Clinical Investigations

Which Patients With Heart Failure Respond Best to Multidisciplinary Disease Management?

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ABSTRACT

Background: Multidisciplinary disease management approaches have been shown to decrease resource use in selected samples of patients with heart failure. We remain uncertain regarding the effectiveness of this approach in a general heart failure population and who can be expected to benefit most. The purpose of this study was to test the effectiveness of a multidisciplinary disease management intervention in an unselected population of patients with heart failure and to determine if subgroups could be identified in which the intervention is most effective.
Methods and Results: Two hundred forty patients with heart failure who were matched on preadmission functional status, comorbidity, and age participated in a quasi-experimental clinical trial. Half (n = 120) were given a multidisciplinary disease management intervention, whereas the other half (n = 120) received usual care. Data on acute care resource use were collected 3 and 6 months after enrollment. No intervention effect was seen in the primary analysis. When the data were analyzed by preadmission functional status (I to IV), acute care resource use was lower in the class II intervention patients. Class I intervention patients had a 288% increase in total costs and a 14-fold increase in heart failure costs. A model of predictor variables explained 17.2% of the variance in heart failure readmission at 3 months.
Conclusions: An intervention of this type and intensity is recommended primarily for functional class II heart failure patients. Increases in cost in class I patients may have resulted from improved access to care.
Key words: heart failure, disease management, functional class, cost, effectiveness research, access to care.

Heart failure (HF) remains the primary reason for hospitalization in the elderly population (1). Disease management has been proposed as an effective method of decreasing health care resource use in these patients (2). Disease management programs have proliferated since the first published reports of success (3,4). Preliminary results of subsequent studies have been promising although limited by testing in selected patient populations (5). Because only the sickest patients with HF were included in these studies, we remain uncertain regarding the population of patients with HF who can be expected to benefit most from multidisciplinary disease management. The primary purpose of this study was to test the effectiveness of multidisciplinary disease management in an unselected population of patients with HF. The secondary purpose was to determine if a subgroup of pa-

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tients with HF who responded best to intervention could be identified.

Disease management has been defined as "a comprehensive, integrated system for managing patients . . . by using best practices, clinical practice improvement information technology, and other resources and tools to reduce overall cost and improve measurable outcomes in the quality of care" (6). Three models of disease management have been proposed: multidisciplinary, case management, and clinic models (7). In multidisciplinary models of disease management, nurses, physicians, pharmacists, dieticians, social workers, and others collaborate to provide a holistic approach to care. Each patient's unique medical, psychosocial, behavioral, and financial circumstances are recognized (5). Systems of care are designed to ease the transition from hospital to home in a coordinated fashion. Home follow-up is included, but it is rarely of the intensity seen in case management approaches. In case management, medical care is augmented with intense monitoring by telephone or home visits after discharge from an acute care facility. Education is the thrust of this intervention. Clinic models are primarily outpatient settings organized by cardiologists and often supported by nurse practitioners with special expertise in the treatment of HF. Optimization of pharmaceutical therapy and correction of underlying pathophysiology is the focus of this intervention, although support from a multidisciplinary team is common (8).

The current research tested a multidisciplinary model of disease management in an unselected population of patients with HF by using effectiveness research methods (9). Two questions guided the analysis. First, what is the effect of multidisciplinary disease management on acute care resource use when studied in an unselected population of patients with HF? Second, which patients with HF respond best to such an approach? In the secondary analysis, preadmission functional status was hypothesized to be a useful predictor for a subset of patients who would respond best to the intervention, but other potential predictors were also explored.

Methods

Study Patients

A total of 323 patients with the clinical diagnosis of HF were enrolled into a quasi-experimental study; 240 patients completed the study. A sample size of 240 was judged to be adequate for the primary analysis of group differences based on a power analysis conducted using an analysis of variance (ANOVA) framework before beginning the study. A small-to-moderate effect size was anticipated, therefore a Cohen d = .35 was used in the calculation along with a power of .80 and a 2-tailed α of 0.05. The power analysis revealed the need for a sample size of 120 patients in each of 2 groups. Only patients confirmed to have chronic HF by a review of the clinical record were included. Those with transient HF (eg, acute myocardial infarction), cognitive impairment, primary renal failure requiring dialysis, severe psychiatric illness, inability to speak English, and individuals discharged to a long-term care facility were excluded.

Participants were solicited from 5 hospitals in Southern California and studied in parallel to control for changes in medical practice and cost. Eligible patients from 2 hospitals were matched with those from 3 other hospitals on preadmission functional status, comorbidity, and decade of age by using nearest available metric matching techniques (10). This technique involves finding the closest possible comparison patient for each intervention group participant from the reservoir of yet unmatched usual care group patients (11).

Study Intervention

Early in 1996, a multidisciplinary team of clinicians implemented a disease management program designed to promote self-management for patients with HF. The program used educational materials, in-hospital counseling by pharmacists and dieticians, discharge assessment by social work, outpatient support groups, physician collaboration, home visits by a HF specialty team of nurses, and telephonic case management by registered nurses with expertise in HF. All patient interactions focused on promoting self-care abilities (eg, daily weights, symptom monitoring, low-sodium diet, medication compliance, exercise). The 6-month intervention was calculated to cost $330 per patient in 1998 (12). Improvements in physician practice patterns were targeted through educational efforts.

Participants who were enrolled in the intervention group were given a standardized educational binder and informed about program resources (eg, nurse case manager, support group). Members of the multidisciplinary team were notified to visit the patient and begin teaching before hospital discharge. Information gathered by the team during hospitalization (eg, social work assessment) was shared with the outpatient team (eg, home health nurse) to ease the transition of care to the home environment. No additional clinical resources were allocated to the program. That is, the clinicians providing the intervention assumed responsibility for these patients in addition to their routine duties. Consequently, components of the intervention were not consistently provided to every patient (Table 1).

In the usual care group, the primary care physician or cardiologist managed those patients without the assistance of a case manager. Staff nurses taught patients about HF during hospitalization by using brochures available from the American Heart Association or phar-

Table 1. Summary of the Intervention Received Over the 6-Month Period (N = 240)

	Intervention Group (n = 120)	Usual Care Group (n = 120)
Average number of total contacts received	13.47 ± 6.75	2.01 ± 6.79
Given an educational binder	100%	0
Watched a HF video	34.2%	0.8%
Attended a HF support group	47.5%	6.7%
Received an in-patient pharmacist visit	42.5%	*
Assessed by social services during hospital admission	31.7%	*
Received an in-patient dietary visit	50.8%	*
Average number of case manager telephone calls	5.62 ± 4.60	0
Average number of home health RN visits	4.29 ± 5.62	1.93 ± 6.78
Average number of home health specialty RN visits	3.27 ± 4.29	0

HF, heart failure; RN, registered nurse.
* Not measured.
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maceutical companies. The dietician and social worker were consulted in problematic situations. Patients were not telephoned after hospital discharge, but some patients were referred for routine home care (Table 1). The hospital had no support group in place.

Study Protocol

The study was reviewed and approved by the Institutional Review Boards of the hospitals and the academic institution of the principal investigator. Patients were enrolled at the time of a HF hospitalization when their physician had confirmed the diagnosis of HF. Nurse research associates were carefully trained to assure that only patients with true HF were enrolled. All baseline data were obtained immediately on enrollment. Participants were followed for 6 months after hospital discharge. Data on acute care resource use were collected 3 and 6 months after index hospitalization discharge by using the financial database. The study was completed in 27 months.

Measurement

Preadmission functional status was hypothesized to be a predictor of patients with HF in whom multidisciplinary disease management would be most effective. Preadmission functional status was measured with the Specific Activity Scale (SAS), a standardized interview in which patients were queried about their abilities to perform various activities (eg, shower without stopping) before hospitalization (13). Responses were used to categorize patients into 1 of 4 functional classes (I to IV) according to the metabolic load associated with the most strenuous activity able to be performed before hospitalization. Functional class I reflects the patient's self-report of perceived normal functional ability, and class IV indicates extreme functional compromise.

Comorbidity was measured with the interview format of the Charleson Index (14). At the time of enrollment, patients were queried about preexisting diseases (eg, myocardial infarction, ulcer disease, diabetes); responses were weighted and indexed into 1 of 3 categories (low, moderate, or high) according to the published method. Most comorbid conditions are scored with 1 point, although some (eg, hemiplegia, cirrhosis, metastatic cancer) are assigned more than 1 point. Raw scores can range from 0 to 34, although every patient in this study had a score of at least 1 because they were all diagnosed with HF. Validity of the scale was shown by the instrument authors when the comorbidity category was shown to predict mortality, complications, health care resource use, length of hospital stay, discharge disposition, and cost (14,15).

Age was captured from the medical record. Severity of illness at the time of index admission was gathered from automated hospital data with the 3M system (3M Health Information Systems, Wallingford, CT). In-hospital functional capacity was measured at the time of index hospitalization by using the New York Heart Association (NYHA) classification method (16). A single nurse practitioner assessed in-hospital functional capacity on all patients to avoid problems of inconsistency among raters. These variables were used to describe the sample and in secondary analyses.

Functional capacity was measured with both the SAS and the NYHA classification method, but the SAS data were used in matching and in most analyses because of problems identified with the NYHA method (17–20). The NYHA classification method has been said to measure prognosis, illness severity, symptoms, and quality of life. Consistency among raters is poor. Conversely, the SAS is clearly a measure of functional capacity. It has significantly higher validity and reproducibility than the NYHA method. When tested by the instrument authors, the NYHA estimates agreed with exercise testing results only 51% of the time, whereas the SAS was in agreement 68% of the time ($P = .01$). The SAS had a higher correlation with the duration of treadmill exercise measured in seconds ($r = 0.66$) than did the NYHA method ($r = 0.54$) (13).

Resource use was retrieved from the cost-accounting database with decision-support software from ECLIPSYS (formerly Transition Systems, Inc) (Boston, MA) and verified by patient self-report. Direct variable costs associated with each use of the hospital (eg, hospitalization) were used because they reflect the resource consumption associated with the treatment of the patient rather than

overhead or the associated costs of running the business (21). Data were collected on hospital admissions, days in the hospital, and direct costs for each participant by using unique patient identifiers. Both all-cause and HF admission data are reported, but model testing was done by using only the HF admission rate at 3 months because these admissions can be assumed to be unplanned. Data were collected for the entire 6 months after the index admission, not including the index admission. Physician visits and personal costs (eg, parking, medications, lost days of work) could not be captured with any accuracy, therefore those costs were not included in this analysis.

Hospitalization rates were calculated as the number of hospitalizations during the study period divided by the sample (4,8,22,23). The index admission was not counted. Readmission rates were calculated as the percentage of patients admitted at least once during the study period (24).

Statistical Analysis

Descriptive statistics, including measures of central tendency and dispersion, were computed for all continuous level quantitative variables. Assumptions such as normality, linearity, and homogeneity of variance were assessed by statistical testing, graphical display (eg, histograms for continuous variables), and box plots for ordinal variables and nonnormal distributions. For categorical variables, frequency tables and bar charts were analyzed before commencing statistical analyses. When the resource use and cost variables were analyzed, there was one outlier ($z = 12.24$) for total cost. This individual was assessed and excluded from analysis on both statistical and clinical grounds.

In the primary analysis, intervention effects were assessed by using one-way ANOVA in SPSS 8.0 (SPSS, Inc, Chicago, IL). In the secondary analysis, the 3 matching variables—preadmission functional status, comorbidity, and age—were considered as possible predictors of differential acute care resource use. Preadmission functional status was hypothesized to be the best discriminator, therefore group differences based on functional status measured by SAS were tested using ANOVA. It should be noted that power was insufficient for this secondary, exploratory analysis, therefore $P < .10$ was used in these analyses. This α level is beyond the conventional cutoff value of .05, but the purpose of this exploratory analysis was to uncover possible patterns and/or relationships. The other matching variables were assessed as a group with other clinical variables by using multiple regression techniques. The purpose of the regression analysis was to determine if this combination of variables could be used to predict HF readmissions at 3 months.

One problematic feature of cost variables is the abundance of zero (0) data points (ie, no costs, no readmissions, and so on). Correction of the highly positively skewed distributions was attempted by using logarithmic and inverse transformations; however, approximation to normality was not achieved. Even though there was a slight improvement in the nature of the distribution with logarithmic transformation, conclusions drawn from statistical testing with both the transformed and untransformed data were essentially the same. Therefore, all cost variables were analyzed in their untransformed state to maintain the continuity of the metric. Findings obtained with ANOVA were reanalyzed with their nonparametric analog (the Mann-Whitney test) because of the skewed distribution. There was no difference in the results between the 2 techniques that would substantively modify the conclusions.

Results

Patient Characteristics

A total of 240 participants, evenly divided by group, completed the study. The sample as a whole was elderly, predominately female, married, educated at the high school level or above, and economically poor (Table 2). Most (70%) were enrolled in a managed care plan. Length of the index hospitalization was approximately 4 days, on average. Only age and the index admission length of stay were significantly different between the groups. The intervention group was significantly older than the usual care group. Length of hospital stay was approximately 1 day shorter for the intervention group.

Clinical characteristics at the time of enrollment are

Table 2. Summary of Demographic Variables at Enrollment (N = 240)

	Intervention Group (n = 120)	Usual Care Group (n = 120)	Total (N = 240)
Age	74.44 ± SD 10.65	70.77 ± SD 11.77*	72.61 ± 11.40
Gender	55% female	55% female	55% female
Marital Status			
Married	49.5%	47.7%	48.6%
Widowed	36.7%	28.8%	32.7%
Divorced/separated	9.2%	13.5%	11.4%
Single	3.7%	6.3%	5.0%
Other	.9%	3.6%	2.3%
Education			
Grade school only	9.3%	10.9%	10.1%
High school only	46.7%	50.9%	48.8%
At least some college	34.6%	31.8%	33.2%
Annual income of <$20,000	56%	60.1%	58%
Length of index hospital stay	3.59 ± 3.57	4.48 ± 3.33*	4.04 ± 3.46

*$P < .05$

Table 3. Summary of Clinical Characteristics at the Time of Enrollment

	Intervention (n = 120)	Usual Care (n = 120)	Total Sample (N = 240)
Preadmission functional status by SAS (N = 240)	I = 19.2% II = 26.7% } 45.9% III = 43.3% IV = 10.8%	I = 24.2% II = 18.3% } 42.5% III = 44.2% IV = 13.3%	I = 22% II = 22% } 44% III = 43% IV = 12%
	2.46 ± .92	2.47 ± 1.0	2.46 ± .96
Severity of illness by 3M system (n = 234)	Low = 12.1% (14/115)	Low = 10.9% (13/119)	11.5%
	Moderate = 49.1% (57/115)	Moderate = 37.8% (45/119)	43.6%
	Major = 37.9% (43/115)	Major = 47.1% (56/119)	42.3%
	Severe = .9% (1/115)	Severe = 4.2% (5/119)	2.6%
Comorbidity category by Charleson Index (n = 239)	Low = 58% (69/119)	Low = 54.2% (65/120)	Low = 56.1%
	moderate = 31.1% (37/119)	moderate = 35.0% (42/120)	moderate = 33%
	high = 10.9% (13/119)	high = 10.8% (13/120)	high = 10.9%
Major comorbid illnesses (N = 240)			
COPD	30%	37.5%	33.7%
CAD	54.2%	50%	52.1%
CVA	11.7%	10.8%	11.2%
Diabetes	28.3%	25%	26.7%
PVD	15.8%	9.1%	12.5%
Renal disease without dialysis	28.3%	27.5%	27.9%
Thyroid disease	11.7%	19.2%	15.4%
Index admission functional capacity by NYHA (n = 237)	I = 0	I = 0	I = 0
	II = 13.3%	II = 8.5%	II = 11%
	III = 55%	III = 49.1%	III = 51.9%
	IV = 31.7%	IV = 42.4%	IV = 37.1%
Discharged on digoxin (n = 195)	51.7% (46/89)	65.1% (69/106)	59%
Discharged on ACE inhibitor (n = 194)	58.4% (52/89)	47.6% (50/105)	52.6%
Discharged on β-blocker (n = 194)	12.4% (11/89)	18.1% (19/105)	15.5%
Discharged on calcium channel blocker not approved for HF (n = 194)	19.1% (17/89)	15.2% (16/105)	17%
Discharged on a diuretic (n = 194)	86.5% (77/89)	83.8% (88/105)	85.1%
Discharged on an antiarrhythmic (n = 194)	11.2% (10/89)	12.4% (13/105)	11.9%
Last serum sodium (n = 156)	139 ± 4.3	138 ± 3.4*	138 ± 4.0
Last serum creatinine (n = 159)	1.31 ± .52	1.46 ± .77	1.39 ± .66
Atrial fibrillation at discharge (n = 232)	36.5% (42/115)	30.8% (36/117)	33.6%
Admission systolic BP (n = 234)	144 ± 32	149 ± 34	146 ± 33
Ventricular dysfunction (n = 172)			
Systolic	52.4% (43/82)	63.3% (57/90)	58.1%
Diastolic	39% (32/82)	34.4% (31/90)	36.6%
Mixed	8.5% (7/82)	2.2% (2/82)	5.2%
Ejection fraction (n = 102)	46.76% Range 19–81%	43.57% Range 13–89%	44.6%
Origin of HF (n = 206)			
Ischemic	43.3% (45/104)	38.2% (39/102)	40.8%
Hypertensive	19.2% (20/104)	23.5% (24/102)	21.4%
Valve disease	10.6% (11/104)	11.8% (12/102)	11.2%
Other (eg, alcoholic, idiopathic, peripartum, chemotherapy)	26.9% (28/104)	26.5% (27/102)	26.7%

SAS, Specific Activity Scale; COPD, chronic obstructive pulmonary disease; CAD, coronary artery disease; CVA, cerebrovascular accident; PVD, peripheral vascular disease; NYHA, New York Heart Association; ACE, angiotensin-converting enzyme; HF, heart failure; BP, blood pressure.
* $P < .05$.

shown in Table 3. HF was a new diagnosis in 36.3% of the sample. Most had systolic dysfunction and little comorbidity. Ischemic origin was the most common cause of HF. Preadmission functional status was poor (43.8% SAS class III) as well as in-hospital functional status (52.1% NYHA class III). Severity of illness during the index admission was moderate to major for most patients. Only serum sodium at discharge differed significantly between the groups.

A significant amount of attrition occurred during the

course of the study. Of those who withdrew voluntarily (n = 83, 26%), more than half (66%) were from the usual care group. Those who withdrew were comparable with the final sample except that they were older (75.4 ± 9.68). Another 22 participants (9.2%) died during their 6 months in the study and 11 were admitted to a skilled nursing facility (SNF). Loss of patients because of death or SNF placement was higher in the intervention group than the usual care group (13 *v* 9 deaths; 7 *v* 4 SNF). This differential loss of patients resulted in a shorter mean duration of follow-up (169.02 ± 39.40 *v* 179.53 ± 33.79 days) that was statistically ($F_{V1,V2}(1 - \alpha) = 4.92$; $df = 1,238$; $P = .03$) but not clinically significant.

Primary Analysis

When acute care resource use was compared by intervention group, no significant differences were evident at 3 or 6 months. At 3 months, there were no significant differences in the overall hospitalization rate (.37 ± .75 intervention *v* .36 ± .70 usual care), days in the hospital (1.68 ± 4.81 *v* 1.46 ± 3.77), or total cost ($1,369 ± $3,841 *v* $1,355 ± $3,612). No differences were evident in the HF hospitalization rate (.22 ± .52 intervention *v* .13 ± .45 usual care), HF days in the hospital (.89 ± 3.34 *v* .48 ± 1.64), or HF costs ($632 ± $2,378 *v* $317 ± $1,188).

At 6 months, there were no significant differences in the overall hospitalization rate (.63 ± .97 intervention *v* .60 ± .93 usual care), days in the hospital (2.66 ± 5.43 *v* 3.03 ± 6.74), or cost ($2,361 ± $4,890 *v* $2,566 ± $5,479). No differences were found in the HF hospitalization rate (.32 ± .58 *v* .23 ± .53), HF days in the hospital (1.31 ± 3.77 *v* 1.08 ± 3.46), or HF cost at 6 months ($1,024 ± $3,017 *v* $686 ± $2,225).

Preadmission Functional Status

When the data on acute care resource use were examined by preadmission functional status, acute care resource use was lower in those intervention group patients who reported minimal functional compromise (ie, SAS class II) before the index hospitalization (Table 4). Days in the hospital for any cause were significantly lower in the class II intervention patients at 6 months. Total cost was 68% lower when the class II intervention patients were compared with the class II usual care group. Readmission rates were 17.6% lower in the intervention group (37.5%) compared with the usual care group (45.5%).

Acute care resource use was higher in the SAS functional class I patients enrolled in the intervention group compared with those in usual care group (Fig. 1). Class I intervention group patients had significantly higher all-cause hospitalization rates, total days in the hospital, and higher all-cause and HF costs than those in the usual care group (total costs 288% higher and HF costs almost 14-fold higher in the intervention group) (Table 4). Readmission rates were 68.1% higher in the SAS class I intervention group compared with the usual care group (34.8% *v* 20.7%).

Table 4. Acute Care Resource Use at 6 Months Separated by Intervention Group and Preadmission Functional Class (N = 239)

	All Hospitalizations		All Days in Hospital		Total Cost	
	Intervention	Usual Care	Intervention	Usual Care	Intervention	Usual Care
Class I (n = 52)	.61 ± 1.08	.21 ± .41*	3.74 ± 8.11	.79 ± 1.82*	$3,613 ± $6,908	$930 ± $2,632*
Class II (n = 54)	.53 ± .76	.82 ± 1.10	1.72 ± 3.75	5.64 ± 11.71*	$1,638 ± $3,848	$5,114 ± $9,151*
Class III (n = 104)	.76 ± 1.11	.75 ± 1.07	3.14 ± 5.27	3.51 ± 6.14	$2,420 ± $4,407	$2,709 ± $4,892
Class IV (n = 29)	.38 ± .65	.50 ± .63	1.23 ± 3.03	1.94 ± 3.13	$1,696 ± $4,854	$1,552 ± $3,031
	HF Hospitalizations		HF Days in Hospital		Total HF Cost	
	Intervention	Usual Care	Intervention	Usual Care	Intervention	Usual Care
Class I (n = 52)	.30 ± .56	.10 ± .31	2.04 ± 6.49	.21 ± .82	$1,696 ± $4,377	$115 ± $432*
Class II (n = 54)	.31 ± .59	.36 ± .79	1.25 ± 3.36	2.32 ± 6.33	$1,147 ± $3,601	$1,618 ± $4,280
Class III (n = 104)	.35 ± .63	.30 ± .54	1.27 ± 2.71	1.26 ± 2.99	$838 ± $2,129	$780 ± $1,763
Class IV (n = 29)	.23 ± .44	.06 ± .25	.31 ± .63	.37 ± 1.5	$264 ± $561	$124 ± $496

HF, heart failure.
* $P < .10$.

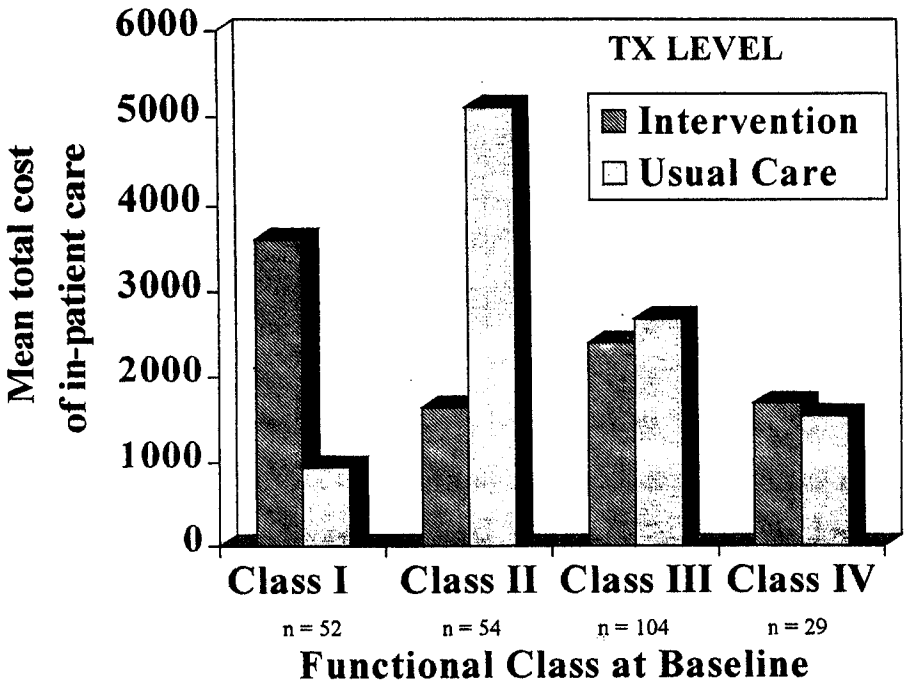

Fig. 1. Data on the total direct costs associated with uses of the acute care setting were collected after patients had been in the study for 6 months. The mean total cost of care was compared by group and separated by functional class (I to IV). This figure illustrates that acute care resource use was significantly lower in SAS class II patients with HF but significantly higher in the SAS class I patients in the intervention group compared with the usual care group.

The SAS class I patients were removed and the primary analysis was repeated (N = 187). Group differences were not significant at 3 or 6 months. At 3 months, all-cause admission rates were down 16%, days in the hospital were down 20%, and total cost was down 21% in the intervention group, but the differences were not statistically significant. At 6 months, all-cause admission rates were down 12%, days in the hospital were down 36%, HF days in the hospital were down 16%, and total cost was down 33% in the intervention group, but the differences were not statistically significant.

Model of Predictors of Readmission

Readmission within the first 3 months for HF was chosen as the most sensitive indicator of treatment effectiveness. Variables thought to be potential predictors of a 3-month HF admission were tested in a hierarchical regression model. In the first step, age, comorbidity, preadmission (SAS) and in-hospital (NYHA) functional capacity, severity of illness, ACE-inhibitor use, atrial fibrillation at discharge, HF type (eg, systolic), index hospitalization length of stay, hospital of enrollment, and treatment group (intervention *v* usual care) were entered into the equation simultaneously. HF type was not available on all patients so inclusion of this variable decreased the number of patients in the analysis from 240 to 187.

This model of variables explained 14.2% of the variance in HF readmission at 3 months ($F_{V1,V2}(1 - \alpha) = 2.40$; $df = 12,174$; $P = .007$). In the second step, the same variables and 3 interaction terms were tested. The interaction of ACE-inhibitor use with HF type was tested because ACE-inhibitors are used most commonly with systolic dysfunction. The interaction between SAS and intervention group was tested based on the prior analysis. Length of index hospitalization and intervention group was tested because length of stay was shorter in the hospitals where the intervention group patients were enrolled. Only another 3.1% of the variance was explained with these additional variables.

Variables significant in the final hierarchical regression model were higher levels of comorbidity ($\beta = .23$, $P = .002$), better (ie, lower) in-patient functional capacity as measured by NYHA ($\beta = -.18$, $P = .02$), length of the index hospitalization ($\beta = .25$, $P = .01$), and the interaction of length of stay and allocation to the intervention group ($\beta = -.31$, $P = .02$). The final hierarchical regression model explained 17.2% of the variance in HF readmission at 3 months ($F_{V1,V2}(1 - \alpha) = 2.37$; $df = 15,171$; $P = .04$).

Discussion

No overall intervention effect was evident from the multidisciplinary disease management intervention tested in this clinical trial in an unselected population of patients with HF. When the treatment groups were separated by preadmission functional status, the intervention seemed to have differential effects. Intervention group patients reporting that they were asymptomatic and fully functional before their index admission (SAS class I) experienced a dramatic increase in acute care resource use 6 months later when compared with those in the

usual care group. Most intervention benefit was evident in patients with HF reporting early functional compromise (ie, SAS class II) before their index admission. No intervention effect was evident in patients in SAS class III and IV from an intervention of the type and intensity tested in this trial. Higher levels of comorbidity, better (ie, lower) in-hospital NYHA functional capacity, and shorter length of index hospitalization in intervention group patients all predicted subsequent HF readmission, although only a moderate amount of variance was explained by the predictor variables.

The lack of an overall intervention effect was surprising in light of the findings of other HF investigators, although disease management has failed to show an effect in other patient populations. For example, Harris et al tested 437 patients with chronic renal insufficiency who were randomly assigned to disease management or usual care (25). Two years of an intense intervention failed to show an effect on renal function, use of health services, or mortality rates up to 5 years after enrollment. Another study of intensive education aimed at improving asthma self-management also failed to show differential effects among 236 patients randomly assigned to an intense intervention, a moderate program of only essentials, or usual care (26).

Possible interpretations of the inability of this intervention to show significant main effects could be insufficient intervention intensity, inadequate medical therapy, differences in analytic methods, or the use of an unselected patient population. The program tested was only moderate in intensity, but other investigators have found benefit from even less intense interventions (27,28). Inadequate medical therapy is probably not responsible for the lack of intervention effect because the pharmacologic therapy provided to these patients compares with or exceeds that documented elsewhere in the country (29-36).

Differences in analytic methods may help to explain the results of this study. Many of the previous studies of disease management conducted with patients with HF have used historical controls. This method may inflate estimates of intervention effectiveness because it ignores the fact that the treatment of HF has improved nationwide since publication of the HF guidelines in 1994 (5).

Use of an unselected patient population is the most likely explanation for the differences in findings. Almost 22% of the sample (n = 52) denied functional compromise (ie, SAS class I) before enrollment into the study. Prior investigators have carefully chosen patients with symptomatic heart failure or those anticipated to be readmitted in the near future as participants in their disease management trials (8,22,37). This number of asymptomatic patients seems to have diluted the intervention effect.

The finding that acute care resource use was increased substantially by the intervention in the functional class I patients may reflect an improvement in access to care. Patients in the intervention group had contact with a variety of different health care providers who undoubtedly asked about symptoms and encouraged patients to seek care. It may be that the increase in acute care resource use reflects an improvement in care. Further study is needed to determine if later savings compensate for the early increase in acute care resource use. The interpretation of increased access is supported by the observation that cost was highest in the class II patients in the usual care group. Early functional compromise may be the usual signal for further testing and treatment, but in the class I patients, access to care accelerated that process.

It is also possible that the intervention worried the SAS class I patients, making them feel ill and motivating them to seek care. Those patients classified as class I may also represent a group of individuals who minimized their disability on enrollment and were more ill than they perceived. This interpretation is supported by the finding that none of the patients enrolled in the study were classified as class I according to the NYHA classification method. Another interpretation is that hospitalized patients who were asked about their preadmission status may have inflated their previous capabilities in comparison with their current status. Future research is needed to understand why acute care resource use was so high in this group of patients.

The finding that some benefit was evident in SAS class II patients supports the early work of Rich et al who argued that a multidisciplinary disease management intervention is effective in moderate-risk HF patients (3,4). In their pilot study, elderly patients with HF admitted to the hospital were categorized into high, moderate, or low hospitalization risk categories by using predictive factors identified in their previous research (3). Low-risk patients (ie, those with no risk factors) were excluded from the study based on the assumption that they would be unlikely to benefit from a program designed to reduce hospitalizations. Their multidisciplinary disease management intervention was effective in those with only 1 risk factor but had no apparent effect on the high-risk patients (2 or more risk factors). They recommended that an alternate approach be used in the high-risk patients. Our data support this recommendation.

It was surprising that only a moderate amount of the variance in HF readmission was explained by a combination of variables chosen to account for both patient characteristics and institutional differences. The fact that better NYHA functional capacity was significant supports the prior analysis with SAS, which also found that better functional status was a predictor of readmission in the intervention group. High comorbidity is an indicator of illness severity that can be expected to predict readmission. The finding that intervention group patients

with a short length of index hospitalization were more likely to be readmitted suggests that perhaps patients with HF would benefit from more hospitalization time used to stabilize and teach about the disease. Together, these variables can be used to identify subgroups of patients who would benefit most from multidisciplinary disease management.

A major strength of this study was the fact that an unselected population of patients with HF was included. Most previous studies have included carefully selected patients in whom an intervention of this nature was expected to be beneficial (5). Such a technique limits the generalizability of the findings. In this study, effectiveness research techniques were used, and an unselected patient population was accepted in the hopes of identifying if the findings of previous investigators can be directly translated into clinical practice. It seems from these results that multidisciplinary disease management may be most effective in those patients with HF with early functional compromise. Such an approach cannot be advocated, however, for patients who perceive themselves to be without functional disability. More intense interventions may be needed for sicker patients.

The major limitation of this study was the use of a nonrandom sample. Another threat to internal validity was selection bias caused by patient attrition that may have been aggravated by the burden of completing research instruments, although the amount of attrition was not unexpected in this ill patient population. Matching was done by combining SAS classes I and II, but analysis was done by separating the classes, which produced an uneven number of patients in those 2 groups. In addition, some of the data collected by other investigators were available only on a subset of patients in this clinical setting (eg, ejection fraction). Despite these limitations, we conclude that the type and intensity of disease management intervention tested in this study seems to be effective in decreasing acute care resource use in patients with HF at the early stages of functional compromise.

The results of this study show that HF disease management programs should be offered only to selected groups of patients with HF. Limited health care resources are wasted when an unselected group of individuals participates in such programs. Exploratory analyses suggest that functional status and perhaps comorbidity can be used to identify subgroups of patients with HF who will benefit from a multidisciplinary disease management approach. Further research is needed to validate these findings and to identify other subgroups of patients with HF who will benefit from disease management.

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