Prolonged Beneficial Effects of a Home-Based Intervention on Unplanned Readmissions and Mortality Among Patients With Congestive Heart Failure

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Background: A single home-based intervention (HBI) applied immediately after hospital discharge in a cohort of “high-risk” patients with congestive heart failure has been shown to decrease numbers of unplanned readmissions plus out-of-hospital deaths during a period of 6 months. The duration of this beneficial effect remains uncertain.

Methods: Hospitalized patients with congestive heart failure who had been randomly assigned to receive either usual care (n = 48) or HBI 1 week after discharge (n = 49) were subject to an extended follow-up of 18 months. The primary end point of the study was frequency of unplanned readmissions plus out-of-hospital deaths. Secondary end points included total hospital stay, frequency of multiple readmissions, cost of hospital-based care, and total mortality.

Results: During 18-month follow-up, HBI patients had fewer unplanned readmissions (64 vs 125; P = .02) and out-of-hospital deaths (2 vs 9; P = .02), representing 1.4 ± 1.3 vs 2.7 ± 2.8 events per HBI and usual-care patient, respectively (P = .03). The HBI patients also had fewer days of hospitalization (2.5 ± 2.7 vs 4.5 ± 4.8 per patient; P = .004) and, once readmitted, were less likely to experience 4 or more readmissions (3/31 vs 12/38; P = .03). Hospital-based costs were significantly lower among HBI patients (Aust $5100 vs Aust $10 600 per patient; P = .02). Unplanned readmission was positively correlated with 14 days or more of unplanned readmission in the 6 months before study entry (odds ratio [OR], 5.4; P = .006). Positive correlates of death were (1) non–English speaking (OR, 4.9; P = .008), (2) 14 days or more of unplanned readmission in the 6 months before study entry (OR, 4.9; P = .008), and (3) left ventricular ejection fraction of 40% or less (OR, 3.0; P = .03); conversely, assignment to HBI was a negative correlate (OR, 0.3; P = .02).

Conclusions: In this controlled study, among a cohort of high-risk patients with congestive heart failure, beneficial effects of a postdischarge HBI were sustained for at least 18 months, with a significant reduction in unplanned readmissions, total hospital stay, hospital-based costs, and mortality.

Arch Intern Med. 1999;159:257-261

Although the introduction of angiotensin-converting enzyme inhibitors has reduced morbidity and mortality rates among a large proportion of patients with congestive heart failure (CHF), the cost of treating these patients still represents a disproportionately large component of health care expenditure worldwide. Attempts to limit this expenditure (estimated to be upward of $10 billion per annum in the United States alone) are confounded not only by the increasing prevalence of CHF and the ongoing management it demands, but by the pattern of recurrent hospital use among a small subset of these patients. The treatment of such “high-cost” patients is often complicated by a combination of advanced age, presence of major concomitant disease, and intractable symptoms despite maximal therapy; it is clear that a proportion of patients receive suboptimal treatment. Two-year mortality among such patients is as high as 80%. We have reported the beneficial effects of a postdischarge home-based intervention (HBI) on the frequency of unplanned readmissions plus out-of-hospital deaths (the primary composite end point for the study) during 6-month follow-up of a cohort of “high-risk” patients with CHF. We were, however, unable to demonstrate a definitive reduction in hospital-based costs or mortality among patients exposed to the study intervention. To examine the medium-term effects of the intervention on the original primary end point and, more importantly, frequency of recurrent hospital admissions, total hospital stay, cost of hospital-based care, and total mortality, we extended follow-up of all surviving patients for a further 12 months (to a maximum of 18 months after the index hospitalization).
PATIENTS AND METHODS

STUDY COHORT

The study cohort of 97 patients with CHF represented the largest subgroup of medical and surgical patients (n = 762) participating in a randomized controlled study examining the effects of a postdischarge home intervention.29 These patients were prospectively selected for more comprehensive follow-up because the combined presence of impaired systolic function (left ventricular ejection fraction [LVEF] ≤55%), persistent functional impairment indicative of New York Heart Association class II, III, or IV status, and a history of at least 1 admission for acute heart failure indicated that such patients were at higher risk for subsequent hospitalization and premature mortality, and therefore more likely to benefit from a postdischarge intervention. The study was approved by the hospital’s Ethics of Human Research Committee, and all patients signed a consent form before study entry.

STUDY INTERVENTION

Patients were randomly assigned to either a postdischarge HBI (n = 49) or to usual care (UC; n = 48). Analysis of all the baseline clinical and demographic profiles of the 2 groups of patients demonstrated that the groups were well matched and receiving appropriate pharmacotherapy; a summary of their baseline characteristics is presented in Table 1. The purpose and details of the intervention are more comprehensively described in the original reports.28,29 In summary, however, HBI involved a single home visit 1 week after discharge (by a nurse and a pharmacist) to optimize medication management, identify early clinical deterioration, and intensify medical follow-up and caregiver vigilance where appropriate. During the home visits, almost all patients demonstrated adequate knowledge of the purpose, effects, and potential adverse effects of their treatment, and approximately 50% were found to be noncompliant with prescribed medication. Approximately one third of patients were referred at this time for immediate review by their primary care physician on the basis of early clinical deterioration and/or adverse medication effects.

STUDY END POINTS

All surviving patients were subject to 18-month follow-up after index hospitalization to determine the frequency of the composite primary end point of unplanned readmissions plus out-of-hospital deaths. Secondary end points were the proportion of patients experiencing an unplanned readmission, frequency distribution of unplanned readmissions, total days of hospitalization, emergency department attendance, overall mortality, and cost of hospital-based health care.

STATISTICAL ANALYSIS

Comparison of end point data involved the following: (1) \( \chi^2 \) analysis (with calculation of odds ratios [ORs] and 95% confidence intervals [CIs]) for discrete variables, (2) Mann-Whitney test for all continuous variables, and (3) log-rank test for comparison of Kaplan-Meier survival curves. Examination of the interaction between treatment mode and other potential correlates of unplanned admission and mortality involved the use of multiple logistic regression (with entry of variables at a univariate significance level of .2 and stepwise rejection of variables at the .05 level of significance). All analyses were performed on an intention-to-treat basis, with significance accepted at the level of .05 (2-sided).

RESULTS

During the 18 months after index hospitalization, 33 (67%) of 49 HBI patients (95% CI, 52%-80%) vs 39 (81%) of 48 UC patients (95% CI, 67%-91%) had experienced either an unplanned admission or an out-of-hospital death (P = .12). Although the 2 groups did not significantly differ in regard to the proportion of patients experiencing a primary end point, patients in the HBI group accumulated significantly fewer unplanned readmissions (64 vs 125; P = .02) and suffered fewer out-of-hospital deaths (2 vs 9; OR, 5.4; 95% CI, 1.0-39; P = .02). The combined total of primary end points was therefore 66 vs 134 for the HBI and UC groups, respectively (1.4 ± 1.3 vs 2.7 ± 2.8 events per patient; P = .03) (Figure 1).

Overall, HBI patients required fewer days of hospitalization (both unplanned and elective) than UC patients (10.5 ± 14.4 vs 21.1 ± 24.1 days per patient; P = .02) in addition to accumulating fewer attendances at the emergency department (2.5 ± 2.7 vs 4.5 ± 4.8 per patient; P = .004). On the basis of this reduction in hospital stay and comparable outpatient clinic costs, the calculated cost of hospital-based care per patient was significantly lower for the HBI group (Aust $5100 ± $6800 vs Aust $10 600 ± $13 000; P = .02). The cost of the original home intervention was Aust $190 per HBI patient.

Analysis of the frequency distribution of unplanned readmissions showed that UC patients, once readmitted, were significantly more likely to experience 4 or more readmissions during study follow-up (12/38 vs 3/31; OR, 4.2; 95% CI, 1.0-22.0; P = .03). Figure 2 shows the frequency distribution of unplanned readmissions for the 2 groups. Overall, 42% (95% CI, 35%-49%) of all unplanned readmissions for the entire cohort were associated with a primary diagnosis of acute heart failure, the remainder being primarily associated with either an acute ischemic syndrome or acute respiratory failure secondary to chronic airway limitation. Once readmitted, UC patients were significantly more likely to require 3 or more admissions for heart failure (8/21 vs 1/18; P = .004).

Patients assigned to HBI were also more likely to survive the 18-month period after index hospitalization; 11 (22%) of 49 HBI patients (95% CI, 10%-34%) vs 20 (42%) of 48 UC patients (95% CI, 30%-49%) died during follow-up (OR, 0.33; 95% CI, 0.12-0.88; P = .05) (Figure 3).

On the basis of initial univariate analysis, the following variables were subjected to multiple logistic regression to determine potential correlates of unplanned readmission:
Of these variables, greater hospital use in the 6 months before study follow-up proved to be the only independent, positive correlate of unplanned readmission within 18 months of index hospitalization (Table 2). Similarly, the following variables were examined as potential correlates of mortality: (1) duration of treatment for CHF, (2) number of admissions for acute heart failure, (3) number of days of unplanned hospitalization in the 6 months before study follow-up, (4) LVEF, (5) New York Heart Association class on hospital discharge, (6) English-speaking vs non–English-speaking background, and (7) study group. Of these variables, greater hospital use in the 6 months before study follow-up, a non–English-speaking background, and lower LVEF were independent, positive correlates of 18-month mortality; conversely, assignment to HBI was a negative correlate (Table 3).

**Comment**

We have reported the beneficial effects of a postdischarge home intervention on the frequency of unplanned readmissions plus out-of-hospital deaths during 6-month follow-up of a cohort of “high-risk” patients with CHF.28 The success of this strategy in reducing subsequent hospital use (42% in comparison with UC patients) was largely mediated via a reduction in repeated admissions for acute heart failure. However, perhaps because of a small sample size, the skewed distribution of costs among UC patients, and limited duration of follow-up, the previous results demonstrated neither definite cost savings nor improved survival.

The current analysis of outcomes among this cohort of patients after 18 months of follow-up was undertaken to determine whether there was any marked accentuation or attenuation of beneficial effects of HBI in the medium term. In this respect, the results of the extended follow-up demonstrated continued benefit in regard to the primary end point of frequency of unplanned readmissions plus out-of-hospital deaths; HBI patients accumulated approxi-

### Table 1. Baseline Characteristics at Index Hospitalization*

<table>
<thead>
<tr>
<th></th>
<th>HBI (n = 49)</th>
<th>UC (n = 48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, No. M/F</td>
<td>22:27</td>
<td>25:23</td>
</tr>
<tr>
<td>Age (range), y</td>
<td>76 ± 11 (40-93)</td>
<td>74 ± 10 (36-88)</td>
</tr>
<tr>
<td>Non-English speaking, No.</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Pharmacotherapy after index hospitalization</td>
<td></td>
<td></td>
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<tr>
<td>No. of prescribed medications (range)</td>
<td>6.9 ± 2.4 (2-15)</td>
<td>6.5 ± 2.5 (3-14)</td>
</tr>
<tr>
<td>Diuretic, No.</td>
<td>49</td>
<td>47</td>
</tr>
<tr>
<td>ACE inhibitor, No.</td>
<td>41</td>
<td>38</td>
</tr>
<tr>
<td>Digoxin, No.</td>
<td>33</td>
<td>32</td>
</tr>
<tr>
<td>Index hospitalization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days of hospitalization 6 mo before admission (range)</td>
<td>3.1 ± 5.8 (0-21)</td>
<td>3.1 ± 6.0 (0-24)</td>
</tr>
<tr>
<td>Duration of index admission (range), d</td>
<td>7.9 ± 6.0 (2-27)</td>
<td>7.7 ± 6.2 (2-28)</td>
</tr>
<tr>
<td>Heart failure profile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left ventricular ejection fraction (range), %</td>
<td>38 ± 11 (18-55)</td>
<td>39 ± 11 (17-55)</td>
</tr>
<tr>
<td>NYHA functional class on discharge from hospital, No.</td>
<td>II 24</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>III 23</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>IV 2</td>
<td>4</td>
</tr>
<tr>
<td>Concomitant disease, No.</td>
<td></td>
<td></td>
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<tr>
<td>Ischemic heart disease</td>
<td>35</td>
<td>30</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>20</td>
<td>21</td>
</tr>
<tr>
<td>Chronic airway limitation</td>
<td>21</td>
<td>14</td>
</tr>
</tbody>
</table>

*Continuous values are represented as mean ± 1 SD. No significant differences between groups were detected for all baseline clinical and demographic variables. HBI indicates home-based intervention; UC, usual care; ACE, angiotensin-converting enzyme; and NYHA, New York Heart Association.

(1) previous admission(s) for acute heart failure, (2) number of days of unplanned hospitalization in the 6 months before study follow-up, (3) plasma albumin concentration on hospital discharge, (4) New York Heart Association class on hospital discharge, and (5) study group. Of these variables, greater hospital use in the 6 months before study follow-up proved to be the only independent, positive correlate of unplanned readmission within 18 months of index hospitalization (Table 2). Similarly, the following variables were examined as potential correlates of mortality: (1) duration of treatment for CHF, (2) number of admissions for acute heart failure, (3) number of days of unplanned hospitalization in the 6 months before study follow-up, (4) LVEF, (5) New York Heart Association class on hospital discharge, (6) English-speaking vs non–English-speaking background, and (7) study group. Of these variables, greater hospital use in the 6 months before study follow-up, a non–English-speaking background, and lower LVEF were independent, positive correlates of 18-month mortality; conversely, assignment to HBI was a negative correlate (Table 3).
whether this was mediated via a sustained reduction in mortality among HBI patients was large (approximately 50%). In our original analysis, out-of-hospital death was included in the primary end point to partially adjust for the overall costs for their respective groups.

Although the difference in group mortality rates just reached statistical significance, the magnitude of the apparent reduction in mortality among HBI patients was large (approximately 50%). In our original analysis, out-of-hospital death was included in the primary end point to partially adjust for the fact that patients would no longer require hospital admission. However, the frequency of out-of-hospital death alone has proved to be far greater than expected, with significantly more of these events occurring among UC patients, both at 6 months in the original heterogeneous cohort of hospitalized patients and at 18 months among this subset of patients with CHF, proving to be the primary difference in both cases in regard to the reduced overall mortality among HBI patients. Such a proportional improvement in survival rates, if verified in larger studies, would be more than comparable with those reported in the original (and larger) angiotensin-converting enzyme inhibitor trials.5.5 The 18-month mortality rate among the UC group in this study was somewhat greater than that reported in more recent clinical trials that have included carefully selected patients with heart failure receiving angiotensin-converting enzyme inhibitors as standard therapy and generally lower LVEFs.30,31 However, the survival profile of UC patients in the current study, at both 6 and 18 months, is comparable with that reported at 6 and 12 months among similar cohorts of hospitalized patients with CHF included in 3 recently reported studies.22,26,32 Furthermore, multivariate analysis demonstrated that the improved survival rate associated with the HBI was independent of other “expected” determinants of mortality, including lower LVEF and a history of prolonged hospital stay.

Many forms of therapeutic intervention have been shown to be highly effective for a short period, but to have no significant beneficial impact beyond the first few days or weeks after withdrawal of the therapeutic agent.33,34 How and why is it possible for a single posthospitalization intervention to continue to exert a beneficial effect on readmissions and mortality for at least 18 months after implementation? On the basis of a preliminary study,35 we anticipated that an early posthospitalization HBI would not only be beneficial in detecting clinical deterioration likely to lead to short-term hospital readmission(s), but detect hitherto unknown problems likely to contribute to poorer longer-term outcomes. Although we have no direct evidence of mechanisms of beneficial effect of the current HBI, the magnitude of prob-

### Table 2. Correlates of Unplanned Readmission During 18-Month Follow-up

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unplanned Readmission</th>
<th>P</th>
<th>Univariate Analysis</th>
<th>Multivariate Analysis</th>
<th>Adjusted OR (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No (n = 28)</td>
<td>Yes (n = 69)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unplanned hospitalization 6 mo before study follow-up, mean ± SD, d</td>
<td>6.8 ± 6.6</td>
<td>12.5 ± 8.8</td>
<td>.002</td>
<td>.006</td>
<td>5.4† (1.1-11.3)</td>
</tr>
<tr>
<td>Assignment to home-based intervention, No. (%)</td>
<td>18 (64)</td>
<td>31 (45)</td>
<td>.08</td>
<td>.09</td>
<td>0.5 (0.2-1.2)</td>
</tr>
</tbody>
</table>

* OR indicates odds ratio; CI, confidence interval.
†Adjusted OR for ≥14 days of unplanned hospitalization.

### Table 3. Correlates of Mortality During 18-Month Follow-up

<table>
<thead>
<tr>
<th>Variable</th>
<th>18-mo Mortality</th>
<th>P</th>
<th>Univariate Analysis</th>
<th>Multivariate Analysis</th>
<th>Adjusted OR (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No (n = 66)</td>
<td>Yes (n = 31)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-English-speaking background, No. (%)</td>
<td>9 (14)</td>
<td>12 (39)</td>
<td>.005</td>
<td>.008</td>
<td>4.9 (1.5-15.4)</td>
</tr>
<tr>
<td>Unplanned hospitalization 6 mo before study follow-up, mean ± SD, d</td>
<td>9.3 ± 7.4</td>
<td>14.4 ± 10.1</td>
<td>.02</td>
<td>.008</td>
<td>4.9† (1.6-15.2)</td>
</tr>
<tr>
<td>Assignment to home-based intervention, No. (%)</td>
<td>38 (58)</td>
<td>11 (35)</td>
<td>.049</td>
<td>.02</td>
<td>0.3 (0.1-0.82)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction mean ± SD, %</td>
<td>40.5 ± 10.7</td>
<td>34.9 ± 10.9</td>
<td>.02</td>
<td>.03</td>
<td>3.0† (1.1-8.6)</td>
</tr>
</tbody>
</table>

* OR indicates odds ratio; CI, confidence interval.
†Adjusted OR for ≥14 days of unplanned hospitalization.
‡Adjusted OR for left ventricular ejection fraction of =40%. 

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lems detected during home visits requiring remedial action, many of which have been identified previously as contributing to unplanned hospitalization (noncompliance with and/or adverse effects of treatment regimen, early clinical deterioration, and suboptimal use of medical care, especially among non–English-speaking patients), is consistent with 2 previous reports on the mechanisms of beneficial effect of interventions that involve a home visit. 18,36 As regards improved survival, it is possible that a combination of increased vigilance of caregivers, improved compliance, and increased awareness of the therapeutic goals of treatment and better use of available medical care among HBI patients led to a reduced incidence of acute deterioration and death before hospital care could be accessed. However, the precise mechanism(s) of beneficial effect of the HBI in this regard is unlikely to be elucidated.

The fact that we are unable to propose the exact mechanism(s) of beneficial effect of HBI underlines some of the limitations of both the original and extended analyses of this cohort of patients with CHF, although this problem is common to other interventions incorporating a multifaceted approach. 23,36 This study represents a subanalysis of the outcomes of a limited number of patients with CHF, and we have no data regarding functional status and quality of life among surviving patients. Possible refinements of this intervention would include (1) more specific components of education in regard to optimal diet, fluid management, and exercise for patients with CHF; (2) prospective identification of the subset of patients at risk of recurrent admissions; and (3) repeated HBI for those patients with recurrent readmissions despite initial intervention.

Nevertheless, this randomized controlled study (to our knowledge) represents the first report of a nonpharmacological intervention improving survival among hospitalized patients with CHF while significantly reducing hospital readmissions. If the efficacy of this relatively novel approach to treating patients with CHF is confirmed in a prospective randomized controlled trial, it would represent an attractive and relatively cheap means to both improve health outcomes among such patients and deliver significant cost savings.

Accepted for publication May 26, 1998.

Mr Stewart received a National Heart Foundation of Australia Postgraduate Medical Research Scholarship.

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REFERENCES