Evaluation of a Home-Based Intervention in Heart Failure Patients. Results of a Randomized Study

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Introduction and objectives. Home-based interventions after hospital discharge in patients with heart failure (HF) have been shown to decrease readmission and mortality rates. The primary aim of this study was to determine the effect of a home-based educational intervention carried out by nursing staff on the readmission rate, emergency department visits, and healthcare costs.

Patients and method. Patients hospitalized with systolic HF were randomly assigned to receive either usual care or a single home-based educational intervention 1 week after discharge.

Results. Between July 2001 and November 2002, 70 patients entered the study: 34 in the intervention group and 36 in the control group. During the 6-month follow-up, there were fewer unplanned readmissions in the intervention group than in the control group (0.09 vs 0.94; *P*<.001), fewer emergency department visits (0.21 vs 1.33; *P*<.001), and fewer out-of-hospital deaths (2 vs 11; *P*<.01). Costs were also significantly lower in the intervention group (difference, €1190.9; *P*<.001). Moreover, patient-perceived health status, as indicated by scores on a quality-of-life questionnaire, increased significantly in the intervention group.

Conclusions. In a cohort of patients with systolic HF who received a home-based educational intervention there were significant reductions in the unplanned readmission rate, mortality, and healthcare costs, and better quality of life. Some limitations of the study warrant validation of the resultats in further studies.

Key words: *Heart failure. Cost-benefit analysis. Prognosis.*

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Evaluación de una intervención domiciliaria en pacientes con insuficiencia cardíaca. Resultados de un estudio aleatorizado

Introducción y objetivos. Conocida la eficacia de los programas domiciliarios para pacientes con insuficiencia cardíaca (IC), nos hemos propuesto evaluar las diferencias en los ingresos hospitalarios, las visitas al servicio de urgencias, los costes económicos y la calidad de vida tras una intervención educativa en el domicilio una semana después del alta, realizada por personal de enfermería.

Pacientes y método. Los pacientes ingresados por IC sistólica en los servicios de cardiología y medicina interna fueron distribuidos, mediante tabla de números aleatorios, en un grupo que recibió intervención educativa y otro grupo control que fue atendido de forma convencional.

Resultados. Desde julio de 2001 hasta noviembre de 2002 se distribuyó a 70 pacientes en los 2 grupos**.** A los 6 meses de seguimiento, el grupo de 34 pacientes que recibió la intervención educativa, comparado con el grupo de 36 pacientes que no la recibió, tuvo en promedio menos visitas a urgencias (0,21 frente a 1,33; p < 0,001), menos ingresos hospitalarios (0,09 frente a 0,94; p < 0,001) y con un menor coste por individuo (diferencia ajustada: 1.190,9 €; p < 0,001). La salud percibida mejoró de forma significativa en el grupo de intervención. También se observó una disminución significativa de la mortalidad (2 frente a 11; p < 0,01).

Conclusiones. Los pacientes con IC sistólica que han recibido una intervención educativa domiciliaria tienen una significativa menor tasa de reingresos, mortalidad y coste, con una mejor calidad de vida. Algunas limitaciones del estudio hacen recomendable la replicación de las observaciones.

Palabras clave: *Insuficiencia cardíaca. Análisis coste-beneficio. Pronóstico.*

ABBREVIATIONS

LVEF: left ventricular ejection fraction.
HF: heart failure.
NYHA: New York Heart Association.

INTRODUCTION

Heart failure (HF) is the main cause of hospitalization in Spain in persons 65 years or older, although more than half these admissions can theoretically be avoided.[1] Annual mortality is 50% in the most advanced cases[2] and 6% of the overall mortality in Spain is attributed to this cause.[3,4] With the progressive aging of the population, the magnitude of the problem is increasing.[5]

The primary cause of cardiac decompensation is poor compliance with treatment (failure to take medication or follow hygienic and dietary measures), which occurs in 15%-65% of cases.[6] The reasons for poor compliance usually reported include lack of knowledge or motivation, poor perception of the efficacy of the treatment, lack of support from family and caregivers, an increased number of drugs or high doses, and cognitive deterioration or depression.[7]

In studies performed in other countries, interventions by multidisciplinary teams at the patient's home that focus on health education and early detection of decompensation have reduced the use of health resources and improved the patients' quality of life and their satisfaction with the attention received.[8-12] The existing differences among the various health care settings have prompted us to design a study to assess the reproducibility of these observations in our situation.[9] Specifically, this study assesses the efficacy of a home-based educational program linked to hospital discharge among patients with heart failure.

PATIENTS AND METHODS

Design

A randomized clinical trial was performed including patients consecutively admitted to the internal medicine and cardiology departments of our center (400-bed urban teaching hospital covering all the medical and surgical specialties and postgraduate teaching tasks) for acute heart failure (HF) according to the Framingham criteria. All patients met both of the following criteria: *a)* New York Heart Association (NYHA) functional class II to IV prior to the acute exacerbation leading to hospital admission, *b)* left ventricular ejection fraction (LVEF) <45% on echocardiography performed during hospitalization or the 6 previous months and willingness to participate in the study. The exclusion criteria were acute coronary syndrome within the previous 8 weeks, active treatment with dobutamine, neoplastic disease, or dementia. Patients residing outside of the city or in a home for the elderly, and those who could not be contacted by telephone were also excluded. The study was approved by the Ethics and Clinical Research Commission of the center and all patients gave informed written consent to participate. The specifications of the CONSORT[13] agreement were adopted during follow-up of the trial.

The clinical and sociodemographic variables (baseline) were measured before randomization for the study. Patients were assigned to the groups (control and intervention) before hospital discharge using a random numbers table.

Within the first month after discharge, patients assigned to the intervention group received a nurse's visit at their home. During this single visit, which lasted approximately two hours, the nurse investigated the patient's habits and established the priority of behavior susceptible to modification for the design and application of the educational plan.[14] By means of a well-established procedure and with the aid of educational guidelines[15] the patient and his/her caregiver were instructed in relevant aspects of the disease and essential points regarding self-management (Table 1).

The control group did not receive a nurse's visit. Apart from this fact, both groups received identical conventional care based on the best available evidence and all patients underwent outpatient follow-up as

TABLE 1. **Description of the Educational Intervention**

The nursing personnel carried out a sequential intervention in the patient's home centered on the following elements:
1. Self-management: knowledge of the benefits and side effects of the various drugs and adequate compliance with treatment. To facilitate this purpose, patients were given a compartmentalized pillbox with capacity for 1 week of drugs. The patient was informed of the factors that favor decompensation, the signs and symptoms once it is established and, if necessary, how to modify the dose of diuretics without waiting for a medical visit
2. Habits: special emphasis is placed on prudent fluid intake, salt-free diet, abstention from tobacco, and limited alcohol consumption
3. Preventive activities: except when contraindicated, flu and pneumococcal vaccinations are recommended. A plan is designed for therapy and physical activity, and lastly the patient's understanding of the information received is reviewed

No changes were made in the treatment proposed at hospital discharge. Once instruction had been completed, the nursing staff member compiled a short log of current symptoms and performed a cardiovascular physical examination

scheduled by their attending physicians.[16-18] The information usually given to patients was not modified during hospitalization or at the time of discharge in any case and always depended on the attending physician, who decided on the treatment and the date of discharge, and was not aware of the group to which the patient had been assigned.

Evaluation and Follow-up

Patient assessment and follow-up were done with the single-blinded technique. The physicians implicated in assessment and follow-up had no knowledge of the assigned group, in contrast to the patients and the person in charge of the statistical analysis.

All patients were assessed prospectively at 6 months by telephone contact with the patient or members of the family and by review of the clinical records.

Measurements

Sociodemographic variables were compiled in all patients (among them, social support: whether the patient lived alone, with the family, with a caregiver or in a home for the aged), clinical variables were collected (including associated diseases quantified by the Charlson index,[19] cognitive assessment with the Spanish version of Pfeiffer's Short Portable Mental Status Questionnaire[20] using the recommended cut-off point of 3 or more errors in literate persons and 4 or more errors in illiterate persons), and functional capacity was evaluated with the NYHA functional classification and the Barthel index.[21]

The primary endpoint was the use of the health services (number of hospitalizations and visits to the emergency room for HF) assessed at 6 months. We estimated the size of the sample as 35 persons per group to detect a difference ≥0.5 units in the mean number of hospitalizations, assuming a common standard deviation (SD) of 0.7 and accepting an alpha risk of .05 and a beta risk of .20 for the bilateral contrast, with an estimated loss during follow-up of 10%. The impact of the intervention on the patient's perception of health and the economic cost were secondary endpoints.

We assessed patient-perceived health before the intervention by a personal interview and at the end of follow-up by telephone, through administration of the SF-36 health questionnaire (version 1.4), a 36-question generic instrument. The physical and mental health summary scores run from 1 to 100 (worst to best health status, respectively).[22]

Calculation of Costs

The total economic cost for each patient was considered to be the sum of the expenditure for health care resources (visits to the emergency room, hospital admissions and home treatment) and the cost of the educational intervention in those receiving it. The mean cost of the educational intervention was €52.81, which included €45.81 for the 3 h that the nursing staff member spent in traveling to the patient's home and the visit, €3 for transportation cost and €4 for educational material (guidelines and daily pill box). The cost of an emergency room visit to our hospital in 2003 was €67.16, and the cost of a stay for HF was €1343.12 (including drug treatment). The mean cost of home treatment was estimated from the medication prescribed for each patient at €0.70 per day.

Statistical Analysis

Comparison between groups of the number of hospitalizations, emergency visits and costs was done with Student's *t* test for independent data. In addition, multivariate analysis was used to study the association between the intervention and the main outcome variables, allowing adjustment for the most marked covariables and confounders. For this purpose, the dependent variables (number of hospitalizations and number of emergency visits) were dichotomized, e.g. *no hospitalization* (*visit*) versus *any hospitalization* (*visit*). Logistic regression models were constructed for each one with *intervention* as the independent variable adjusted for LVEF, NYHA functional class, and a history of therapeutic noncompliance as the cause of admission at the time of selection.

The effect on perceived health was evaluated by comparison of means for paired data.

All analyses were performed using the statistical significance level considered for calculation of the sample size (α=.05) with SPSS for Windows (version 12.0).

RESULTS

From July 2001 to November 2002, 244 patients were admitted for HF. Among them, 174 were excluded on the basis of the inclusion and exclusion criteria. Among the total, 90% of the patients admitted to the Internal Medicine Department (80% for LVEF>45%) and 60% of those admitted to the Cardiology Department (30% for LVEF>45% and 20% for acute coronary syndrome) were excluded. Among the 70 patients included in the study, 34 were assigned to the intervention group and 36 to the control group. The 2 groups were comparable for clinical and sociodemographic characteristics and for baseline patient-perceived health (Tables 2 and 3).

At 6 months of follow-up, the educational intervention had resulted in a marked, statistically significant reduction in the number of emergency visits and hos-

pitalizations as compared to the control group (Table 4). The logistic regression models confirmed that the hospitalizations and emergency room visits were significantly higher in the group that had not received the educational intervention (Table 5). In the multivariate model therapeutic noncompliance as the cause of hospital admission was not related with any of the outcome variables. Although mortality was not included as an outcome measure in the study design, the analysis of differences for this factor showed lower mortality in the intervention group (2 patients as compared to 11 controls; $P< .05$).

In the assessment of impact on perceived health, 7 patients in the intervention group and 12 in the control group were lost to follow-up because of inability to respond to the questionnaire by telephone, death of the patient or refusal to answer. At 6 months, patient scores in the intervention group were significantly higher for the physical and mental health summary scales, whereas scores for the control patients remained stable (Table 6).

The total cost per person was €314.80±403.30 for the intervention group and €1505.60±1391.60 for the control group, with a statistically significant difference of €1190.90 ($P<.001$). There was almost no change in this figure after adjusting for differences in NYHA

TABLE 2. **Sociodemographic Variables, Comorbidity and Function***

	Intervention (n=34)	Control (n=36)	*P*
Age, years, mean ± SD	79.1±5.5	76.3±6.2	.052
Sex, n (%)			
Men	23 (64)	19 (56)	.626
Women	13 (36)	15 (44)	
Service, n (%)			
Cardiology	25 (69)	25 (73)	.794
Internal medicine	11 (30)	9 (27)	
Social support, n (%)			
Family	34 (94)	28 (82)	.158
Paid caregiver	1 (3)	1 (3)	
Alone	1 (3)	5 (15)	
Educational level, n (%)			
No education	0 (0)	0 (0)	.896
Primary school	7 (19)	6 (18)	
Secondary school	26 (72)	26 (76)	
University	3 (9)	2 (6)	
Marital status, n (%)			
Single	3 (9)	1 (3)	.598
Married	26 (72)	25 (74)	
Widowed	7 (19)	8 (23)	
Comorbidity, n (%)			
Hypertension	17 (47)	24 (70)	.932
Diabetes mellitus	12 (33)	17 (50)	
Hypercholesterolemia	12 (33)	13 (38)	
COPD	13 (36)	11 (32)	
Chronic renal failure	6 (18)	5 (15)	
Chronic liver disease	1 (3)	2 (6)	
Cerebrovascular accident	5 (14)	3 (9)	
Smoking	16 (44)	18 (54)	
Barthel index, n (%)			
100	29 (80)	27 (79)	.499
<80	4 (12)	4 (12)	
Pfeiffer score, n (%)			
0	26 (72)	31 (91)	.153
>3	2 (6)	2 (6)	
Hospitalizations in the last year, mean ± SD	0.9±0.7	1.1±1.1	.365

*SD indicates standard deviation; COPD, chronic obstructive pulmonary disease

TABLE 3. **Cardiological Variables***

	Intervention (n=34)	Control (n=36)	*P*
NYHA functional class, n (%)			
II	9 (26)	18 (50)	.06
III	18 (53)	6 (17)	
IV	7 (21)	12 (33)	
Left ventricular ejection fraction, mean ± SD	35.4±6.8	34.3±6.4	.498
Etiology, n (%)			
Hypertensive	6 (18)	7 (19)	.856
Ischemic heart disease	15 (44)	16 (48)	
Dilated cardiomyopathy	8 (24)	10 (28)	
Valvular	2 (6)	2 (6)	
Toxic	3 (9)	1 (3)	
Decompensation trigger, n (%)			
Infection	10 (29)	9 (27)	.555
Drugs	3 (9)	3 (9)	
Anemia	2 (6)	1 (3)	
Arrhythmia	6 (18)	9 (27)	
Hypertension	5 (15)	1 (3)	
Noncompliance with treatment	6 (18)	7 (19)	
Noncompliance with diet	2 (6)	6 (18)	
Electrocardiographic findings, n (%)			
Sinus rhythm	19 (56)	18 (54)	.715
Atrial fibrillation	11 (32)	14 (38)	
Pacemaker rhythm	4 (12)	4 (12)	
Treatment, n (%)			
Diuretics	34 (100)	32 (88)	.898
Spironolactone	12 (32)	11 (30)	
ACE-inhibitors	25 (73)	25 (69)	
ARA-II	2 (6)	2 (6)	
Beta-blockers	11 (32)	16 (48)	
Digoxin	12 (32)	12 (26)	
Calcium channel blockers	3 (9)	3 (9)	
Nitrates	7 (21)	7 (19)	
Amiodarone	4 (12)	5 (14)	
No. of drugs per patient, mean ± SD	6.6±1.6	6.7±2.6	.883

*ACE indicates angiotensin-converting enzyme; ARA-II, angiotensin II receptor antagonists; NYHA, New York Heart Association; SD, standard deviation.

TABLE 4. **Primary Endpoints at 6 Months' of Follow-up: Emergency Visits and Hospital Admissions***

	n	Emergency Room Visits			Hospital admissions		
		Total	Mean ± SD	*P*	Total	Mean ± SD	*P*
Intervention	34	7	0.21±0.41	<.001	3	0.09±0.29	<.001
Control	36	47	1.33±1.12		33	0.94±0.98	

*SD indicates standard deviation.

class in the multivariate analysis (coefficient β [intervention]=–€1185.20; *P*<.001).

DISCUSSION

By means of a simple educational intervention for patients with systolic HF, consisting in a single home visit by a nursing staff member one week after hospital discharge, with no subsequent visits or monitoring by telephone contact, a notable decrease in the mean number of hospitalizations (90.6%) and emergency room visits (84.2%) was observed per patient as well as a decrease in associated costs and an improvement in patient-perceived health.

It is known that the main causes of destabilization in these patients are respiratory infection and arrhythmia,[7,23] followed by pharmacological and dietary noncompliance, which, in our patients resulted in 30% of the admissions. This figure is not surprising after observing that only 47% of our patients adhered to the therapy at home, a percentage even lower than the 65% reported by Rich et al.[10] This elevated noncompliance with diet and treatment regimens may be one of the main reasons why such a simple home-based intervention achieved better results than interventions performed during hospitalization. Koelling et al[24] observed a 51% decrease in hospitalizations for HF in the 6 months following a single educational intervention just before discharge. We believe that the higher decrease in events observed in this study is mainly due to the fact that the intervention was performed in the patient's home, which not only provided the opportunity for education, but also for detecting lack of compliance with the treatment prescribed, thereby optimizing this factor. Moreover, since the intervention took place during the first week after hospital discharge, it was possible to detect early decompensation, which occurs in up to 40% of patients at 7-14 days after leaving the hospital.[10] This would make possible faster medical assessment, which could prevent progressive clinical deterioration leading to subsequent hospitalization. This factor might explain the differing results of the home-based intervention reported by Kimmelstiel et al,[25] with only a 52% decrease in rehospitalizations in the following 3 months. In that study the intervention was performed in various clinical settings during outpatient follow-up, not during the immediate post-discharge period.

Rich et al[10] were the first to demonstrate a decrease in hospitalizations with this type of intervention, which reached 56% during 3 months in their study. Their program was applied in an elderly population with a predominance of hypertension and little use of angiotensin-converting enzyme (ACE) inhibitors, despite their demonstrated efficacy.[26] This fact could explain the differences in the results from our study, since at the time of discharge 77% of our patients were taking ACE inhibitors or angiotensin II receptor antagonists, and 40% beta-blockers, and compliance with these drugs was reinforced in the group receiving the intervention.

Our results were more favorable than those observed in other studies on educational programs in HF, possibly because our study targeted a high-risk population consisting of elderly, recently hospitalized pa-

TABLE 5. **Effect of the Educational Intervention on the Outcome Variables: Logistic Regression Models With Dependent Variables***

	Emergency Room Visits		Hospital Admittances	
	Odds ratio	*P*	Odds ratio	*P*
Intervention	0.10	<.001	0.10	<.001
Therapeutic noncompliance†	0.44	.34	0.30	.20
NYHA II	9.35	.07	7.61	.07
NYHA IV‡	5.67	.15	26.35	.05
LVEF	1.03	.96	0.57	.45

*LVEF indicates left ventricular ejection fraction; NYHA, New York Heart Association.
†Therapeutic noncompliance as the cause of hospital admission.
‡NYHA functional class. Reference category: NYHA II or IV.

TABLE 6. **Measurement of Perceived Health (SF-36): Baseline and at 6 Months**

	n	Physical Health Summary			Mental Health Summary		
		Baseline	Final	*P*	Baseline	Final	*P*
Intervention	27	37.00	50.2	<.01	35.73	52.13	<.01
Control	24	38.74	37.75	.712	37.27	30.98	.120

tients, among whom 74% received the intervention in NYHA functional class III and IV. Given that other interventions in low-risk patients have not yielded benefits,[27] we believe that these high-risk patients with poor functional class may benefit the most from this type of intervention.

Our results support those obtained in other studies on educational programs in HF, with reductions of up to 87% in hospitalizations[28] and 67% in emergency room visits, as well as improvements in survival.[29] In the previous year, the mean number of hospitalizations was one per year, a higher rate than in other studies,[23,28] possibly due to the lower LVEF in our sample. Evolution in patients in the control group was similar to that of the HF population,[6] with a mean of 0.9 admissions and 33% mortality in the following 6 months. Since the prognosis in these patients was similar to that of the HF population, it is improbable that there were any deficits in their health care that would be counterbalanced by the intervention and thus explain the magnitude of the differences detected. The home-based intervention used in our program had a cost per unit of €52.81, a lower figure than that described by Stewart et al[9] ($350) or Rich et al[10] ($216), but similar to that reported by Koelling et al[24] ($100). This cost is compensated by a saving of €1190.90 per patient, mainly derived from the lower rate of hospital admissions. The saving is smaller than the $2823 per patient reported by Koelling et al.[24]

There is little information on the quality of life of patients with HF.[30] We applied the most extensively used instrument in Spain[31] and found that patients in the intervention group presented a better score at 6 months in both the physical and mental components. These data are similar to those found by West et al,[28] who reported an improvement in the SF-36 score after the intervention, and no improvement in the control group.

This study has certain limitations and should be interpreted with caution. Even though evidence is available on the magnitude of the impact attributable to an educational program at the time of hospital discharge (30% reduction in hospitalizations during a 4.2-year follow-up),[29] some authors have demonstrated that the efficacy of these interventions decreases in the long-term.[25] Our short follow-up and the small sample size are important limitations that hinder extraction of precise conclusions on the differences in morbidity and mortality; the results should be confirmed in larger prospective studies. The reduction in mortality observed, and particularly the magnitude of the decrease (82.4%) raises doubts as to the comparability of the groups. Nevertheless, the only between-group difference was in the functional class and, precisely, this difference would go against the findings. Seventy-four percent of the patients in the intervention group were classified as NYHA functional class III or IV as compared to only 50% of the control group, a fact that confers a poorer overall prognosis on the intervention patients. Moreover, in order to avoid bias regarding the morbidity and mortality results, we excluded all patients hospitalized for acute coronary syndrome because of the elevated incidence of rehospitalizations in this population.[32]

We included only patients with systolic dysfunction in order to homogenize a population with a definite diagnosis of severe HF with a poor prognosis, and because it is difficult to establish diagnostic criteria of HF with preserved systolic function, particularly when there is coexisting atrial fibrillation and/or pacemaker rhythm.[33] Morbidity and mortality is not substantially different when comparing elderly patients with or without preserved systolic function, and educational intervention could be beneficial to all of these patients.

The study was performed in a single hospital that provides medical assistance to a population with a middle-to-high social and cultural level, where 82% of the patients included had a secondary or university education. These figures contrast with the mean educational level of the Spanish HF population in which 41% have a primary or university educational level[23]; hence, these findings should be confirmed and the applicability of this type of intervention assessed in sectors of the society with a lower educational level.

The cost of an illness is the sum of direct, indirect and intangible costs. These last two, which comprise loss of income, travel expenses, nonquantifiable costs derived from physical and emotional deterioration, and other costs resulting from community care and diagnostic tests, were not calculated in the present study. Only the cost of the home-based educational intervention and the direct costs secondary to hospitalization and treatment were studied, which, in fact, account for 70% of the total cost.[34]

Lastly, although specific estimations of the minimum clinically important difference for the SF-36 health summary scales are not available in patients with HF, the magnitude of the difference justifies the interpretation as a clinically relevant difference.[35]

CONCLUSIONS

Variations among the different interventions reported in the literature hinder comparisons and definition of the ideal procedure. The simple educational program used in this study, consisting of a single visit one week after hospital discharge in the patient's home, resulted in a substantial decrease in the number of hospital admissions and emergency room visits. It is a cost-effective health management option that improves the

quality of life of patients with systolic HF. Programs implemented by specialized nursing professionals should be encouraged. In addition to educating, they have the capacity to introduce treatment modifications in accordance with a medical protocol and under the supervision of a physician.

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