

Survival rate and predictors of mortality in patients hospitalised with heart failure: a cohort study on the data of Persian registry of cardiovascular disease (PROVE)

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ABSTRACT

Objectives Heart failure (HF) has a high rate of hospitalisation and mortality. We examined its risk factors, survival rate and the predictors.

Methods In this prospective cohort study, demographic, clinical and treatment data of 1223 patients hospitalised with HF were extracted from the Persian Registry Of cardio Vascular disease (PROVE)/HF registry. Survival rate and HR and their association with other variables were assessed.

Results 835 (68.3%) were censored, while 388 (31.7%) patients were deceased. Mean age and frequency of hypotension during hospitalisation, tachycardia, pulmonary hypertension and anaemia, hyponatremia, heart valve disease and renal disease of the deceased patients was significantly higher than censored patients (15.2vs6.1%, 51.1vs40.1%, 24.4vs16.7%, 39.0vs31.8%, respectively, $p<0.05$). ACE inhibitor (ACEI)/angiotensin receptor blocker (ARB) (89.8%vs82.1%, respectively) and beta blocker (BB) (81.1%vs75.5%, respectively) were higher in follow-up in the censored group ($p<0.001$ and 0.02 , respectively). Crude Cox regression analysis identified age, tachycardia, hypotension, anaemia, pulmonary hypertension and heart valve disease as predictors of mortality (HR >1) and using ACEI/ARB and BB as predictors of life (HR <1 , $p<0.05$). After adjustment, all variables lost their significance, except BB (HR 0.63, $p=0.03$) and tachycardia (HR 1.74, $p=0.01$) and New York Heart Association (NYHA) class IV (HR 1.90, $p=0.04$) became significant predictors.

Conclusions We found a high mortality rate (31.7%). As NYHA class IV and tachycardia were significant predictors of mortality after adjustment, an effective measure can be treatment of underlying diseases, which deteriorate patients' conditions. Monitoring of medications for at-risk group, especially BB that predicts life, is important.

INTRODUCTION

Cardiovascular diseases (CVDs) are one of the world's top three causes of mortality and a major cause of morbidity and disability, responsible for 1 in every 2–3 deaths (1 death each 40s) in the USA, causing more than 2200 Americans' deaths each day.¹ In addition, the incidence and mortality rate of CVDs are anticipated to rise by 2020, especially in low-income and middle-income countries.² In

Iran, short-term survival rate of patients hospitalised with myocardial infarction is less than 10%,^{3,4} while Iranian men have a higher mortality rate⁵ and earlier age of incidence.⁶

Among different types of CVDs, heart failure is of great importance.⁷ HF accounts for one in every eight deaths in the USA and despite tremendous advances in medicine, the rates of hospitalisation and mortality of HF in 2010 is as high as the year 2000.⁸ Moreover, HF is considered the common endpoint of all CVDs.⁹ The increasing prevalence and mortality rate of HF has changed this disease to a critical and life-threatening condition. Therefore, identifying the prevalence, risk factors and survival rate and predictors has been the focus of extensive current research.^{10,11}

Although about 80% of CVDs occur in low-income and middle-income countries,¹² most studies come from the developed and European countries and few available studies report high prevalence of HF in Asian countries.¹³ In Iran, there are few reliable epidemiologic statistics available to estimate the incidence/prevalence of CVDs and long-term survival rate of HF. While data of HF survival rates around the world are based on national registry systems,^{10,11} few studies available in Iran have reported high prevalence, mortality rate and unfavourable survival rates or high in-hospital mortality rates.^{14–16} Furthermore, these studies have reported short-term results or were done with a small sample size.

Consequent to the necessity of establishing a national registry for the accurate recording of the data of patients with CVD, systematic analysis and long-term follow-up, the first registry programme of CVDs was launched in Isfahan (as a pilot study) in 2014; the Persian Registry Of cardioVascular disease (PROVE) continually registers patients with acute coronary syndrome (ACS), ST elevation myocardial infarction (STEMI), stroke, atrial fibrillation (AF), heart failure (HF), congenital heart disease (CHD), percutaneous coronary intervention (PCI), chronic ischaemic cardiovascular disease (CICD) and familial hypercholesterolemia (FH).^{13,17} We aimed to report the 1-year survival rate of patients hospitalised with acute or decompensated HF and the predictors of its mortality based on data of the PROVE/HF registry to assist health decision-makers in proper management and control of this disease.



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Table 1 Comparison of patients' characteristics based on the dead or live groups

Demographic and clinical characteristics	Censored (n=835)	Deceased (n=389)	P values*
Patients' sex, No. (%)			
Male	511 (61.2)	232 (59.8)	0.66
Female	324 (38.8)	156 (40.2)	
Age, mean± SD	68.75±13.41	72.56±12.56	<0.001
Male	67.37±13.32	70.49±13.11	0.003
Female	70.93±13.27	75.65±10.92	<0.001
Heart rate			
Bradycardia, No. (%)	37 (4.7)	17 (4.7)	0.005
Normal heart rate, No. (%)	653 (82.1)	272 (74.7)	
Tachycardia, No. (%)	105 (13.2)	75 (20.6)	
Hypotension (blood pressure < 100 during hospitalisation)	51 (6.1)	59 (15.2)	<0.001
Frequency of comorbidities, No. (%)			
Hypertension	513 (61.9)	256 (66.3)	0.13
Ischaemic heart disease	681 (83.8)	296 (80.9)	0.22
Diabetes mellitus	388 (46.8)	177 (45.6)	0.69
Kidney disease	199 (24.1)	132 (34.2)	<0.001
Hyponatremia	125 (16.7)	85 (24.4)	0.003
Anaemia	281 (40.1)	170 (51.1)	0.001
Heart valve disease	263 (31.8)	149 (39.0)	0.01
Pulmonary hypertension	274 (41.3)	144 (49.3)	0.022
LVEF<40%	621 (82.9)	281 (83.6)	0.77
NYHA class IV	473 (81.7)	234 (86.3)	0.09
Medications used in follow-up, No. (%)			
ACEI/ARB	733 (89.8)	303 (82.1)	<0.001
Beta blocker	645 (81.1)	271 (75.5)	0.02
Diuretics	768 (94)	363 (96)	0.14
Aldosterone antagonist	524 (67.6)	235 (67)	0.82

*All p values are obtained from the result of X^2 test, except the age variable that used t-test, significance level of <0.05.

ACEI, ACE inhibitor; ARB, angiotensin receptor blocker; LVEF, left ventricular ejection fraction; NYHA class, New York Heart Association classification.

Materials and methods

Study design, sample and setting

In the present observational prospective cohort study, data of patients hospitalised with acute or decompensated HF from March 2015 until March 2016 were extracted from PROVE/HF registry. PROVE/HF was conducted in accordance with the Declaration of cinki provided in Persian language. All patients provided written informed consent for participation in the study and follow-up.¹⁷

PROVE/HF is part of this registry that registers acute or exacerbated and decompensated hospital-based patients with HF using the cold pursuit or retrospective method. In this method, trained personnel visit the archives of all 18 hospitals with cardiology wards in the city of Isfahan, including academic, public, private, military and charity ones. Their visits are done on daily basis, and after the confirmation of diagnosis by a cardiologist, using Framingham criteria,¹⁸ they collect the patients' information from their medical records. To check the content validity of the questionnaire, it was assessed whether the questions measure the desired attribute or not and whether the questions include the entire content of the test by 10 faculty members, cardiologists and experts from outside the project that resulted in a minimum acceptable content validity ratio (CVR) of 62%. Also, the minimum acceptable value for Content Validity Index (CVI)

was 0.79, so questions with values below this levels were omitted. The protocol and the related dictionary were written according to the validated questionnaire and approved by Quality Control Committee of PROVE. Then, the questionnaire, protocol, dictionary and data entry were taught to the personnel in three 2-hour sessions, in addition to monthly training sessions. The team visited the archives of the hospitals and corrected existing mistakes and data were reviewed for accuracy by the data management team and external quality control by the Quality Control Committee.

The recorded data included demographic information, underlying diseases and comorbidities, medications and treatments, the results of diagnostic and paraclinical tests, signs and symptoms and the results of physical examination. Based on the physical examination, tachycardia as HR >100 beats per minute (bpm) and normal rate as HR between 60 and 100 bpm. Hypotension was defined as systolic blood pressure <100 mm Hg and hypertension was defined as systolic blood pressure >140 mm Hg. Based on serum tests, hyponatremia was defined as serum sodium <135 mEq/L, anaemia was defined as serum haemoglobin <13 g/dL in male and <12 g/dL in female patients. Pulmonary hypertension was defined as pulmonary artery pressure >30 mm Hg.

Medications registered in follow-up included ACE inhibitor (ACEI), angiotensin receptor blocker (ARB), beta blocker (BB), diuretics and aldosterone antagonist. The history of ischaemic heart disease and heart valve disease, left ventricular ejection fraction (LVEF) and New York Heart Association (NYHA) classification were also collected.

In order to determine the survival rate of patients with HF and its relationship with demographic, clinical and treatment characteristics, the data of all patients registered in PROVE/HF questionnaire between March 2015 and 2016 were reviewed for repetition, resulting in 1223 non-repeated patients with complete data that included the study population.

Follow-up of PROVE/HF programme is performed by telephone calls and if necessary, by specialist physician visits at 1, 6, and 12 month(s) after the first admission in 2015. During follow-up, the collected data included the patient's current status, medications death, cause and place of death. Survival was defined as date of death (based on the death record) within a year after the first entry into PROVE/HF registry database; patients alive after 1 year were explained as 'censored' and dead patients as 'deceased'.

Statistical analysis

To describe quantitative variables, mean±SD deviation (SD), and for categorical outcome, number and percentage were used. To describe survival rate, Kaplan-Meier method and log-rank test was used. To compare quantitative characteristics between deceased or censored individuals, t-test and for categorical characteristics, X^2 test were used. To assess the HR of death and controlling the effect of confounders and other covariates, proportioned Cox regression was tested. For the statistical analysis, the statistical software STATA/SE (V.9.2) was used. P values of 0.05 or less were considered statistically significant.

RESULTS

Among 1223 patients with complete data, 835 (68.3%) patients were censored after 1 year, while 388 patients (31.7%) were deceased. Accordingly, we analysed the main predictors of mortality separately based on the deceased or live groups and compared their characteristics. As demonstrated in [table 1](#),

Table 2 Crude and adjusted analysis of predictors of 1-year mortality

Demographic and clinical characteristics	Crude coefficient			Adjusted coefficient		
	HR	CI	P values	HR	CI	P values
Male	0.95	0.78 to 1.17	0.66	0.89	0.59 to 1.32	0.57
Age	1.01	1.01 to 1.02	<0.001	1.01	0.99 to 1.02	0.23
Normal heart rate (60–100)	reference					
Tachycardia (HR >100)	1.47	0.86 to 2.49	0.15	1.74	1.13 to 2.68	0.01
Hypotension during hospitalisation	2.40	1.82 to 3.17	<0.001	1.80	0.96 to 3.40	0.06
History of hypertension	1.14	0.92 to 1.41	0.20	1.24	0.80 to 1.93	0.32
Ischaemic heart disease	0.82	0.63 to 1.07	0.15	1.35	0.81 to 2.24	0.24
History of diabetes mellitus	0.93	0.76 to 1.13	0.48	0.87	0.58 to 1.32	0.53
History of kidney disease	1.47	1.19 to 1.82	<0.001	1.40	0.92 to 2.13	0.11
Hyponatremia	1.57	1.23 to 2.01	<0.001	1.19	0.74 to 1.92	0.45
Anaemia	1.47	1.19 to 1.83	<0.001	1.14	0.78 to 1.67	0.48
Heart valve disease	1.35	1.10 to 1.66	0.003	1.11	0.74 to 1.66	0.58
Pulmonary hypertension	1.30	1.03 to 1.63	0.02	1.38	0.92 to 2.06	0.11
LVEF≤40	0.99	0.74 to 1.33	0.99	1.11	0.64 to 1.92	0.71
LVEF>40	reference					
NYHA class III	reference					
NYHA class IV	1.33	0.94 to 1.89	0.10	1.90	1.03 to 3.52	0.04
ACEI/ARB	0.51	0.39 to 0.67	<0.001	0.92	0.46 to 1.84	0.83
Beta blocker	0.72	0.56 to 0.92	0.008	0.63	0.40 to 0.97	0.03
Diuretic	1.37	0.82 to 2.30	0.22	1.11	0.39 to 3.17	0.84
Aldosterone antagonist	0.93	0.74 to 1.16	0.55	1.19	0.76 to 1.85	0.44

ACEI, ACE inhibitor; ARB, angiotensin receptor blocker; LVEF, left ventricular ejection fraction; NYHA class, New York Heart Association classification.

mean±SD age of the deceased patients' was significantly higher than alive patients ($p<0.001$), in both sexes. Sex did not differ between the two groups ($p>0.05$). The frequency of hypotension and tachycardia during hospitalisation was significantly higher in deceased patients ($p<0.05$). Among the comorbidities, the frequency of hypotension during hospitalisation, anaemia, hyponatremia, heart valve disease and renal disease of deceased patients was significantly higher in the deceased group (15.2 vs 6.1%, 51.1 vs 40.1%, 24.4 vs 16.7%, 39.0 vs 31.8%, respectively, $p<0.05$). The frequency of using two medications (ACEI/ARB and BB) in follow-up was higher in the alive group (89.8% vs 82.1%, $p<0.001$ and 81.1% vs 75.5%, $p=0.02$, respectively) (table 1).

Then, we tested the predictors by crude and adjusted analysis in the deceased group; as shown in table 2, crude analysis showed that age (HR 1.01, $p=0.01$), hypotension (HR 2.40, $p<0.001$), history of renal disease (HR 1.47, $p<0.001$), hyponatremia (HR 1.57, $p<0.001$), pulmonary hypertension (HR 1.30, $p=0.02$), heart valve disease (HR 1.35, $p=0.003$) and anaemia (HR 1.47, $p<0.001$) significantly predicted patients' mortality rate. Furthermore, HR was statistically significant for HF medications as survival predictors, including ACEI/ARB (HR 0.53, $p=0.001$) and BB (HR 0.67, $p=0.01$), but not for aldosterone antagonists and diuretics ($p>0.05$).

After adjustment, all variables which were significant lost their significance, except BB (HR 0.63, $p=0.03$), and tachycardia (HR 1.74, $p=0.01$) and NYHA class IV (HR 1.90, $p=0.04$) became significant predictors. Most patients in the present study had an NYHA class III or IV and only 31 patients had a NYHA class I and II, not entered in the model.

The Kaplan-Meier survival analysis of cumulative survival function of variables with statistically significant association and also medication consumption are demonstrated in figures 1 and 2.

DISCUSSION

The present study used the data of a pilot study called the first national registry of patients with CVDs and reported 1-year survival rate of 68.3% for patients with HF. To the best of our knowledge, it is one of the unique studies and the first result of the nationwide registry in Iran and the region. Several studies have reported the survival rates of patients with HF worldwide and quite few are similar to our results. For example, similar community-wide studies have reported 1-year mortality rate of nearly 38%^{19 20} and 30%,²¹ that are close to our results (nearly 32%). An Iranian cohort study investigated patients hospitalised with myocardial infarction (MI) in 540 hospitals in Iran and reported the 1-year mortality rate of patients with HF to be 18.2%,¹⁴ while the present study indicated a much higher mortality rate (31.7%), which is probably due to the different study design, as the nested case-control design in their study might underestimate the mortality rate. In addition, the differences in the demographic characteristics of the studied patients, such as age and male-to-female ratio, could be another justification for such a difference. Another Iranian study on 301 patients reported the 6-month mortality rate of 45.8%,¹⁵ which is much higher than the present study. Considering the fact that the cause of HF has a tremendous effect on the mortality rate,²² the difference between the studies could be due to the difference in the study population, as the study by Cheraghi and colleagues¹⁵ included only patients with decompensated congestive HF, which might have severe HF and lower LVEF due to the chronicity of their HF, compared with the patients with acute HF in the present study.²³

A deeper look into the results of different studies in the world shows diverse statistics for 1-year survival rate of patients with HF, ranging from 20% in US communities²⁴ to over 60% in Framingham Heart study,²⁵ which indicates various predictors for survival rate of patients with HF, as discussed further. Based

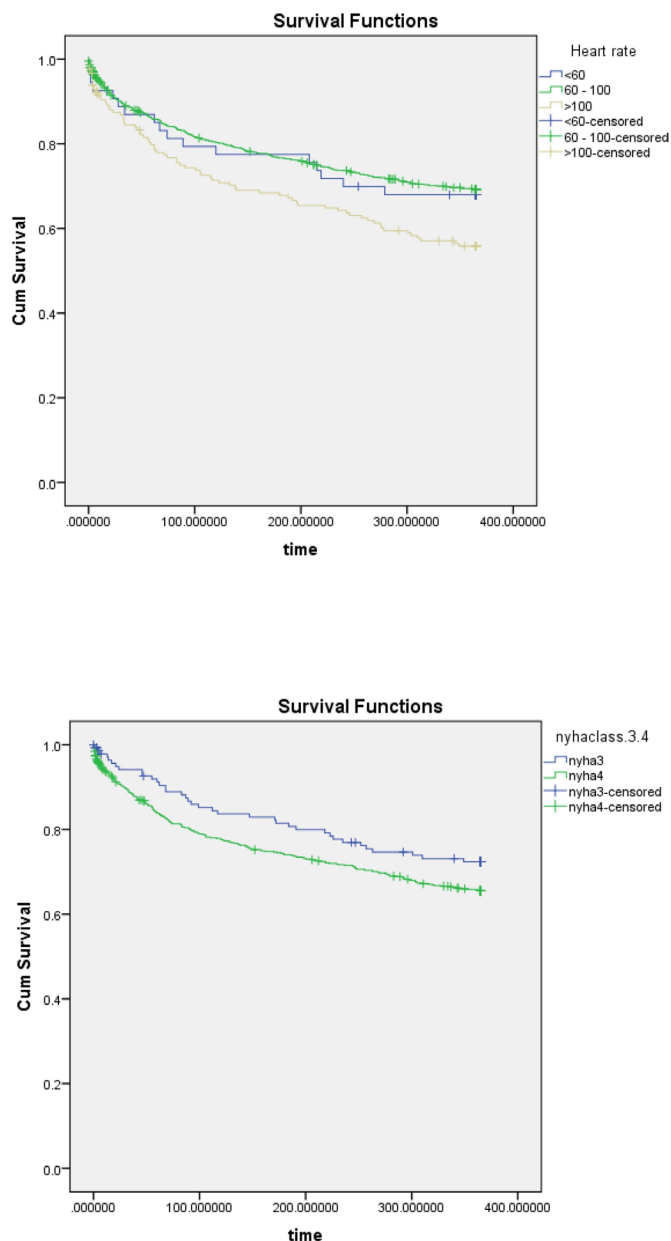


Figure 1 Kaplan-Meier analysis of cumulative survival function of variables with statistically significant association. NYHA class, New York Association Classification.

on the data of HF registry, various factors were statistically different between the live and deceased group. The mean age of deceased patients was significantly higher and further analysis indicated a HR of close to 1 for age and non-significant association of gender with mortality, which is consistent with the results of most studies, indicating no effect of demographic characteristics such as age and gender.^{20 26 27} Although some others have also raised a significant difference between mortality rate of patients with HF according to patients' sex,^{28 29} review studies suggest that this association may result from a bias,³⁰ and the difference in mortality rate of male and female patients is attributable to the difference in adherence to medications,³¹ which can explain the results of the current study on no significant difference between mortality rate of male and female patients. Furthermore, mean age of deceased patients was higher both in male and female patients in our study that shows the effect of increasing age on mortality rate of HF,⁵ rather than patients' sex alone.³²

In addition, the results of the present study indicated significant role of comorbidities on mortality rate. Investigating cardiac related factors showed that the only significant predictor of mortality after adjustment of other variables was NYHA class IV (end-stage HF). According to this classification, patients at the fourth stage of HF have dyspnoea at rest that results from decreased LVEF and a series of functional heart problems.³³ The significant role of NYHA class IV on patients' mortality indicate the significant effect of HF-associated comorbidities on patients' mortality; even though other variables including hypotension, hyponatremia, pulmonary hypertension and heart valve disease which were significant predictors of mortality lost their significance after adjustment, the significance of NYHA shows the importance of cardiac-related factors. Therefore, it is suggested that the underlying disease and cardiac conditions of patients with HF should be thoroughly followed by the physician. In the next step, non-cardiac comorbidities had a significant association with mortality rate at crude analysis, including tachycardia, hypotension, renal disease, hyponatremia, anaemia and pulmonary hypertension. These results are in line with the previous studies reporting the role of non-cardiac comorbidities (such as renal dysfunction, depression and anaemia) on survival of HF.^{22 34 35} The higher mortality rate in patients with hypotension is a logical finding, as lower blood pressure in HF is associated with cardiogenic shock and is indicative of lower LVEF and pump failure.²² The role of anaemia on HF mortality has been explained in several studies, which have suggested treatment of anaemia as an effective preventive factor for HF mortality.^{36 37} Therefore, appropriate treatment of the patients' comorbidities could be the key to reduce the mortality of the patients suffering from HF, which has to be further considered by healthcare staff, especially physicians.

Another noteworthy result of the present study was the statistically significant difference between live and deceased cases considering adherence to the use of medications in 1-year follow-up and emphasised on the protective effect of medication use (HR <1), which is consistent with the results of previous studies in other countries. As to the results of this study, BBs were more frequently used in the censored group and were protective factors of mortality in crude and adjusted logistic regression analysis. The beneficiary effect of BBs on HF-associated mortality has been well documented, hypothesised to be due to effects on left ventricle's geometry and function and myocardial energy balance.^{38 39} According to the results of this study, in line with previous studies, BBs should be the cornerstone of HF treatment.^{33 38 39} Investigating the predictive role of other drugs in the present study showed that ACEI/ARBs were also more frequently used in the censored group and were protective factors of mortality in crude logistic regression analysis, while after adjustment it lost its significance. ACEIs are prescribed in cases with HF following acute MI that inhibits apoptotic and remodelling effects of ACE and thus delays the progression of HF.⁴⁰ Nonetheless, the effect of ACEIs on mortality is controversial; some have associated it with decreased hospitalisation and mortality rates,⁴¹ while others have found no significant difference in mortality rate of the group using valsartan or placebo,⁴² which is in line with the results of the present study. There is also discrepancy in the results of different studies on the role of diuretics on mortality of HF, as some researchers suggested protective,⁴³ while others suggested higher mortality rates by diuretic use in patients with HF,⁴⁴ which is consistent with the results of the present study, although adherence to medications might be different among patients in different studies and as far as the assessment of taking medications regularly is exposed

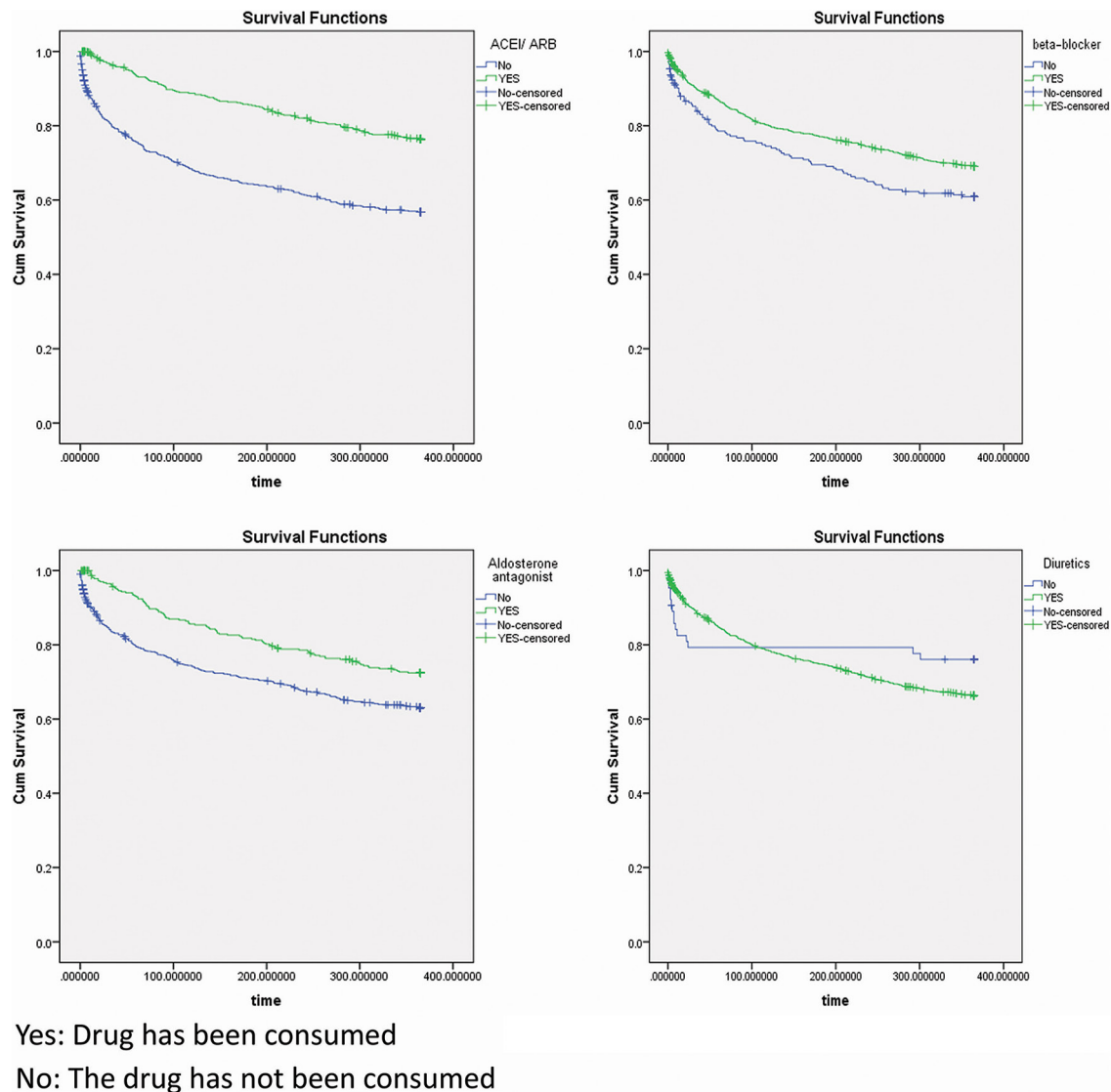


Figure 2 Kaplan-Meier analysis of cumulative survival function of medication consumption.

to recall bias, it might be hard to determine the pure effect of medications on HF mortality. Combinational therapy was investigated in an analysis of about 5000 patients hospitalised with acute HF in France that showed the significant effect of medications on the survival rate of patients and suggested better survival rate by diuretics+vasodilators and higher mortality rates for catecholamine inotropes,⁴⁵ which confirm the results of the present study regarding the significant role of medications on survival of patients with HF. These results suggest that education of patients and their caregivers on the benefits of the medications can improve the survival outcome of patients with HF, which has to be considered by policy-makers and managers of the health sectors in Iran.

Although the present study was the first to report HF survival rate from the pilot phase of the national registry, we could only report 1-year survival rate, but further data were not available, due to the recent start of this registry system. The results of the present study was also limited to in-hospital patients and a population-based study can better predict the real state of the community.

The 1-year mortality rate of in-hospital patients with HF was high in this study (31.7%), which necessitates paying more

attention to the predictors, such as treatment of underlying diseases and comorbidities (such as hypotension, tachycardia, pulmonary hypertension, anaemia) and patients' adherence to the medications (specifically ACEI/ARB and BB) to reduce the

Main messages

- The present study on survival rate of 1223 non-repeated patients with heart failure in Iran from a national registry showed 31.7% mortality rate.
- Comparison of demographics, medical history and other variables showed that deceased patients had higher frequency of hypotension during hospitalisation, anaemia, hyponatremia, heart valve disease and renal disease, pulmonary hypertension, tachycardia and less use of medications, ACE inhibitor/ angiotensin receptor blocker and beta blocker (BB) in the follow-up period.
- Adjusted Cox regression analysis identified tachycardia and New York Heart Association class IV as predictors of mortality and using BB as predictors of life.

Original article

Current research questions

- What is the 5-year survival rate of patients hospitalised with heart failure?
- What is the survival rate of out-patients plus in-patients with heart failure, which can show the real state of the community?
- Is the results of prospective studies on survival rate of patients hospitalised with heart failure different from the present study?

high mortality in Iranian patients with HF. The unanswered question of this study is the role of diuretics in mortality of HF has to be further investigated.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Ethics Committee of Isfahan University of Medical Sciences (project registry code: 394422).

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