

Specialized Care Program for End-Stage Heart Failure Patients. Initial Experience in a Heart Failure Unit

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Introduction and objectives. End-stage heart failure is associated with very high morbidity and mortality. Palliative care has been little studied in affected patients.

Patients and method. Between January 1998 and December 2004, 61 patients with end-stage heart failure participated in a specialized advanced heart failure care program. The program included patient education on advanced heart failure, with day-care and home-care elements, and involved intravenous drug administration when necessary.

Results. The mean age of the study population was 64 (13) years (range 32-87 years), with 92% being male. Their mean ejection fraction was 23 (6%), mean systolic blood pressure 100 (16) mm Hg, mean blood sodium level 137 (4) mEq, mean creatinine level 1.7 (0.8) mg/dL, and mean hemoglobin level 12 (2) mg/dL. The number of hospitalizations, number of days in hospital per admission, and number of emergency room visits in the year before inclusion in the specialized heart failure care program were 5.7 (0.5), 53 (5), and 8.3 (1.1), respectively. After inclusion, these figures decreased significantly to 1.9 (0.2) ($P=.0001$), 19 (3) ($P=.0001$), and 1.2 (0.2) ($P=.0001$), respectively. During a mean follow-up period of 11 (10) months, 28 patients died (47%) and 23 (38%) underwent heart transplantation. In addition, use of the program led to a reduction in healthcare costs.

Conclusions. Although mortality in end-stage heart failure patients remained very high, use of a specialized advanced heart failure care program decreased the number of hospitalizations, days per hospitalization, and emergency room visits, and reduced the cost of care.

Key words: Heart failure. Follow-up studies. Cardiomyopathy. Transplantation.

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Programa de atención especializada en la insuficiencia cardíaca terminal. Experiencia piloto de una unidad de insuficiencia cardíaca

Introducción y objetivos. La insuficiencia cardíaca terminal tiene una morbilidad y una mortalidad muy elevadas. En estos pacientes, la optimización del tratamiento médico es difícil y las medidas paliativas que pueden aliviar los síntomas han sido poco estudiadas.

Pacientes y método. El objetivo del estudio es revisar la atención especializada recibida por 61 pacientes con insuficiencia cardíaca severa terminal en un programa realizado en hospital de día y a domicilio. En este programa se facilitaba el control de los síntomas, la optimización del tratamiento médico y la administración de fármacos intravenosos.

Resultados. La edad media fue de 64 ± 13 años (rango, 32-87). La fracción de eyección media fue del $23 \pm 6\%$, la presión arterial sistólica de 100 ± 16 mmHg, la natriemia de 137 ± 4 mEq, la creatinina de $1,7 \pm 0,8$ mg/dl y la hemoglobina de 12 ± 2 mg/dl. El número de ingresos hospitalarios, de días de ingreso y de consultas a urgencias en el año previo a la inclusión en el programa de atención especializada fueron de $5,7 \pm 0,5$; 53 ± 5 , y $8,3 \pm 1,1$ respectivamente, reduciéndose de forma significativa después de la inclusión a $1,9 \pm 0,2$ ($p = 0,0001$), 19 ± 3 ($p = 0,0001$) y $1,2 \pm 0,2$ ($p = 0,0001$), respectivamente. La disminución de las hospitalizaciones y las consultas a urgencias se asoció con una reducción del coste sanitario.

Conclusiones. Aunque la mortalidad de los pacientes con insuficiencia cardíaca terminal sigue siendo muy elevada, el programa de atención especializada en régimen de hospital de día o a domicilio reduce el número de hospitalizaciones, los días de ingreso, las consultas a urgencias y el coste sanitario en estos pacientes.

Palabras clave: Insuficiencia cardíaca. Estudios de seguimiento. Miocardiopatía. Trasplante.

ABBREVIATIONS

ACE: angiotensin converting enzyme.
 HF: heart failure.
 SCP: specialized care program in end-stage heart failure.

INTRODUCTION

End-stage heart failure (HF) refractory to medical treatment is associated with very high rates of morbidity and mortality.¹⁻³ The final stage of the disease is marked by a lack of response to medical treatment, disabling symptoms and repeated hospital stays, which are usually prolonged and very costly in terms of health care resources.^{4,5} Although the creation of specialized units has improved the management of HF patients, reducing the number of hospital readmissions, there has been little progress in the care of end-stage patients.⁶⁻⁸ These individuals present severe ventricular dysfunction and are symptomatic at rest, despite the optimization of the drug treatment (stage D in the new classification of HF),⁹ and multiple comorbidities such as chronic renal failure, anemia and cachexia, are common. Although heart transplantation is the sole treatment that can improve the prognosis in these cases, it can be performed in only a small number of patients.¹⁰ Moreover, given that the time spent on the waiting list has increased in recent years, many of these patients continue to deteriorate and require repeated hospital admissions.¹¹ However, most of the patients with end-stage HF are elderly and, thus, are not suitable candidates for heart transplantation and, in the majority of cases, all the treatment options have been exhausted.¹² On the other hand, the implantation of ventricular assist devices is still not very widespread in Spain and they are considered only as bridges to transplantation. Intravenous inotropic support is regarded merely as a palliative measure, according to the latest update of the Clinical Practice Guidelines of the European Society of Cardiology¹³; nevertheless, it is usually administered when the patient is admitted with decompensated HF and hemodynamic instability and, while it should be discontinued once the patient is stabilized, this is sometimes difficult to do.

The objective of this study is twofold: on the one hand, to review the specialized care received by our patients with severe end-stage HF in a program carried out in the day hospital and home care settings and, on the other, to determine whether or not this strategy reduced hospital admissions and emergency room visits and was associated with lower costs.

PATIENTS AND METHOD

Study population

Between January 1998 and December 2004, 61 patients with refractory HF and left ventricular dysfunction were treated under a specialized care program (SCP) for patients with end-stage HF. This study population represents 15% of the 401 patients being followed in our HF unit. The diagnosis of ischemic cardiomyopathy as the underlying cause of HF was based on coronary arteriography (in which stenosis of more than 70% in at least one coronary artery was considered significant) or a history of acute myocardial infarction documented by the clinical record and electrocardiogram. When the coronary arteries were normal and there was no evidence of primary valve disease, dilated cardiomyopathy was considered to be the cause of the ventricular dysfunction. Restrictive cardiomyopathy was diagnosed on the basis of the echocardiographic findings.

All patients underwent two-dimensional echocardiography using the available instrument (Sonos 5500, Agilent Technologies, Philips, Germany) to measure the ventricular diameter and ejection fraction (on the basis of Simpson's rule). An ejection fraction less than or equal to 40% was considered to indicate the presence of left ventricular dysfunction.

Specialized Care Program

Two criteria had to be met for inclusion in the program. First, it had to be demonstrated, in the hospitalized patient receiving the maximum tolerated medical treatment and intravenous inotropic agents, that it was not possible to discontinue inotropic support without the patient developing hemodynamic instability, indicated by the presence of symptomatic hypotension, poor peripheral perfusion, aggravation of chronic renal failure or resting dyspnea. The second criteria was the persistence of severe symptoms and signs of HF requiring readmission, despite optimized maximum treatment, after ruling out reversible causes of decompensation. These patients were offered the chance to participate in the SCP as an alternative to hospital admission.

The selected patients were asked to come to the day hospital, where their vital signs were measured and a blood sample was taken for standard laboratory analysis. They were interviewed by a specialized nurse and a cardiologist who assessed the status of the patient and, if necessary, commenced intravenous therapy. In addition, the nurse played an educational role, helping the patient to recognize the symptoms and stressing the need to control his or her weight on a daily basis, as well as the importance of diet and medication. Those patients who were stable and required no additional treatment were asked to return once a month; those who required

palliative treatment with intravenous inotropic drugs had to come to the day hospital twice a week for treatment and the evaluation of their condition. Those who required repeated intravenous inotropic therapy underwent insertion of a Portacath (an implantable venous access device) into the subclavian vein to avoid repeated venous puncture. For the initial perfusions, the patient was monitored and the vital signs were assessed every 15 minutes for the first hour and once an hour thereafter. Special care was taken to avoid hypokalemia and hypomagnesemia, for which purpose, potassium and magnesium supplements were administered when necessary. Every effort was made to reduce the intravenous inotropic therapy to a minimum if the patient showed clinical improvement and, whenever possible, it was discontinued. We did not monitor intracavitary pressures using a Swan-Ganz catheter for the purpose of adjusting the medication.

In the second year, home monitoring for patients living near the hospital was introduced into the SCP. Under this part of the program, a specialized nurse visited the home of the patient, carried out a simplified interview to assess the signs and symptoms of decompensation and measured the patient's vital signs. Depending on the previously prescribed medication, she administered diuretics or inotropic agents, using portable pumps (Ladd-Legacy) which enable the programming of continuous or intermittent administration of the treatment. The visiting nurse phoned the medical specialist in the HF unit whenever necessary. In addition to her educational role, the nurse helped to fill out the questionnaires for calculating the Barthel index¹⁴ and, together with the social worker, assessed individual patient needs.

Statistical Analysis

For the statistical study, the SPSS statistical software package (version 10 for Windows) was employed. The distribution of the variables was analyzed using the Kolmogorov-Smirnov test. Discrete variables, expressed as percentages, were analyzed by means of the χ^2 test. The continuous quantitative variables that exhibited a normal distribution, expressed as the mean plus or minus the standard deviation, were compared using Student's *t* test for independent samples or for paired samples, depending on the circumstances. Kaplan-Meier curves were employed for the analysis of survival, and a *P* value of less than .05 was considered to indicate statistical significance.

The costs prior to and after inclusion in the SCP were compared in those patients who remained alive without transplantation after 1 year of follow-up. The pre-SCP cost per patient was calculated by adding the cost of the mean number of days spent in the hospital due to HF to that of the visits to the emergency room

and outpatient clinic. The costs after inclusion in the SCP were calculated by adding the cost of the mean number of days spent in the hospital due to HF to that of the visits to the emergency room, plus the cost of the visits to the day hospital. The cost of home care was calculated on a similar basis, adding the cost of the home visits (including those of the nurse, material and transportation) and the medical visits in the day hospital.

RESULTS

Clinical Characteristics of the Patient Population

The clinical characteristics, laboratory and echocardiographic parameters and treatment of the study population are summarized in Table 1. All the

TABLE 1. Clinical Characteristics, Echocardiographic Parameters, and Treatment of the Study Patients*

| | |
|-------------------------------|-----------|
| Age, mean±SD, y | 64±13 |
| Men | 56 (92%) |
| Ischemic heart disease | 34 (56%) |
| Dilated cardiomyopathy | 24 (34%) |
| Valvular heart disease | 6 (10%) |
| Restrictive cardiomyopathy | 1 (2%) |
| NYHA functional class | |
| IV | 38 (62%) |
| III | 23 (38%) |
| SAP, mean±SD, mm Hg | 100±16 |
| Heart rate, mean±SD, b/min | 77±12 |
| EF, mean±SD, % | 23±6 |
| LVEDD, mean±SD, mm | 71±10 |
| LVESD, mean±SD, mm | 58±11 |
| Serum sodium, mean±SD, mEq/mL | 137±4 |
| Potassium, mean±SD, mEq/mL | 4.3±0.5 |
| Creatinine, mean±SD, mg/dL | 1.7±0.9 |
| Creatinine >2 mg/dL | 20 (33%) |
| Hemoglobin, mean±SD, mg/dL | 12.3±2 |
| ACE inhibitors | 46 (75%) |
| Dose, mean±SD, mg/day | |
| Enalapril | 9±8 |
| Captopril | 39±21 |
| Losartan | 12 (21%) |
| Dose, mean±SD, mg/day | 34±14 |
| Furosemide | 61 (100%) |
| Dose, mean±SD, mg/day | 122±67 |
| Beta-blockers | 17 (28%) |
| Digoxin | 43 (71%) |
| Spironolactone | 29 (48%) |
| Amiodarone | 36 (59%) |
| IAD | 9 (11%) |

*ACE indicates angiotensin converting enzyme; IAD, implantable automatic defibrillator; EF, ejection fraction; LVEDD, left ventricular end-diastolic diameter; LVESD, left ventricular end-systolic diameter; NYHA, New York Heart Association; SAP, systolic arterial pressure; SD, standard deviation.

patients had severe ventricular dysfunction, while 30 presented secondary mitral insufficiency that was moderate in 14 cases (23%) and mild in 16 (26%). The administration of beta-blockers was considered in all patients, but was tolerated in only a few cases (Table 1). Prior to their inclusion in the SCP, 56 patients (92%) had received intravenous inotropic support during previous hospital stays.

Of the 61 patients studied, 24 were on the waiting list for heart transplantation and, although these patients were significantly younger (56 ± 10 years vs 69 ± 12 years; $P=.0001$), there were no significant differences between the 2 groups in terms of clinical, echocardiographic and laboratory findings or the Barthel index.

Program of Specialized Care

The possibility of administering intravenous inotropic agents in the day hospital facilitated the discharge of 42 hospitalized patients (69%); in this group, a number of attempts were made to discontinue inotropic support, but failed due to severe hypotension in 23 cases and hypotension with deterioration of renal function and decreased urine output in 19. In these patients, the attempt was made to change from continuous perfusion to 8 hours of intermittent perfusion; if the latter was well tolerated and the patient was stabilized, he or she was discharged under the SCP in the day hospital. The remaining 19 patients were included in the SCP due to repeated hospital admissions and the persistence of severe symptoms and signs of worsening HF despite the optimization of medical treatment, after reversible causes of decompensation had been eliminated.

During follow-up, all the patients required intravenous inotropic therapy as a palliative support measure; the mean number of sessions per week was 2.3 ± 0.9 . The agents used were dobutamine at a dose of $5\ \mu\text{g}/\text{kg}/\text{min}$ in 57 patients and milrinone at a dose of $0.375\ \mu\text{g}/\text{kg}/\text{min}$ in the remaining 4. The use of dobutamine predominated because, being the agent most widely employed in acute heart failure, it is more familiar to the medical staff and its cost is lower. In 8 patients (13%), a progressive eosinophilia was observed in the baseline blood count upon dobutamine administration, which returned to normal when the drug was discontinued; it was replaced by milrinone in 4 of the patients and by levosimendan in the other 4.

During the final year, 18 patients were included in the home care program, which was well accepted and well tolerated. The mean Barthel index of the patients was 59 ± 27 , a fact that indicates a serious limitation of their functional capacity for the performance of the basic activities of daily life. The percentage of patients that had to be readmitted to the hospital at least once during the follow-up involving home care was similar to that of patients being treated in the day hospital (67% vs 65%);

the mean number of days spent in the hospital was also similar (21 ± 25 days vs 18 ± 24 days, respectively).

Outcome

During the mean follow-up of 11 ± 10 months, 28 patients died (47%); the causes of death are shown in Table 2. Most of them were hospitalized at the time and only 2 died in their homes. Heart transplantation was possible in 23 patients (38%); it was performed in the emergency setting in 2 cases and was elective in the remainder. Only 1 patient died while on the waiting list. Three patients died following transplantation, 1 due to infection and 2 due to primary graft failure. The probability of surviving 6 and 12 months without heart transplantation was 54% and 29%, respectively (Figure).

The mean number of hospital admissions required, the days spent in the hospital, and the number of visits to the emergency room per patient decreased very significantly after inclusion in the SCP, as can be seen in Table 3. During the 12 months prior to inclusion in the SCP, there were a total of 308 hospital admissions, a number that was reduced to 108 during the SCP. The reasons for readmission are summarized in Table 2.

After consulting with the family, inotropic support was discontinued in four patients as their general condition was considered to be too poor for them to benefit from the treatment. In 8 cases (13%), the clinical status of the patients improved to the point that inotropic therapy could be discontinued, and 2 patients who met the criteria for resynchronization underwent implantation of a 3-chamber pacemaker. Serious ventricular arrhythmias were not observed; only 1 patient presented an episode of recurrent ventricular fibrillation and died 24 hours later as a consequence of cardiogenic shock. There were 2 cases of atrial fibrillation in patients receiving intravenous milrinone. The 4 patients with fever and positive blood

TABLE 2. Outcome: Causes of Death and Hospital Readmission During Follow-Up*

| | |
|-----------------------|----------|
| Mortality | 28 (47%) |
| Cause of death | |
| Cardiogenic shock | 26 (93%) |
| Sudden death | 1 (3%) |
| Noncardiac | 1 (3%) |
| Heart transplantation | 23 (38%) |
| Readmissions | 108 |
| Cause of readmission | |
| Decompensated HF | 90 (83%) |
| Infection | 4 (4%) |
| Severe arrhythmia | 1 (1%) |
| Angina | 7 (6%) |
| Others | 6 (5%) |
| Lost to follow-up | 2 (3%) |

*HF indicates heart failure.

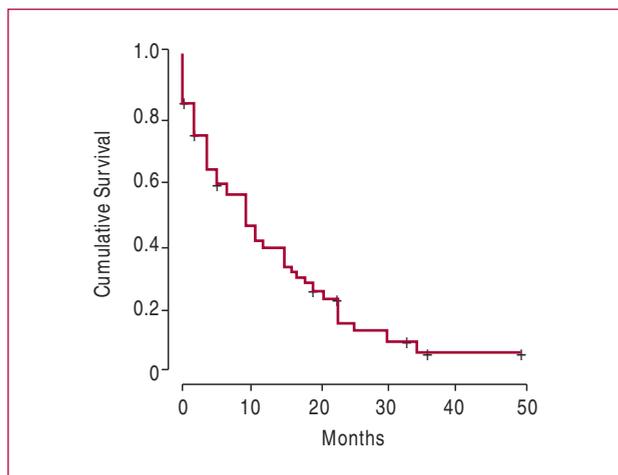


Figure. Survival curve corresponding to the study patients who did not undergo heart transplantation, showing a probability of survival at 6 and 12 months of 54% and 29%, respectively.

cultures received antibiotic therapy, but it was not necessary to withdraw the Portacath in any case.

Cost Analysis

Prior to the inclusion of a patient in the SCP, the mean cost of health care per patient-year, derived from the sum of the cost of the days the patient spent in the hospital and the visits to the emergency room and outpatient clinic, was €19 175; the highest cost corresponded to the hospital stays. Under the SCP, the latter cost was added to those of the visits to the emergency room and to the day hospital, for a total of €17 585; the highest cost corresponded to the visits to the day hospital. Thus, the application of the SCP resulted in a savings of €1590 per patient. When, under the SCP, home care replaced the day hospital, the cost was reduced to €14 675, resulting in an even greater savings with respect to conventional care.

DISCUSSION

The authors of this study report their experience with a program of individualized, specialized care in patients

with refractory end-stage HF being treated at a tertiary hospital. The management of these patients, especially during hospital stays, consumes great amounts of health care resources. The study patients presented severe refractory HF, despite the efforts made to optimize the medical treatment and systematically eliminate reversible causes of decompensation of heart failure. The SCP actually facilitated the discharge of hospitalized patients who were dependent on intravenous inotropic support, avoided further readmissions due to decompensated HF and reduced the number of visits to the emergency room and length of the hospital stay when admission was necessary. Moreover, the introduction of home care for patients with end-stage HF has been shown to be effective and well-tolerated by the patients, and results in a reduction of health care costs.

Previous studies have reported lower numbers of emergency room visits and readmissions among patients treated in a HF unit.¹⁵⁻²⁰ In fact, the patients included in the Oregon Heart Failure Project presented a decrease in the risk of hospitalization of 52% and of visits to the emergency room of 72%.²¹ Likewise, programs that include an educational role on the part of a nurse specialized in HF improve compliance with the drug treatment and make it easier for the patient to identify the warning signs of decompensation, thus reducing hospital admissions and the consumption of resources. Home care for HF has recently been introduced. It includes specialized management with visits from nurses who are experts in HF, as in our program. This approach to management has been associated with an improvement in the quality of life of the patients and a reduction in health care costs.²²⁻²⁴

In our patients, survival without cardiac transplantation was somewhat longer than that recorded in the COSI program,²¹ in which all the patients received intravenous inotropes continuously and the survival rate at 3, 6, and 12 months was 51%, 26%, and 6%, respectively. In another group of patients with severe HF who did not tolerate ACE inhibitors due to hypotension, deterioration of renal function, or hyperkalemia, the mortality at 8 months was 57%, and the mortality or need for heart transplantation or a ventricular assist device was 67%.⁴ Our 1-year survival without heart transplantation of 29% is similar to that of the group receiving medical treatment in the REMATCH

TABLE 3. Number of Admissions Required, Number of Days Spent in the Hospital, and Number of Visits to the Emergency Room per Patient, Before and After Inclusion in the Specialized Care Program (SCP)*

| | Before Inclusion | After Inclusion | Mean Difference | P | 95% CI |
|------------------------------|------------------|-----------------|-----------------|-------|---------|
| No. of admissions, mean±SD | 5.7±0.5 | 1.9±0.2 | 3.8±4 | .0001 | 5-2.9 |
| Days in hospital, mean±SD | 53±5 | 19±3 | 34±44 | .0001 | 45-22 |
| No. of visits to ER, mean±SD | 8.3±1.1 | 1.2±0.2 | 7.1±8 | .0001 | 9.3-4.8 |
| >3 admissions/year, n (%) | 42 (69%) | 7 (11%) | | .0001 | |

*CI indicates confidence interval; ER, emergency room; PSC, program of specialized care in end-stage heart failure.

study, in which 72% of the patients received inotropic support and the survival at 1 year was 25%.²⁴

Such a high 1-year mortality indicates the seriousness of HF in our study population; in these patients, the quality of life maintained during the final stage prior to death is of crucial importance. Taking into account the pathophysiology of HF, all the inotropic drugs that increase cardiac contractility through the activation of the adrenergic pathway promote arrhythmias and increase oxygen consumption and cardiac work; thus, they presumably can contribute to a further deterioration of ventricular function and a poorer prognosis. In this context, inotropic therapy has been quite controversial since. While it improves the quality of life of these patients, sometimes the price is an increased risk of death.²⁵⁻²⁸ Nevertheless, in the few randomized studies in which low-dose dobutamine was administered, no significant increase in the mortality rate was observed.^{29,30} On the other hand, an improvement in peripheral endothelial function has been reported with these strategies, a circumstance that could contribute to the improvement observed in the functional capacity. In fact, inotropic agents are employed in the treatment of acute HF,³² and are usually utilized in patients who had worsening heart failure especially if it is associated with hemodynamic instability. In these cases, the inotropic therapy should be discontinued once the patient is stabilized, although this is not always possible. Given that patients with end-stage HF have been excluded from the majority of the pharmacological studies, decision making concerning these patients and their therapeutic management is highly complicated. As a consequence, their medical treatment should be individualized and, on occasions, the patient should be included in the decision-making process, which must take into account the risk/benefit ratio.

The administration of inotropic support as a bridge to transplantation, an approach that requires prolonged hospital stays, is a common practice in Spain. As time goes by and the patient continues on the waiting list, as is occurring in recent years, the risk of the deterioration of HF increases, while the therapeutic options in this phase are very limited.^{11,33} In our program, the use of the day hospital or home care to avoid readmission while the patient remained on the waiting list proved to be a valid alternative, but is not widely employed in our hospitals. In fact, in our series, the SCP was applied in the cases of 24 patients who were on the transplant waiting list and most of them lived to undergo transplantation. These findings are similar to those reported previously for a group of 21 patients who, while on the waiting list, were receiving inotropic support at home; 15 became transplant recipients and 3 died while waiting.¹¹

Ninety-six percent of the patients received ACE inhibitors or angiotensin receptor antagonists; although the doses administered were low, a great effort was made

to ensure that they corresponded to the maximum tolerated. In fact, no significant differences were observed in terms of patient mortality when low-dose and high-dose ACE inhibitors were compared.³⁴ The percentage of patients who tolerated the beta-blockers was very low, only 28%; however, it is similar to that observed in previous studies, such as REMATCH, in which they were tolerated by 20% and 24% of the patients undergoing medical treatment and those with assist devices, respectively.^{24,35}

Dobutamine was the inotrope most frequently utilized and, although it is associated with an increased risk of arrhythmias, they were not common in our patients. The incidence of eosinophilia during this therapy varies widely, ranging between 2.4% and 23%, depending on the study³⁶; among our patients, it was 13%. Although cases of eosinophilic myocarditis have also been reported, it is more difficult to evaluate, and we were unable to rule out the possibility that dobutamine had been a factor in the cases of 2 patients who required emergency transplantation due to severe hemodynamic deterioration. Milrinone is also arrhythmogenic and can produce myocarditis.³⁷ Levosimendan, which has recently been introduced in the treatment of acute HF, may be better tolerated and have fewer secondary effects, although experience with its use in the management of chronic HF is still limited.³⁸

Limitations of the Study

Given that this is an observational study, the results should be assessed with caution. In fact, due to the absence of a control group, the results might be overestimated. It should be pointed out that the hemodynamic status of the patients was compromised, a circumstance that led to the choice of this type of care; thus, they themselves were their own control as they compared their courses prior to and after inclusion in the SCP. A nurse specialized in the treatment of advanced HF and a cardiologist from the HF unit of a tertiary hospital collaborated in the program and, thus, these results can not be extrapolated to another context or care setting.

CONCLUSIONS

Programs of specialized care are of great utility in patients with end-stage HF; they reduce the numbers of readmissions and emergency room visits and, consequently, health care costs. Moreover, home care offers considerable advantages to patients with severe physical limitations and advanced age, especially in terms of reducing the number of visits to the hospital, while it is not associated with an increase in the rate of complications. We should look forward to the development of new, more effective treatments that permit specialized home care for the patient with end-stage HF, but with fewer secondary effects.

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