Home-Based Intervention in Congestive Heart Failure
Long-Term Implications on Readmission and Survival

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Background—It is not known to what extent initially observed benefits of postdischarge programs of care for patients with chronic congestive heart failure (CHF) in respect to event-free survival, readmissions, and healthcare costs persist in the long term.

Methods and Results—We prospectively studied the long-term effects of a multidisciplinary home-based intervention (HBI) in a cohort of CHF patients randomly allocated to either to HBI (n=149) or usual care (n=148). During a median of 4.2 years of follow-up, there were significantly fewer primary end points (unplanned readmission or death) in the HBI versus usual care group: a mean of 0.21 versus 0.37 primary events per patient per month ($P<0.01$). Median event-free survival was more prolonged in the HBI than usual care group (7 versus 3 months; $P<0.01$). Fewer HBI patients died (56% versus 65%; $P=0.06$) and had more prolonged survival (a median of 40 versus 22 months; $P<0.05$) compared with usual care. Assignment to HBI was both an independent predictor of event-free survival (RR 0.70; $P<0.01$) and survival alone (RR 0.72; $P<0.05$). Overall, HBI patients had 78 fewer unplanned readmissions compared with usual care (0.17 versus 0.29 readmissions per patient per month; $P<0.05$). The median cost of these readmissions was $A325 versus $A660/month per HBI and usual care patient ($P<0.01$).

Conclusions—The beneficial effects of HBI in reducing frequency of unplanned readmissions in CHF patients persist in the long term and are associated with prolongation of survival. **(*Circulation*. 2002;105:2861-2866.)**

Key Words: congestive heart failure ■ cardiovascular nursing ■ health policy ■ outcome research

Hospitalizations for chronic congestive heart failure (CHF) impose a considerable burden on the healthcare system.[1,2] In the UK, the proportion of healthcare funding directly attributable to CHF has almost doubled since 1990 to 2% of health expenditure in the year 2000.[3,4] As in other developed countries,[5,6] hospital activity represents the greatest component of cost.[3,4] Although some hospitalizations for CHF are central to its management, a large proportion are avoidable.[7] With an ageing population of CHF patients in whom hospital readmissions are becoming more frequent,[1,2] there is also an increasing economic imperative to limit hospital activity in favor of less expensive community-based care.[4,8]

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Patients with CHF tend to have extremely poor quality of life[9] and a prognostic outlook that is comparable to many forms of cancer.[10] Although a range of therapeutic strategies (eg, ACE inhibitors[11] and β-blockers[12]) have provided modest improvements in population survival,[13] it is often problematic to apply them in typically old and fragile patients.[14]

As such, there has been increasing interest in the role of multidisciplinary programs that optimize the management of CHF. Appropriately powered, randomized studies from a wide range of developed countries have shown that these programs are remarkably effective in reducing readmissions and improving quality of life in CHF patients predominantly in the 3- to 6-month period after acute hospitalization.[15–20]

However, the success of these programs, particularly in relation to any effect on survival, must be qualified on the basis of limited follow-up data beyond 1 year.[21] It remains possible that their therapeutic and overall cost benefit may be transient, especially as most programs primarily involve contact with patients in the immediate posthospitalization period.

This study is a prospective evaluation of the long-term effects of a postdischarge home-based, multidisciplinary intervention (HBI) on a primary end point of death or unplanned readmission in a cohort of typically older patients with CHF who participated in 2 previously reported randomized studies.[17,22,23] These studies examined the same end points and showed a similar effect of HBI on morbidity and mortality rates in the short- to medium-term.

Methods

Participants

As described previously,[17,23] we conducted 2 randomized studies of HBI in Adelaide, South Australia. Patients were recruited from the

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same tertiary referral center for the region with a specialist cardiology unit. The institution's Ethics of Human Research Committee approved both studies.

In both studies, all patients with an acute admission to the cardiology unit were systematically screened via a process of chart review and active consultation with admitting physicians. Initially, a total of 97 of 107 eligible (see below) patients with CHF (91%) were recruited over 18 months as part of a large randomized study (n=762) of chronically ill patients.[22] They were then subject to more intensive scrutiny to specifically examine the role of HBI in managing CHF.[17,21] Two years later, a subsequent study recruited 200 of 223 eligible CHF patients (90%) over 15 months.[23] All 297 of these patients signed a consent form and were randomly allocated using a blinded computerized protocol to either HBI (n=149) or to usual postdischarge care (n=148). The baseline characteristics of the 33 patients who did not participate were similar to the study cohort.

Inclusion Criteria

Identical inclusion/exclusion criteria were used to select patients. Inclusion criteria were as follows: age ≥55 years, discharge to home, and a diagnosis of CHF (as determined by a Cardiologist during the index admission) with a history of ≥1 admission for acute heart failure. Symptomatic CHF was defined as impaired left ventricular systolic function (left ventricular ejection fraction [LVEF] ≤55%) within 3 months of study entry and persistent functional impairment indicative of New York Heart Association (NYHA) Class II, III, or IV status. Acute heart failure was defined as pulmonary congestion/edema and acute dyspnea at rest. Specific exclusion criteria included presence of terminal malignancy or planned cardiac surgery.

Baseline Data

Patients were interviewed and their medical records reviewed before discharge to document baseline clinical, demographic, and psychosocial characteristics (see Table 1). The 2 study cohorts had similar baseline profiles.[17,23]

Patient Management

All patients were subject to preexisting levels of discharge planning at the time of recruitment. No restrictions were imposed on the extent and intensity of follow-up. Most patients had an appointment with their primary care physician and the cardiology outpatient clinic within 14 days of discharge. All patients were subject to regular outpatient-based review by a cardiologist at the hospital and attended the same primary care clinics.

Study Intervention

In both studies, patients assigned to HBI, while receiving the same level of care as those assigned to "usual care," received a structured home visit within 7 to 14 days of discharge. In the original study, this was undertaken by a nurse and pharmacist in order to provide expertise relevant to a wide range of disease states. In the subsequent study, a qualified cardiac nurse undertook the home visit. In the first study only, patients received additional education about their condition and treatment (this had a minimal effect on subsequent outcomes[22]), and in the second study only, a small number of patients received repeat home visits.

The fundamental aim of HBI is to optimize the management of the patient's chronic disease state(s) and to facilitate the rapid recognition and treatment of potential problems. In both studies, the principles of assessment and intervention were the same. Initial assessment included a physical examination and a review of the patient's adherence to, and knowledge of, prescribed treatment and their social support system, in addition to identification of any other factors likely to increase the probability of readmission or death. A report (with recommendations) was sent to the patient's treating physicians and a combination of short- and long-term strategies applied. The nurse played a pivotal role in both studies by coordinating efforts to optimize the patient's management and providing a critical link to the appropriate health care if problems arose.

TABLE 1. Baseline Clinical and Demographic Characteristics

	Study Intervention (n=149)	Usual Care (n=148)
Demographic profile		
Male	84 (56%)	83 (56%)
Mean age in years	75 (9)	75 (8)
Live alone	54 (36%)	61 (41%)
Non-English speaking	44 (30%)	42 (28%)
Heart failure profile		
Previous admission for heart failure	94 (63%)	82 (55%)
Mean LVEF	38 (11)	38 (10)
Comorbidity		
Past myocardial infarction	82 (55%)	74 (50%)
Chronic airways disease	48 (32%)	59 (40%)
Chronic hypertension	86 (58%)	85 (57%)
Non-insulin/insulin–dependent diabetes	46 (31%)	39 (26%)
Mean Charlson Index of comorbidity score	2.9 (1.4)	2.8 (1.4)
Index admission profile		
Median duration of index admission in days	5 (3, 9)	5 (3, 9)
Acute pulmonary edema	78 (52%)	83 (56%)
Atrial fibrillation	46 (31%)	50 (34%)
Pharmacotherapy at hospital discharge		
Mean no. of prescribed medications	7.3 (2.3)	7.2 (2.2)
Diuretic	141 (95%)	146 (99%)
ACE inhibitor	113 (76%)	108 (73%)
Digoxin	103 (69%)	93 (63%)
β-Adrenoceptor antagonist	35 (24%)	28 (19%)
Blood profile at hospital discharge		
Sodium, mmol/L	138 (3.8)	138 (3.5)
Potassium	4.1 (0.5)	4.1 (0.5)
Creatinine, mmol/l	155 (8)	143 (7)
Albumin, g/L	38.8 (3.9)	38.2 (4.3)
Haemodynamic status at hospital discharge		
Heart rate, beats/min	77 (11)	78 (15)
Systolic/diastolic blood pressure, mm Hg	123 (21)/66 (10)	121 (19)/67 (12)
Sinus rhythm	97 (65%)	104 (70%)
Left bundle branch block	48 (32%)	31 (21%)
Status at hospital discharge		
Dry weight, kg	71 (14)	69 (16)
Dependent for≥1 activity of daily living	72 (48%)	73 (49%)
NYHA Class II:III:IV (%)	47:45:8	44:45:11

Values are mean (±SD) or median (interquartile range [IQR]).

Study Follow-Up

All inpatient and outpatient hospital activity were monitored through the institution's computerized medical records system, individual case records, and contact with primary care physicians to determine the status of surviving patients. Official records of the time and location of all deaths in the region were used to compile mortality data. With no loss to follow-up, these 297 patients were studied for a median of 4.2 years (IQR 3.4 to 5.0) after discharge (range 3 to 6 years).

Study Hypothesis

We tested the null hypotheses that there would be no difference in the frequency of unplanned readmission plus all-cause out-of-hospital death (primary end point), event-free survival, and all-cause mortality, over a minimum period of 3 years, on the basis of exposure/nonexposure to HBI incremental to usual care.

Cost of Health Care

We also calculated the cost of hospital and community-based health care for each patient. As the period of costing activity spanned 6 years (1995 to 2001), all costs have been standardized (adjusting for inflation) for the last financial year of the study (2000/2001) and are expressed in Australian dollars ($A).

The cost of applying HBI was determined from original data and includes the additional cost of primary care, cardiology, and pharmacist consultations prompted by the HBI. Similarly, the cost of hospital activity was calculated using the institution's inpatient and outpatient costing system, which is based on coding of admissions using the WHO International Classification of Disease system[24] and subsequent reimbursement of hospital activity based on Diagnostic Related Groupings.[25]

Statistical Analysis

Based on an 80% event rate over 3 years, this study was powered to detect a 12% variance in the primary end point and, based on an event rate of 60% within 3 years, a 16% variance in all-cause mortality according to study assignment when assuming a 2-side α of 0.05 and a β of 0.2.

Comparison of baseline and end point data involved χ^2 analysis (with calculation of odds ratio [OR] and 95% confidence intervals [CI] where appropriate) for discrete variables, Student's t test for normally distributed continuous variables, and Mann-Whitney test for non-normally distributed variables. To adjust for differences in survival and duration of follow-up, event frequency was calculated as a mean number of events per patient per month.

Kaplan-Meier survival curves were constructed using time-dependent, all-cause survival and event-free survival data followed by analysis with both the log-rank test and the Breslow test to determine any differences in the number and/or timing of events. Data for all surviving patients were censored on August 31st, 2001.

To examine the independent effects of treatment mode and the 55 baseline variables measured on event-free survival and all-cause mortality, we used Cox-Proportional Hazards Models (with initial entry and step-wise rejection of baseline variables at the 0.1 and 0.05 levels of significance, respectively). All analyses were performed on an intention-to-treat basis according to study group assignment using SPSS for Windows (10.0).

Results

Baseline Characteristics

Table 1 shows the pooled comparison of the baseline characteristics of patients randomly allocated to usual care (n=148) or HBI (n=149). The groups were well matched for all but 3 parameters: HBI patients being more likely at the time of recruitment to have a prior acute myocardial infarction (AMI), left bundle branch block, and a higher blood urea concentration.

The majority of patients were aged >65 years (75%), had moderate to severe systolic dysfunction (75% with a LVEF of <45%), and at least one other chronic disease state other than hypertension and coronary heart disease (86%). Although only 161 (54%) of the index admissions were for acute heart failure, all 297 patients had such an admission in the 2 years before randomization. A majority of patients were prescribed a pharmacological regimen appropriate to contemporary guidelines.

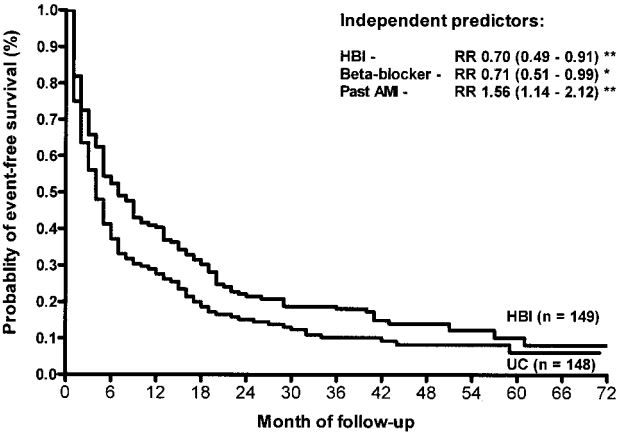

Figure 1. Cumulative probability of event-free survival during study follow-up. Level of significance: *$P<0.05$; **$P<0.01$. Relative risk (RR) plus 95% CI for independent predictors.

Frequency of the Primary End Point

During study follow-up, a total of 130 (87%) HBI and 135 (91%) usual care patients had either an unplanned readmission or out-of-hospital death. The combined total of these primary end-points was 959 (434 versus 525 in the HBI and usual care groups). Adjusting for duration of follow-up and survival, this equated to a mean of 0.21 versus 0.37 primary events per patient per month of follow-up ($P<0.01$).

Event-Free Survival

Figure 1 shows the event-free survival curves for both groups. Assignment to HBI was associated with both significantly prolonged event-free survival ($P<0.01$) and an increased probability of remaining event-free ($P<0.05$) relative to usual care. Median event-free survival in the HBI group was 7 (IQR 2 to 21) versus 3 months (IQR 1 to 15) in the usual care group. The 12% absolute difference in favor of HBI at 1 year (41% versus 29% event-free survival) was largely maintained at 3 years (20% versus 10%) but was attenuated thereafter. During entire follow-up, patients assigned to HBI remained event-free for 2299 of a possible 7865 months (29%); the equivalent figure for those assigned to usual care was 1625 of 7700 months (21%). On an adjusted basis, HBI was associated with an additional 674 months of event-free survival (4.6 month per patient).

Assignment to HBI was independently associated with a 30% reduced risk of death or readmission during follow-up ($P<0.01$), whereas prescription of a β-blocker at baseline was associated with a similarly reduced risk, and prior AMI was associated with an increased risk (see Figure 1). Other baseline variables not retained in the multivariate model were serum sodium and urea concentration, white cell count, Charlson Index of Comorbidity,[26] and LVEF.

All-Cause Mortality

A total of 83 (56%) patients assigned to HBI compared with 96 (65%) usual care patients died. Figure 2 shows the survival curves for both groups. Assignment to HBI was associated with strong trends in respect to prolonged survival ($P=0.056$) and reduced risk of death ($P=0.058$) relative to usual care.

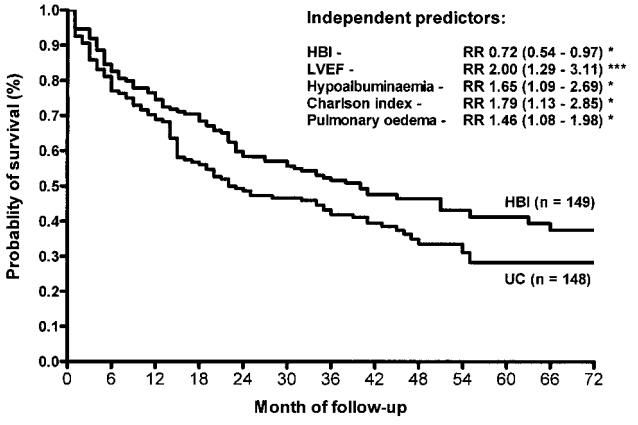

Figure 2. Cumulative probability of survival during study follow-up. Level of significance: *$P<0.05$; ***$P<0.001$. RR plus 95% CI for continuous values calculated for bottom vs top quartiles: LVEF (<30% vs >46%) and albumin concentration (<36 vs >41 g/L).

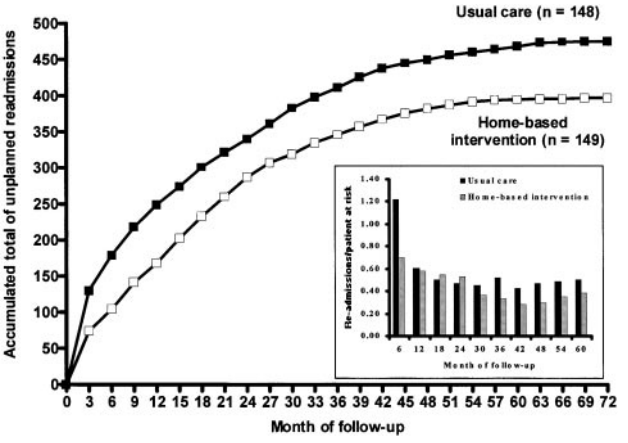

Figure 3. Accumulative total and rate of unplanned readmission per patient during study follow-up.

Median survival in the HBI group was 40 (IQR 26 to 54) versus 22 months (IQR 11 to 33) in the usual care group. At 6 months, the completion of active intervention, the absolute survival benefit in favor of HBI was 4% (18% versus 22% mortality). At 3 years, this benefit had increased to 11% (46% versus 57% mortality) and appeared to persist in the long term. Overall, patients assigned to HBI survived a total of 4906 of a possible 7865 months (62%). The equivalent figure for those assigned to usual care being 4092 of 7700 months (53%). On an adjusted basis, HBI was associated with an additional 817 months of survival (5.5 months per patient).

Assignment to HBI was independently associated with a 28% reduction in the risk of all-cause death during this period ($P<0.05$), whereas LVEF, albumin concentration, extent of comorbidity as measured by the Charlson Index,[27] and acute pulmonary edema at baseline were also independently associated with all-cause death (see Figure 2). Other baseline variables not retained in the multivariate model were serum creatine and urea concentration and prescription of amiodarone.

Hospital Activity

Despite more prolonged survival, fewer patients assigned to HBI had an unplanned readmission (75% versus 80%; P=NS). Overall, HBI patients accumulated 16% fewer unplanned readmissions (396 versus 475) and had a lower rate unplanned readmission compared with usual care: a mean of 0.17 versus 0.29 readmissions per patient per month ($P<0.05$). Figure 3 shows that the absolute difference of 77 readmissions in favor of HBI at 9 months after discharge (36% fewer) persisted in the long term. It also shows that although the greatest difference in this parameter occurred in the first 6 months (0.70 versus 1.22 admissions per patient in favor of HBI; $P<0.001$), the greater number of surviving patients in the HBI group had equivalent rates of readmission in the 6- to 24-month period after discharge and had significantly ($P<0.05$) lower rates of readmission thereafter.

The duration of readmissions in the HBI group were generally shorter than for usual care (mean length of stay 8.2 versus 8.8 days; P=NS). Patients assigned to HBI had a total of 3123 days (median of 14 days per patient) of unplanned readmission versus 4126 days (17 days per patient) in the usual care group. This equates to an absolute difference of 1003 days (24% less) in favor of HBI. The rate of hospital stay in the HBI group was significantly less in comparison to the usual care group: a mean of 1.2 versus 2.3 days per patient per month ($P<0.001$). Patients in the HBI group, however, had more elective admissions than the usual care group (99 versus 61; P=NS). The total number of associated days of admission being 213 versus 115 days (P=NS).

Healthcare Costs

The usual care group were also more likely to be admitted to more expensive hospital units (eg, intensive care). The mean per diem cost of hospitalization in the usual care group was, therefore, higher than the HBI group ($A711 versus $A595). The median cost of this hospital activity was $A325 (IQR 21 to 831) versus $A660 (IQR 74 to 1987) per month per patient in the HBI and usual care groups, respectively ($P<0.01$). Subsequently, the total cost of unplanned readmissions in the HBI group was $A1.07 million less ($A1.86 versus $A2.93 million). Alternatively, the total cost of elective admissions was marginally greater in the HBI group ($A68 672 versus $A46 561; P=NS).

Initially, patients in the HBI group, due to a greater rate of referral to address newly identified problems, accumulated more hospital outpatient clinic visits (for any reason). Thereafter, patients in the usual care group had more clinic visits because of the greater number of hospitalizations in the long term; each admission typically attracts a “cluster” of visits as part of routine postdischarge care. On average, patients assigned to HBI had a total of 4.3 outpatient visits per hospitalization (a total of 1707 visits) versus 4.2 visits in the usual care group (1948 visits). The total cost of these clinic visits was $A165 579 versus $A241 552 for the HBI and usual care groups, respectively. The average cost of applying the HBI, taking into account both the cost of home visits and additional cardiology, primary care, and pharmacy consultations, was $A600/patient.

TABLE 2. Summary of Primary/Secondary End Points According to Study Assignment

	First Study (n=97) (Median Follow-Up 5.9 yrs)		Second Study (n=200) (Median Follow-Up 3.8 yrs)		Combined (n=297) (Median Follow-Up 4.2 yrs)	
End Point	Usual Care (n=48)	HBI (n=49)	Usual Care (n=100)	HBI (n=100)	Usual Care (n=148)	HBI (n=149)
Mean no. of primary events per patient per month	0.34	0.20	0.39	0.22*	0.37	0.21†
Mean event-free survival, mo	12	16	11	15*	11	15*
Median survival, mo	21	41	25	37	22	40*

*$P<0.05$ and †$P<0.01$ for the comparison between groups.

Summary of Study End Points

Table 2 summarizes the primary and 2 major secondary end points according to study assignment and cohort. Importantly, the number and pattern of end points, both in the short and long term, were similar in the equivalent cohorts in the 2 studies.

Discussion

This unique study has shown that the short- to medium-term benefits of a postdischarge HBI, in respect to prolonged event-free survival, reduced hospital use, and associated costs,[17,23] are largely sustained over the long term. Although our original data of the beneficial effects of HBI within 6 to 18 months of hospital discharge[17,21] are consistent with those from the USA[15,20] and Europe,[16,19] there is a paucity of data to show that these effects persist in the long term. Not surprisingly, considering the natural history of CHF,[1,2,10] the majority of patients assigned to HBI were readmitted or died during extended follow-up. Compared with the usual care group, however, patients exposed to HBI not only had more prolonged event-free survival but also, when adjusting for all other variables, were 30% less likely to experience such an event. Overall, HBI patients accumulated 78 fewer unplanned readmissions and 1000 fewer days of associated hospital stay—an approximate 25% reduction relative to usual care. With an associated cost difference of $A1.1 million, this represented nominal savings of $A7000 per HBI patient; the cost of initially applying HBI being less than 10% of this figure.

These data have a number of implications that require comment. This is the first study to provide strong evidence that this type of program can improve survival in the long term (a 10% difference in favor of HBI). Although other studies of this type have suggested survival benefits, they have been underpowered and too short in duration to demonstrate such an effect. Any change in survival secondary to the application of a new treatment strategy has important implications for long-term healthcare costs. For example, the greater number of surviving patients in the HBI group may have accumulated more costly hospitalizations in the long term, thereby negating initially observed cost-benefits. This was not the case, however. Although HBI had its greatest effect in the first 9 months of follow-up, surviving patients had equivalent-to-lower rates of readmission in the medium-to-long term compared with usual care. Furthermore, although a transient HBI does not appear to totally "immunize" patients against readmission, it is likely that repeat home visits will confer additional benefits in the long term.

Given that this was a "short-term" intervention, why was it associated with prolonged beneficial effects? We have speculated that identifying inherently high-risk individuals (especially those with early clinical deterioration[27]) and addressing external factors that place them at greater risk for subsequent morbidity and mortality will confer long-term beneficial effects. Moreover, it would not be unreasonable to expect a synergistic and prolonged effect between the strategies implemented in the short term as part of HBI and the application of an optimal pharmacological regimen, particularly one that promotes greater adherence/vigilance and informed medical care.

If our findings are correct, how widely applicable are they? This cohort is very representative of the overall CHF population. We have recently shown[28] that event rates in this cohort are similar to those observed in the USA[15] and the UK,[19] and the mortality rate in the usual care group is consistent with recent reports from other developed countries.[10]

This study does have limitations that require comment. First, these data are derived from a conglomerate cohort. However, apart from the close similarities in study methods, event rates were similar in the 2 cohorts based on study assignment (see Table 2). Second, when examining the determinants of study end points, we did not take into account changes in a potentially important confounder: pharmacological therapy. Third, when calculating healthcare costs, community-based costs were not measured over the long term. We did, however, collect data on the costliest component of CHF-related health care: hospital activity.[3,4] Finally, we relied on hospital records rather than a specific "End-Point Committee" to compile outcome data.

In conclusion, we have previously shown that HBI prolongs event-free survival and minimizes costly readmissions in the short-to-medium term.[17,21–23] Using a unique opportunity to study its effects on a large patient cohort over a much longer period, we now report that these beneficial effects are sustained in the long term. Not only is HBI associated with prolonged event-free survival and survival alone, but also reduced levels of hospital activity and associated costs. Overall, these data suggest that HBI represents an extremely cost-effective option to improve health outcomes in CHF.

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