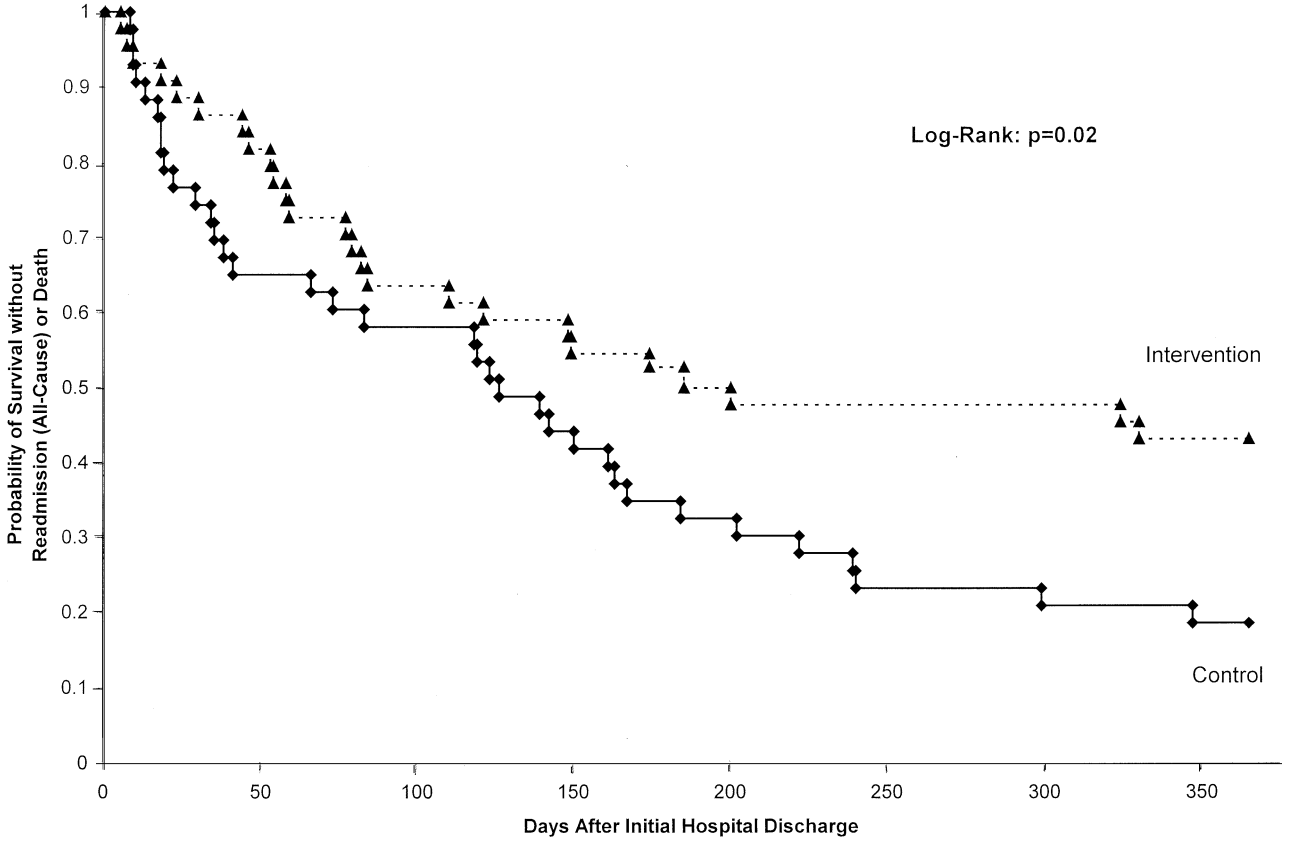

Figure 1. Kaplan-Meier curve for all-cause related readmission or death.

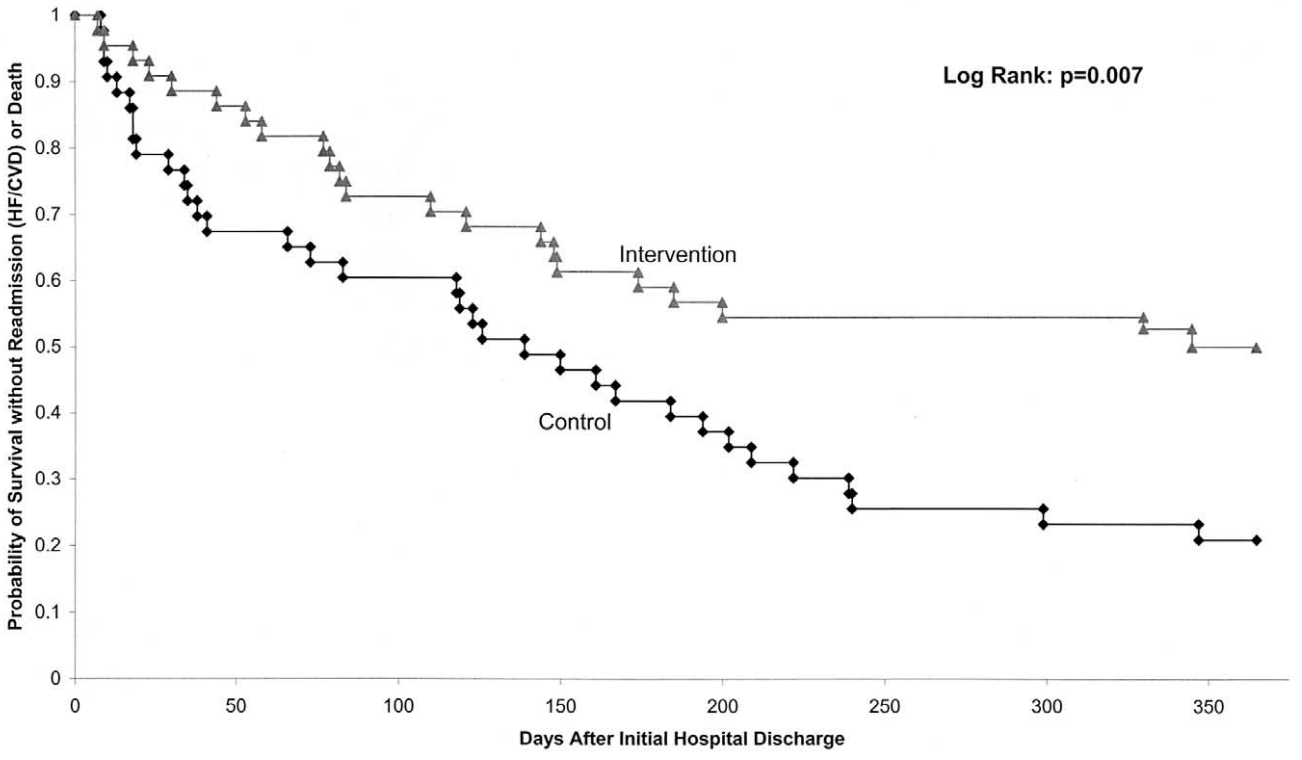

Figure 2. Kaplan-Meier curve for congestive heart failure (HF)/cardiovascular disease (CVD)-related readmission or death.

intervention group (p = 0.01). For HF readmissions, costs per patient were $9,575 in the control group and $5,232 in the intervention group (p = 0.04) (Table 4).

DISCUSSION

We report that an education and support intervention without medical management components was highly effective in reducing readmissions and in-hospital costs among patients with HF. Fewer patients in the treatment group experienced readmission or death as well as multiple readmissions, for a reduction in total number of admissions and substantially lower costs in the first year after discharge. Intervention patients also exhibited significantly longer readmission-free survival. Reductions of nearly 40% in total readmissions and nearly 50% in HF readmissions are comparable to those reductions achieved by other more intensive HF case-management programs. This program, however, is distinctive in its focus on patient empowerment through education on managing chronic illness and through support for seeking appropriate care.

The percentage of patients with all-cause readmission was reduced by over 30% and by 40% for HF readmission. While the percentage of patients with all-cause readmission is close to results found in previous studies (1), the subset of readmissions related to HF was relatively high compared with previous reports, with 68.2% of patients in the control group having at least one HF-related readmission. Previous studies, however, used only principal diagnosis codes to classify readmissions, while our study provides the percentage of patients readmitted for HF using a review of medical records and discharge summaries. Thus, HF-related readmissions may be more prevalent in this patient population than previously suggested, underscoring the importance of this intervention in targeting and preventing readmissions due to acute exacerbation of HF.

Independent value of education and support. This study extends previous work on disease management for patients with HF (2,7–10) by specifically evaluating the impact of education and support without medication management intervention on the outcome of these patients. While multifaceted studies have suggested a benefit of comprehensive case management for HF patients, the "optimal" intervention from a clinical and cost perspective has not yet been defined. Our intervention is different from other published programs, as it focuses on enabling patients to take an active role in managing their chronic illness based on knowledge and education and does not rely on physicians or nurses actively intervening to adjust medical care and regimens.

Our study has some similarities to the study by Jaarsma et al. (11) who demonstrated that a brief education and support intervention by a nurse could increase self-care behaviors among patients who had been hospitalized with HF. Unlike our study, the nurse in the Jaarsma study made a home visit to every intervention patient, and all of the intervention occurred within 10 days of discharge. In contrast to our findings, Jaarsma et al. (11) found no significant change in resource utilization, although there were trends that favored the intervention group.

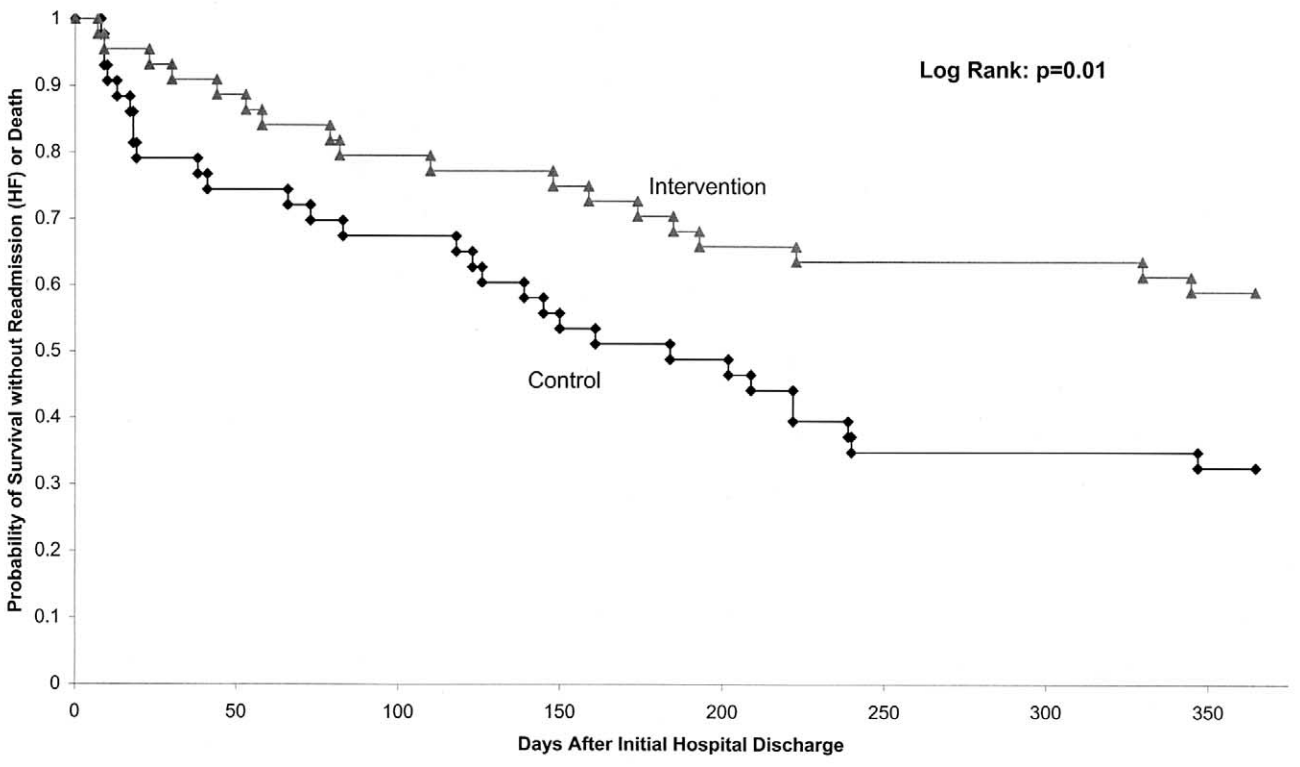

Figure 3. Kaplan-Meier curve for congestive heart failure (HF)-related readmission or death.

Rich et al. (2) randomized 282 patients to usual care versus a nurse-directed multidisciplinary intervention and reported that the intervention group had a 56% reduction in HF readmissions. The intervention by Rich et al. (2) not only included intensive education about HF but also nurse participation in the medical management of the patients, in some cases visiting homes to administer intravenous diuretics. Other recent studies of more intensive disease management of patients with HF have reported a benefit associated with these programs. For example, Australian investigators reported that a home-based intervention produced a 50% reduction in deaths and unplanned admissions (7) and in a later study reported a 40% reduction in a larger patient sample (12). As in our study, the intervention may have been most effective in reducing the frequency of multiple readmissions.

The focus of these interventions, however, was on a home visit by a nurse-pharmacist team that addressed medical management and compliance as well as intensive medical follow-up. In our intervention, medical management was left to the patients' physicians and, thus, benefits were likely mediated chiefly through the knowledge and efforts of the patients. Although it was theorized that these outcomes were achieved through promotion of patient compliance and empowerment, this trial did not explicitly test the mechanism of intervention. Future studies may explore potential mechanisms for maximal benefits of education and support.

Notably, the reductions in readmissions in our trial, though sizable, were slightly less than those found in management programs with pharmacologic components. These differences could be attributed to interstudy variability or potential residual benefit from the pharmacologic component of those interventions. Additionally, while the benefits of the previous studies are apparent by 90 days, differences in our treatment groups were significant only after 180 days of follow-up. An education and support paradigm emphasizes long-term change, reinforcement of care domains and patients' incorporation of these changes into their lifestyle.

Table 3. Proportional Hazards Model: Intervention Versus Control

Outcome	RR	95% CI	p Value
Time to first all-cause readmission	0.56	0.32, 0.96	0.03
Time to first HF or CVD readmission	0.51	0.29, 0.90	0.02
Time to first HF readmission	0.52	0.28, 0.98	0.04

All models were adjusted for age, gender, history of heart failure and admission serum creatinine.

CI = confidence interval; CVD = cardiovascular disease; HF = heart failure; RR = relative risk.

Table 4. Mean Readmission Costs ($ Per Patient)

	Intervention	Control	p Value
All-cause readmission	14,420 ± 31,453	21,935 ± 23,701	0.02
HF or other CVD readmission	8,888 ± 13,411	18,421 ± 21,308	0.01
HF readmission	5,232 ± 9,852	9,575 ± 15,801	0.04

CVD = cardiovascular disease; HF = heart failure.

Study limitations. Although the intervention was conducted at a single center, the relative simplicity of our education-focused intervention should make it easily applicable to a broad spectrum of patients with HF. Our intervention was directed by an experienced nurse, and these findings may not be reproducible when implemented by someone without clinical knowledge of this condition. Furthermore, since the intervention lasted only one year, the optimal length of education and support through telemonitoring is unknown, and the minimum time period necessary for patients to manifest benefits of this intervention is still unknown.

The study sample size of 88 patients was relatively small, but the study yielded a positive result. The randomization groups were comparable with respect to demographic and clinical characteristics, although differences in some characteristics were noted. Comparisons of outcomes were supplemented by a multivariate analysis that adjusted for potential baseline differences in the randomization arms, and the outcome was not changed.

Finally, despite the cost analysis that employed detailed estimates from a comprehensive cost-accounting system, this analysis did not account for all costs, specifically nonhospital costs. However, hospital costs likely dominate total patient costs in the first year after discharge. The study by Rich et al. (2) included a more comprehensive analysis of cost in a subset of their patients and found that the hospital costs were responsible for the differences between the groups.

Conclusions. Although many studies have shown the benefits of multidisciplinary interventions with medical components, this study suggests that education and support intended to prompt patient participation in the management of chronic illness has independent effects on markedly reducing poor outcomes. The magnitude of benefits from this trial rivals the outcomes reported by more comprehensive programs, which have achieved reductions of 40% or more. These results, building on the work of others, suggest that all patients with HF should be offered an education and support program that extends beyond the hospitalization.

Reprint requests and correspondence: Dr. Harlan M. Krumholz, Yale University School of Medicine, 333 Cedar Street, PO Box 208025, New Haven, Connecticut 06520-8025.

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