European Geriatric Medicine 5 (2014) 252–257

Available online at ScienceDirect www.sciencedirect.com

Elsevier Masson France EM|consulte www.em-consulte.com/en

Research paper

Effectiveness of a follow-up program for elderly heart failure patients after hospital discharge. A randomized controlled trial

J.L. González-Guerrero [a,*], T. Alonso-Fernández [a], N. García-Mayolín [b], N. Gusi [c], J.M. Ribera-Casado [d]

[a] Geriatric Service, Hospital Ntra. Sra. de la Montaña, Complejo Hospitalario de Cáceres, Avenue España 2, 10004 Cáceres, Spain
[b] Department of Patient Management, Complejo Hospitalario de Cáceres, Cáceres, Spain
[c] Faculty of Sports Sciences, University of Extremadura, Cáceres, Spain
[d] Geriatric Service, Hospital Clínico San Carlos de Madrid, Madrid, Spain

ARTICLE INFO

Article history:
Received 9 January 2014
Accepted 15 May 2014
Available online 10 June 2014

Keywords:
Heart failure
Elderly patients
Disease management programs

ABSTRACT

Purpose: Management programs for high-risk heart failure (HF) patients reduce admission rates, improve quality of life and survival, and lower costs. These benefits are controversial in elderly patients because these individuals are frequently excluded from the studies. Our aim was to evaluate the effectiveness of disease management programs (DMPs) for HF elderly patients attending a geriatric day care hospital (GDCH) subsequent to hospital discharge.

Methods: A randomized prospective study was performed using 117 HF patients who were divided into two groups as follows: 59 patients undergoing an interventional program including health education, therapeutic control, and close follow-up in a GDCH; and 58 patients receiving standard healthcare. Results were measured in terms of event-free survival, where "event" is defined as readmission or mortality for any cause.

Results: The mean age was 85 years, and 73% of the patients were women. After a year of follow-up, the intervention group had fewer patients with events compared with the control group (27 vs. 38 patients), which indicates a 30% reduction (RR: 2.25; 95% CI: 1.07–4.74; $P = 0.032$). The probability of having an event between the first visit and the year of follow-up was significantly lower in the intervention group (log-rank: 5.79; $P = 0.016$). Moreover, the quality of life improved significantly in the intervention group ($P = 0.035$).

Conclusion: A developed DMP in a GDCH improves the event-free survival and the quality of life in elderly patients with HF.

Trial registration: isrctn.org identifier: ISRCTN10823032.

1. Introduction

Heart failure (HF) is the result of diverse cardiac-related diseases. In developed countries, HF has become a main health expenditure because its incidence and prevalence have increased [1,2]. Some of the causes are progressive aging of the population; improved treatments, particularly for myocardial infarction and hypertension; and a higher survival rate in HF patients [1,2]. Increasingly, older HF patients are afflicted with concurrent geriatric syndromes such as frailty, which play an important role in determining outcomes in this population [1].

Hospital readmissions and mortality are elevated despite the advances in treatment, particularly in elderly patients [3]. Studies on the outcome of follow-up programs (known as disease management programs [DMPs]) subsequent to hospital discharge have demonstrated that these programs reduce readmissions and improve the patients' quality of life and health without increasing the health expenditure [4,5].

The aim of the present investigation was to evaluate the effectiveness of a DMP in elderly HF patients after a hospital discharge. The study was performed in a geriatric day care hospital (GDCH), and the patients were monitored by a multidisciplinary team. Our main hypothesis was that, compared with the standard

* Corresponding author. Tel.: +34 927256886; fax: +34 927256816.
E-mail addresses: jlgonzalez@movistar.es, joselglezg@gmail.com (J.L. González-Guerrero).

http://dx.doi.org/10.1016/j.eurger.2014.05.005
1878-7649/

healthcare, an interventional program would extend event-free survival in patients.

2. Methods

2.1. Patients

Consecutive patients diagnosed with acute HF and discharged from the Geriatric Service of the Cáceres Hospital Complex (Spain) were included. The patients were diagnosed according to the criteria of the European Society of Cardiology [6] and had a hospital stay of more than 2 days. The following individuals were excluded from the study: patients with terminal disease (with an expected survival of less than 6 months), bedridden patients, patients with severe dementia (Global Deterioration Scale > 5) [7] or other serious psychiatric disease, patients who were impossible to follow-up, patients in retirement homes with their own medical service, and patients who refused to participate.

The study was approved by the Ethics Committee for Provincial Clinical Research, and all the patients, or their proxies when they had cognitive impairment, signed their previous informed consent. The study was internationally registered with the ISRCTN10823032.

2.2. Study design and data collection

The investigation consisted of a randomized controlled clinical trial with a 12-month follow-up period. The patients were separated randomly using a computer-generated list and were grouped either as part of a DMP in a GDCH or as the control group, which received standard healthcare. Upon hospital discharge, the patients and the researchers ignored the group assigned to each patient.

Socio-demographic and clinical data were collected before the group selection. These data included the Barthel Index to measure the performance in activities of daily living previous to hospitalization (at least 2 weeks prior) [8], the Global Deterioration Scale to measure the degree of cognitive impairment [7], the Charlson Comorbidity Index [9], and the impact of health in the quality of life (IHQL) using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) [10]. In addition, the results from the diagnostic tests and the HF drug treatment were registered (Appendix 1).

The last follow-up was performed 12 months after the patient was discharged or in the event of death of the patient.

2.3. Intervention group follow-up program

A DMP multidisciplinary team, consisting of a geriatrician (case manager), a nurse, and a social worker, evaluated the patients and their caregivers prior to the hospital discharge. After the first encounter, the patients were given an information manual [11] explaining details regarding the disease, such as diet, weight control, exercise, lifestyle, and medication, as well as how to recognize cardiac decompensation symptoms.

A nurse contacted each patient, via telephone, 48 hours after the hospital discharge, to record any problems. After 10 days, the team examined the patients in the GDCH, using educational reinforcements and evaluating for possible cardiac decompensation.

The subsequent follow-up occurred at the GDCH, 1 and 6 months after the hospital discharge. During these programmed sessions, the team assessed the patients for treatment compliance, reinforced the health education, and assessed the ability of the patients to fulfill the recommendations; in addition, the prescriptions and doses were adjusted according to clinical guidelines [6,12,13]. The global therapeutic regime and comorbidities were reevaluated by considering possible changes in the functional, cognitive, affective, and social capacities in the patient.

During the third month, the geriatrician contacted each patient via telephone. All the follow-up involved health-educational reinforcement and the evaluation for possible cardiac decompensation.

Furthermore, the team provided the contact number of the geriatrician who was available on a morning schedule (from 09:00 to 14:00 hours) for consultation regarding the study. Each patient received attention in the GDCH or via telephone when he or she required an unscheduled evaluation for clinical decline due to a medical problem.

2.4. Control group

Before the hospital discharge, each patient and the caregiver received an information manual explaining the HF education [11].

Following the hospital discharge, treatment and follow-up were provided by the primary care physician. Visits were scheduled, and treatment was prescribed depending on the case. Outpatient appointments at the Geriatric Service or other medical facilities were provided by non-members of the research study.

2.5. Results measures

Event-free survival was the main measure of the study. This variable was defined as the time elapsed until the first readmission or until death of the patient for any cause during the study period. The hospital readmissions (total and HF-related), mortality (total or HF-related), functional capacity, and IHQL were accounted for.

The results were obtained from the patients and their relatives, the hospital records, and the National Death Index. For event-free patients, the data were censored on the last day of the study. The result variables were adjudicated by a researcher of the Department of Patient Management, who was unaware of the group to which the patients belonged.

2.6. Statistical analysis

Based on previous studies, the sample size was calculated assuming an event-free rate of 65% in the control group [14–16]. With our intervention, was expected to reduce this percentage by 30% [4] (two-sided alpha = 0.05 and beta = 0.90). To perform this calculation, each group required 56 patients. When comparing the groups, the normally distributed continuous variables were analyzed using Student's *t*-test. When normality was not obtained, the variables were compared using the Mann-Whitney U test. Categorical variables were analyzed with the Chi^2 test. The event-free variable was tested using the Kaplan-Meier survival curve and the log-rank test. A sequential survival analysis was performed, using the Cox model, to determine if the treatment of the patients was an independent event predictor after adjustment for other relevant covariables.

The function capacity and the IHQL were compared by a secondary analysis with the Mann-Whitney U test. For this comparison, the missing values from censored cases were included [17]. As described in a previous study [14], the final values were transformed into ordinal scales, namely 0 for patients who died during the study and 1 for patients who were transferred to other medical services or hospitalized at the final evaluation. Other missing cases were assigned their initial value. Non-missing cases were grouped into quartiles, for which 2 was the lowest quartile, and 5 was the highest quartile.