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Research paper

Long-term survival of a cohort of patients with heart failure: Perspective from the real world



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ARTICLE INFO

Article history:

Received 30 January 2017

Accepted 28 April 2017

Available online 24 May 2017

Keywords:

Exitus
 Ejection fraction
 Heart failure
 Prognosis
 Survival

ABSTRACT

Introduction: Heart failure (HF) is the leading cause of hospitalization in Spain over 65 years of age, with a large morbidity and mortality problem and costs. The objective of this work is to evaluate the 15-year survival of the EPICOUR study cohort and analyze the variability of the risk factors of mortality according to age and progression of HF.

Material and methods: Prospective observational study of a cohort of 384 patients with follow-up at 15 years.

Results: The mean age was 74.84 (\pm 11.0) years. 53.4% were men and almost 75% belonged to rural areas. 305 patients (82.4%) were exitus against 65 (17.6%); in 14 cases, it was not possible to carry out a follow-up. The factors associated with a higher mortality risk were the age and diagnosis of ischemic heart disease, high blood pressure (HBP), diabetes mellitus, chronic obstructive pulmonary disease, acute myocardial infarction, valvulopathy, peripheral arteriopathy, and intraventricular and high-degree atrioventricular block (Mobitz 2nd and 3rd degree). The drugs with protective effect were anticoagulants and beta-blockers. The probability of survival was 77.6% the first year, 42.4% at 5 years, 24.3% at 10 years, and 16.7% at 15 years of follow-up. **Conclusion:** Mortality due to HF was high (82.4%), although there are hardly any references in the literature that allow us to make such long-term comparisons (15 years). Reduced ejection fraction is a powerful predictor of long-term mortality, especially after the 6th year.

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1. Introduction

Heart failure (HF) is considered the third cause of cardiovascular death in Spain, behind ischemic heart disease and cerebrovascular disease [1]. In recent decades, the increase in life expectancy and the ageing of the population have led to an increase in the prevalence of HF in developed countries, which is around 2–5%. It is a pathology that mainly affects the population older than 65 years and, above all, women [2,3]. It is expected that its frequency will continue to increase in the coming years, although its survival rate has improved due to the availability of better therapeutic alternatives, greater control of cardiovascular risk factors such as high blood pressure (HBP) and coronary heart disease (CHD), and a health care policy of cardiovascular prevention, based on the application of guidelines of clinical practice [4,5]. Nevertheless, health care control should also be a priority in health systems, with costs ranging from 1% to 5.4% of the total health cost of a western country [6].

In Spain there are about 80000 hospital admissions for HF per year. As in other developed countries, it is the leading cause of hospitalization in people over 65 and accounts for approximately 5% of all hospitalizations and in many population series is the most frequent cause of readmission. Clinical trials as well as daily clinical practice report on the variability of prognostic factors predicting morbidity and mortality.

The objective of the present study was to evaluate the 15-year survival of the EPICOUR [7] study cohort in northwest Spain and to analyze the variability of the causes of mortality according to the age of the patients and the progression of HF.

2. Material and methods

A prospective cohort study was performed, considering patients hospitalized in the “Complejo Hospitalario Universitario de Ourense” due to HF from 1 January 1999 to 31 December 2002 who had undergone an echocardiography that showed systolic or diastolic dysfunction. We collected the patient during the 1st hospital admission when patient were diagnosed. In our center, patients with HF may be admitted to internal medicine or

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cardiology. The diagnosis and treatment protocol was the same in both departments and the place of entry only depends on the professional workload. Patients were followed during 15 years.

Exclusion criteria were: under 14 years of age at HF diagnosis, neoplastic disease of any origin at advanced or terminal stage, degenerative (advanced stage) pathology of the central nervous system (CNS), lack of documented echocardiogram at admission, incapacity or circumstances that would limit the follow-up or participation in the study, or lack of authorization (verbal and written) to participate [7].

2.1. Study variables

We studied long-term survival and analysis of the causes of mortality according to the age of the patients and the progression of HF. Demographic (age, gender, urban or rural place of residence), clinical (personal history and signs/symptoms at admission), analytical, electrocardiographic, radiological, echocardiographic variables, treatments at discharge and prognosis were recorded. Analytical determinations and instrumentation (electrocardiogram and echocardiogram) were the same as in the EPICOUR study [7].

2.2. Sample size

As in the EPICOUR study, assuming that cardiovascular mortality was 20% for patients with HF, and admitting a maximum error of 4% at a 95% confidence interval, the resulting sample size was calculated to be 384 patients.

2.3. Ethical aspects

This study has been carried out in accordance with national and European legislation on clinical research, following international ethical recommendations, the Declaration of Helsinki and the Council of Europe with regard to the Convention on Human Rights and Biomedicine.

The study has complied at all times with the requirements established in the Spanish legislation in the field of biomedical research, personal data protection, and bioethics.

This study was approved for an ethical committee (Autonomous committee of research ethics in Galicia – 30/09/2014) with registration code:2014/231, IP Code: MOU-ICC-2014-01.

2.4. Statistical analysis

The quantitative variables were described by mean, standard deviation and median [minimum–maximum]. The qualitative variables were described by frequencies and percentages (%).

Parametric/non-parametric tests (Student's *t*-test and Mann–Whitney U test) were used to compare the variables, and Chi-square and Fisher's exact statistical tests were used to compare categorical variables. Subsequently, global and specific survival studies were performed. In continuous variables, regression models of univariate COX were performed using *P*-spline smoothing. The objective of this analysis was to determine, in those non-linear variables, and the different strata or categories, to be then introduced in the multivariate analysis. Significant variables in this first analysis and those that proved to be of clinical interest were introduced in the multivariate COX analysis (regardless of those that presented collinearity or were a linear combination of others). C-statistic were performed to determine the best predictor multivariate cox model.

In all analyses we considered statistically significant differences with $P < 0.05$. The sample size was calculated using the software Epidat 4.1 and the analyses were performed with SPSS 22.0 and the

free software R (<http://www.r-project.org>)—library survival, library smoothHR.

3. Results

On the basis of the EPICOUR Study Group, 384 patients were followed-up for 15 years. The mean age at the beginning of the study was 74.84 (± 11.0) years (range [36–95]), with the mean age of women being 4.3 years higher than that of men. One-third of all patients were older than 80 years. 53.4% were men, and almost 75% belonged to rural areas.

The majority of the patients had been admitted to the cardiology (56.1%) and Internal Medicine (39.8%) Services.

During the analysis period (1999–2012), 305 patients (82.4%) were exitus versus 65 (17.6%) who were still alive; in 14 cases, a follow-up was not possible. Table 1 shows and summarizes the sociodemographic characteristics, personal history, and treatments of patients with HF in terms of the mortality. We also analyzed the laboratory data of patients obtained at the time of diagnosis of HF as a function of mortality (Table 2).

Univariably, the factors associated with an increased mortality risk were the age and diagnosis of ischemic heart disease, HBP, diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), acute myocardial infarction (AMI), valvulopathy, peripheral arteriopathy, and both high-grade ventricular and atrioventricular block (AV) (Mobitz 2nd and 3rd degree). The drugs with protective effect were anticoagulants and beta-blockers.

In the same way, upon stratification of the percentage of ejection fraction (EF%) into three categories: $< 30\%$, $30\text{--}50\%$, and $> 50\%$, an increase in the mortality rate was observed for patients with $EF\% < 30\%$ ($P = 0,052$) (Fig. 1).

The HF survival probability after 1, 5, 10, and 15 years of follow-up is detailed in Table 3.

In the multivariate analysis (Table 4), the variables that were significantly associated with an increase in mortality were advanced age (equal to or older than 75 years) (Hazard ratio (HR) = 1.99; HF95%: [1.39–2.84]), DM (HR = 1.90, HF95%: [1.31–2.76]), ischemic heart disease (HR = 2.17, HF95%: 1.32–3.59), AMI (HR = 0.46, HF95%: [0.25–0.85]), and COPD diagnosis (HR = 1.91, HF95%: [1.34–2.73]). A higher risk of mortality was also found in patients with sodium values < 135 mg/dL (HR = 2.20, HF95%: 1.45–3.34), potassium values > 5 mg/dL (HR = 2.66, HF95%: [1.68–4.23]), and in those whose hemoglobin values were > 13 (HR = 0.57, HF95%: [0.41–0.79]) and albumin values were ≤ 3 (HR = 0.66, HF95%: [0.47–0.93]).

4. Discussion

HF is one of the main causes of death in the general population and in cardiac patients but the prognosis varies widely depending on the comorbidity of each patient. Risk quantification could improve and individualize the treatment offered. Although the risk of death has declined by a third in recent decades, experts point out that prevention remains the best defense against this serious disease [8].

Comparability between studies is limited by the lack of follow-up studies beyond 10 years. In our sample, the survival after 1, 5, 10, and 15 years was 77.6%, 42.4%, 24.3%, and 16.7%, respectively, similar to the results by Moster A et al. in which the survival was reported to be 89%, 79%, and 59% at 1, 2, and 5 years, respectively [6]. Quirós R et al. concluded that more than half of the patients died after 10 years (50.3%) [9]. In the Framingham study, the mortality rate was 17% after one year, 30% after 2 years, and 78% after 10 years [10]. The NHANES (National Health and Nutrition Estimation Study) found a 10-year mortality of 37.6% and a 15-year

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