ORIGINAL INVESTIGATION

Effects of a Home-Based Intervention Among Patients With Congestive Heart Failure Discharged From Acute Hospital Care

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Background: We examined the effect of a home-based intervention (HBI) on readmission and death among "high-risk" patients with congestive heart failure discharged home from acute hospital care.

Methods: Hospitalized patients with congestive heart failure and impaired systolic function, intolerance to exercise, and a history of 1 or more hospital admissions for acute heart failure were randomized to either usual care (n=48) or HBI at 1 week after discharge (n=49). Home-based intervention comprised a single home visit (by a nurse and pharmacist) to optimize medication management, identify early clinical deterioration, and intensify medical follow-up and caregiver vigilance as appropriate. The primary end point of the study was frequency of unplanned readmissions plus out-of-hospital deaths within 6 months of discharge. Secondary end points included duration of hospital stay and overall mortality.

Results: During follow-up, patients in the HBI group had fewer unplanned readmissions (36 vs 63; *P*=.03) and fewer out-of-hospital deaths (1 vs 5; *P*=.11): 0.8±0.9 vs 1.4±1.8 (mean ± SD) events per patient assigned to HBI and usual care, respectively (*P*=.03). Patients in the HBI group also had fewer days of hospitalization (261 vs 452; *P*=.05) and fewer total deaths (6 vs 12; *P*=.11). Patients assigned to usual care were more likely to experience 3 or more readmissions for acute heart failure (*P*=.02). Predictors of unplanned readmission were (1) 14 days or more of unplanned readmission during the 6 months before study entry (odds ratio [OR], 5.2; 95% confidence interval [CI], 1.8-16.2), (2) previous admission for acute myocardial ischemia (OR, 3.3; 95% CI, 1.2-9.1), and (3) an albumin plasma concentration of 38 g/L or less (OR, 2.4; 95% CI, 1.2-6.0). Home-based intervention was also associated with a trend toward reduced risk of unplanned readmission (OR, 0.4; 95% CI, 0.2-1.1).

Conclusion: Among a cohort of high-risk patients with congestive heart failure, HBI was associated with reduced frequency of unplanned readmissions plus out-of-hospital deaths within 6 months of discharge from the hospital.

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COSTS associated with readmissions to the hospital have been estimated at approximately 24% of total Medicare inpatient expenditures in the United States.[1] The distribution of costs is non-Gaussian, with a disproportionate effect on total costs by those patients categorized as "high-cost users"[2,3]: occurrence of unplanned readmissions provides a basis for these incremental costs. For example, among patients with congestive heart failure (CHF), the leading cause of hospitalization among patients older than 65 years,[4] reported readmission rates range from 6% to 14% per month during the 6 months after initial discharge.[5-9]

Randomized controlled studies examining the effect of various interventions on frequency and duration of rehospitalization among patients with CHF have been conflicting, with favorable,[8] inconclusive,[10] and even unfavorable[11] results reported. We examined the effect of a home-based intervention (HBI) on the frequency of unplanned readmissions plus out-of-hospital deaths for 6 months among "high-risk" patients with CHF discharged from acute hospital care.

RESULTS

CLINICAL AND DEMOGRAPHIC PROFILE

Table 1 is a summary of the clinical and demographic profile of the study cohort. Most patients were elderly and of lower socioeconomic status. All but 1 of the study cohort were receiving a diuretic, 79 (81%) were receiving an angiotensin-convert-

PARTICIPANTS AND METHODS

STUDY COHORT

The study was initiated within a tertiary referral hospital that services a largely elderly population of lower socioeconomic status, with a higher prevalence of chronic illness and admission rates per capita for the region. Of a cohort of 762 medical and surgical patients prospectively examined after hospital discharge,[12] the largest subgroup of patients were individuals with CHF. Presence of CHF was defined on the basis of formal demonstration (via echocardiography or radionuclide ventriculography) of impaired systolic function (left ventricular ejection fraction, ≤55%) and persistent functional impairment indicative of New York Heart Association class II, III, or IV status. Acute heart failure was defined on the basis of pulmonary congestion or edema evident on chest radiography,[13] with a clinical syndrome of acute dyspnea at rest. Chronicity of heart failure was diagnosed on the basis of exclusion of factors such as acute myocardial infarction or unstable angina pectoris, which might have precipitated emergence of reduced systolic function at the time of the index admission. However, patients admitted with acute ischemia or infarction with previously documented CHF were eligible for inclusion. Other exclusion criteria were presence of terminal malignancy requiring palliative care and home address outside the hospital catchment area.

The effects of an HBI were compared with those of usual postdischarge care (UC) in this subset of patients. General eligibility criteria for the study included being discharged to home and requiring continuous pharmacotherapeutic intervention for a chronic condition. Patients with CHF who were determined to be at high risk for unplanned readmission were identified on the basis of 1 or more unplanned admissions for acute heart failure before study entry.

RANDOMIZATION

The study was approved by The Queen Elizabeth Hospital's Ethics of Human Research Committee. Informed consent was obtained before hospital discharge, and participating patients were randomized to either UC or HBI. Randomization was initiated via a telephone call to an investigator (S.S.) who was unaware of the patient's demographic and clinical profile. Of the 107 eligible high-risk patients with CHF initially identified, 97 (91%) agreed to participate in the study.

STUDY TREATMENT

Before discharge, patients assigned to an HBI (n=49) were visited by the study nurse (S.P.) and counseled in relation to complying with the treatment regimen and reporting any sign of clinical deterioration or acute worsening of their heart failure. One week after discharge, these patients were visited at home by the study nurse and pharmacist. On arrival, the study pharmacist performed an assessment of the patient's knowledge of the prescribed medications (via questionnaire) and the extent of compliance (via pill count). Patients who demonstrated poor medication knowledge (<75% composite knowledge score of dosage, intended effect, potential adverse effects, and special instructions) or malcompliance (≥15% deviation from prescribed dosage at discharge) received a combination of the following: (1) remedial counseling, (2) initiation of a daily reminder routine to enhance timely administration of medications, (3) introduction of a weekly medication container enabling predistribution of dosages, (4) incremental monitoring by caregivers, (5) provision of a medication

ing enzyme inhibitor, and 65 (67%) were receiving digoxin. Clinical data recorded at the time of the index admission revealed that 57 patients (59%) were treated for acute pulmonary edema: of these, 16 (28%) were associated with new onset of rapid, uncontrolled (≥120/min) atrial fibrillation and 12 (21%) were associated with an acute ischemic syndrome.

EXTENT OF STUDY INTERVENTION

Seven patients assigned to HBI (14%) did not receive a home visit because of early readmission or withdrawal of consent. Among patients who were subject to a home visit, 22 (52% [95% CI, 36%-68%]) were found to be malcompliant with, and 38 (90% [95% CI, 77%-97%]) had inadequate knowledge of, their treatment regimen. On this basis, most patients required remedial intervention during HBI, and 9 patients were referred to a community pharmacist for more intensive follow-up thereafter. Furthermore, 14 patients (33% [95% CI, 20%-50%]) demonstrated either early clinical deterioration or adverse effects from their medication regimen (most commonly postural hypotension) and required immediate examination by their primary care physician.

END POINTS

During the study, the incidence of the primary composite end point (unplanned readmission plus out-of-hospital death) was 0.8±0.9 vs 1.4±1.8 (mean ± SD) per patient assigned to HBI and UC, respectively (P=.03) (**Figure**). This comprised fewer unplanned readmissions (36 vs 63; P=.03) and out-of-hospital deaths (1 vs 5; P=.11) among patients in the HBI group. There was no significant difference between groups regarding time to first primary end point, although patients in the HBI group tended to be readmitted earlier. Furthermore, although fewer patients in the HBI group experienced an unplanned readmission (24 of 49 vs 31 of 48; P=.12) or died (6 of 49 vs 12 of 48; P=.11), neither difference reached statistical significance. Results of post-hoc analysis suggested that HBI was effective in preventing individual patients from requiring large numbers of readmissions with acute heart failure: no patient assigned to HBI had 3 or more such admissions, compared with 5 patients assigned to UC (P=.02). Patients assigned to HBI also recorded significantly fewer attendances to the hospital emergency department (48 vs 87; P=.05)

information and reminder card, and (6) referral to a community pharmacist for more regular review thereafter.

Patients were further evaluated by the study nurse to detect any clinical deterioration or adverse effects of prescribed medication since discharge; those requiring medical review were immediately referred to their primary care physician. After the home visit, all patients' primary care physicians were contacted by the study nurse to inform them of the home visit and to discuss the need (if any) for further remedial action or more intensive follow-up thereafter.

USUAL CARE

Patients assigned to the UC group (n=48) received the preexisting levels of postdischarge care: all patients in the UC group had appointments to be reviewed by their primary care physician or cardiologist (in the hospital's outpatient department) within 2 weeks of discharge. Furthermore, 13 patients (27%) were receiving regular home support (eg, domiciliary care or community nurse visits) after discharge.

STUDY END POINTS

The prospectively elected primary end point was frequency of unplanned readmissions plus out-of-hospital deaths.[8,14] Secondary end points were time to first primary end point, rate of unplanned readmission, total days of hospitalization, emergency department attendance, overall mortality, and cost of hospital-based health care.

DATA COLLECTION

After enrollment, data were collected regarding the patients' demographic profile, past medical history, and details of the index admission (including signs and symptoms, treatment regimen, and results of diagnostic investigations). Extent of comorbidity was assessed using the Charlson Index.[15]

All subsequent inpatient and outpatient activity was tracked via the hospital's computerized medical records system, with costs provided by the hospital's finance department. Records of the time and location of all deaths occurring in the region were compiled via the local Birth, Deaths, and Marriages Registry. Costs associated with the HBI were calculated from detailed diary entries of study personnel activity and invoices from external services used. In a randomly selected subset of 34 patients, the cost of community-based health care (including pharmacotherapy and consultation with primary care physicians) also was determined.

STATISTICAL ANALYSIS

Comparison of baseline and end point data involved use of the following: (1) χ^2 analysis (with calculation of odds ratio [OR] and 95% confidence interval [CI]) for discrete variables, (2) the Student *t* test for normally distributed continuous variables, (3) the Mann-Whitney *U* test for non-Gaussian distributed variables, and (4) the log-rank test for analysis of the mortality data (Kaplan-Meier curve) and time to first primary end point. All analyses were performed on an intention-to-treat basis, with significance accepted at the .05 level (2 sided).

Multiple logistic regression, with entry of variables at a significance level of .20 from univariate analysis and stepwise rejection of variables at the .05 level of significance, was used to examine the interaction between treatment mode and other potential correlates of unplanned admission and mortality.

and fewer days of hospitalization (261 vs 452 days; *P*=.05).

Mean cost of hospital-based care tended to be lower for the HBI group ($3200 [95% CI, $1800-$4600]) compared with the UC group ($5400 [95% CI, $3200-$6800]); this difference did not reach statistical significance. On the other hand, the additional cost of implementing the study intervention was $190 per patient. Costs associated with community-based health care for those patients subject to audit (n=34) were similar for both groups: $620 per patient assigned to HBI (95% CI, $460-$740) vs $680 per patient assigned to UC (95% CI, $550-$800). (Amounts of currency are expressed in Austalian dollars.)

Correlates of readmission and death during the study are summarized in **Table 2**; univariate and multivariate data are given. On multiple logistic regression, significant correlates of unplanned readmission are (1) prolonged unplanned readmission before study entry, (2) living alone, and (3) hypoalbuminemia. Allocation to the UC regimen was a borderline correlate (*P*=.06). Significant correlates of mortality are (1) non–English-speaking background, (2) regular home support, and (3) multiple readmissions during study follow-up.

COMMENT

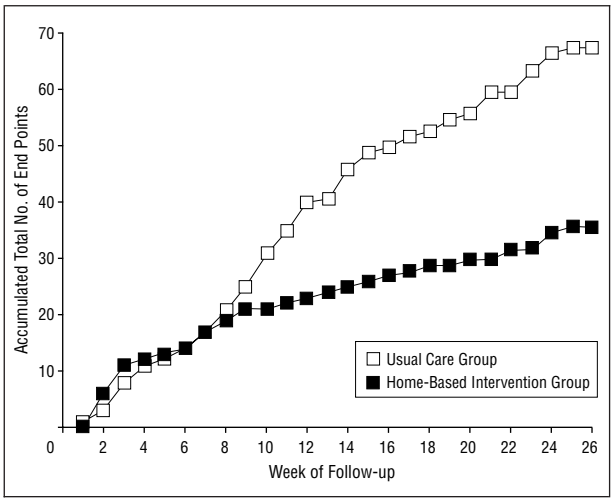
Despite the introduction of more effective modalities of treatment (most notably angiotensin-converting enzyme inhibitors),[16-18] CHF is associated with poor quality of life,[19,20] frequent and costly hospitalizations,[5-9] and approximately 50% mortality at 5 years[21]; among New York Heart Association class IV patients, mortality is as high as 60% to 80% at 2 years.[16,21,22] In theory, elderly patients with CHF would benefit most from interventions that address those factors associated with increased hospital use, including malcompliance with, or adverse effects of, treatment regimen[23-27]; inadequate follow-up[10,28-31]; suboptimal use of medical care[30-32]; and early clinical deterioration.[30,32-34] We postulated that an early HBI program might ameliorate all of these factors (both directly and via increased vigilance of patients' physicians, community pharmacists, and caregivers) and might be most effective in reducing readmissions among patients with CHF and clinically significant impaired systolic function and a history of 1 or more hospitalizations for acute heart failure.

During follow-up, patients in the HBI group had significantly fewer unplanned readmissions plus out-of-

Table 1. Baseline Clinical and Demographic Data According to Treatment Group*

	Home-Based Intervention (n = 49)	Usual Care (n = 48)
Demographic profile		
Men:women	22:27	25:23
Age, y*	76 ± 11 (40-93)	74 ± 10 (36-88)
Live alone	20	18
Non–English-speaking background	10	9
Discharge medications		
No. of prescribed medications*	6.9 ± 2.4 (2-15)	6.5 ± 2.5 (3-14)
Diuretic	49	47
Angiotensin-converting enzyme inhibitor	41	38
Digoxin	33	32
Nitrate	29	28
Hospitalization data 6 mo preceding study entry*		
Hospitalization before index admission, d	3.1 ± 5.8 (0-21)	3.2 ± 6.0 (0-24)
Duration of index admission, d	7.9 ± 6.0 (2-27)	7.7 ± 6.2 (2-28)
Congestive heart failure profile		
Congestive heart failure documented before the index admission	35	39
Left ventricular ejection fraction, %*	38 ± 11 (18-55)	39 ± 11 (17-55)
New York Heart Association class II:III:IV on discharge from hospital	24:23:2	24:20:2
Comorbidity		
Ischemic heart disease:myocardial infarction	35:20	30:21
Chronic airways limitation	21	14
Chronic hypertension	19	20
Atrial fibrillation	15	15
Noninsulin:insulin-dependent diabetes	7:2	10:2
Charlson index score	2.1 ± 0.7	2.2 ± 0.5
Admission profile		
Acute pulmonary edema	30	27
Heart rate, beats/min	101 ± 24	94 ± 26
Systolic blood pressure, mm Hg	138 ± 29	132 ± 27
Discharge profile		
Sodium, mmol/L	138 ± 4.8	139 ± 3.4
Potassium, mmol/L	4.0 ± 0.4	4.3 ± 0.5
Albumin, g/L	39 ± 3.5	38 ± 4.3
Creatinine, μmol/L (mg/dL)	133 ± 43 (1.5 ± 0.5)	150 ± 79 (1.7 ± 0.9)
Heart rate, beats/min	79 ± 9	79 ± 13
Systolic blood pressure, mm Hg	120 ± 21	120 ± 19
Sinus rhythm:atrial fibrillation	31:18	34:14

**Normally distributed continuous data are presented as mean ± 1 SD, with figures in parentheses indicating range. There were no significant differences between groups regarding baseline characteristics.*



Accumulated total number of unplanned readmissions plus out-of-hospital deaths during follow-up using the unpaired Student t test (P=.03).

hospital deaths. Despite the greater number of deaths in the UC group (and hence no further potential for admission), there was still a 42% difference in overall duration of hospital stay. The overall improvement in health outcomes among patients assigned to HBI is consistent with the degree of intervention during, and subsequent to, the home visit. Many of the problems uncovered during this visit would have hitherto remained undetected. Analysis of the pattern and potential predictors of an unplanned readmission suggest that this type of HBI is most effective among patients with problems that contribute to poor control of their CHF resulting in multiple readmissions, especially if they have more severe systolic dysfunction or less social support. There was also a trend toward fewer out-of-hospital deaths among patients assigned to HBI; the present study was not designed, however, to explore mode of putative effect.

The present study should be compared with 3 previously reported, randomized controlled investigations including high proportions of patients with CHF. In 2 of these studies, "broad" interventions (comprehensive discharge planning[10] and increased access to outpatient primary care[11]) yielded inconclusive and unfavorable results, respectively, in relation to extent and duration of rehospitalization. In the remaining study, however, use of a similar but more intensive intervention specific to management of CHF was associated with a significant increase in the time to first readmission or out-of-hospital death at 3 months after discharge.[8] As with the present study, the difference between groups regarding frequency of readmissions was largely mediated via fewer multiple readmissions among patients exposed to the nurse-directed HBI. It is possible that the success of the regimen examined in the present study may result from a combination of a home visit (a central component of the approach used by Rich et al[8]) with a broad-based examination of chronic morbidity: in the present study, as in some previous investigations in patients with CHF,[6,22,35,36] approximately 40% of readmissions were primarily associated with conditions other than CHF.

Table 2. Correlates of Unplanned Readmission and Mortality During Study Follow-up

Variable	Readmission		*P*		
	No (n = 42)	Yes (n = 55)	Univariate Analysis	Multivariate Analysis	Adjusted Odds Ratio (95% Confidence Interval)
Home-based intervention, No. (%)	25 (60)	24 (44)	.12	.06	0.4 (0.2-1.1)
Unplanned hospitalization ≤6 mo before entry, d	8.1 ± 7.4	13.0 ± 8.9	.005	.002	5.2* (1.8-16.2)
Lives alone, No. (%)	12 (29)	26 (47)	.09	.07	2.3 (0.9-5.7)
Previous admission for an acute ischemic syndrome, No. (%)	25 (60)	40 (73)	.2	.02	3.3 (1.2-9.1)
Albumin plasma concentration, g/L	39 ± 3	37 ± 2	.06	.01	2.4* (1.2-6.0)
	Died				
	No (n = 79)	Yes (n = 18)			
Non–English-speaking background, No. (%)	11 (14)	8 (44)	<.001	<.001	5.0 (1.6-18.0)
Regular home help, No. (%)	23 (29)	17 (94)	<.001	.03	15.7 (1.3-186.0)
Total readmissions during study follow-up	0.95 ± 1.4	1.9 ± 1.6	.01	.003	3.4* (1.3-11.2)

**Odds ratio is shown for patients with 14 days or more of unplanned hospitalization, albumin plasma concentration of 38 g/L or less, and 2 or more unplanned readmissions.*

Several correlates of unplanned readmission among this cohort are consistent with previous studies, including greater hospital use before follow-up,[6,9] previous hospitalization associated with an ischemic syndrome,[9,37] hypoalbuminemia,[36] and living alone.[25,32,33]

One explanation for the results of this study might be that patients in the UC group received inadequate care relative to currently established norms, resulting in a higher incidence of readmission and mortality. However, clinical data, pharmacotherapy, and morbidity were all similar to data for analogous groups in recent publications[5-9] and guidelines for the management of CHF.[21] In a recent multicenter study[6] of hospital readmissions and mortality among a broad population of patients with CHF in the United States, the 6-month rates of readmission and mortality were 44% and 24%, respectively. In the present study, the proportion of patients assigned to UC who were readmitted at 6 months was not unexpectedly higher at 65% (95% CI, 49%-78%), and mortality was similar at 25% (95% CI, 14%-40%).

The results of this preliminary study are promising. However, it would be appropriate to confirm the efficacy of this type of HBI and to explore the potential mechanisms of beneficial effect in a randomized controlled study that (1) includes a similar cohort of high-risk patients with CHF, (2) is sufficiently powered to detect significant differences in all the end points examined in the present study, and (3) assesses any potential improvement in patient quality of life or functional status.

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