ORIGINAL ARTICLE

Characteristics of patients with heart failure from Romania enrolled in - ESC-HF Long-Term (ESC-HF-LT) Registry

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Abstract: The ESC-HF Long-Term (ESC-HF-LT) Registry is a permanent, prospective, observational study conducted in 211 Cardiology Centers of 21 European and Mediterranean countries, members of the European Society of Cardiology (ESC). The present manuscript aims to assess 1-year outcomes of patients with HF, both acute and chronic, in the subset of patients enrolled in Romania, and to compare to the rest of patients enrolled in the registry.

From May 2011 to April 2013, a total of 12 440 patients were enrolled, 40.5% with acute HF and 59.5% with chronic HF. A number of 380 patients were enrolled in 10 Romanian centers, 329 with acute HF and 51 with chronic HF. In Romania, 1-year mortality was substantially higher in patients with acute HF compared to chronic HF patients (22.4% vs 6%), data similar to the rest of European countries. Notably, o proportion of 35.8% of patients with acute HF, have died or have been re-hospitalized during 1-year follow up. Although pharmacological treatments tend to increase over the time, these are underutilized when compared to other European countries. In Romania, utilization of HF device-based therapies is still very low.

The ESC-HF-LT registry shows that Romanian patients have similar prognostic characteristics as patients enrolled in other countries. 1-year mortality of patients with acute HF is higher than the mortality of chronic HF patients.

INTRODUCTION

Heart failure (HF) is a clinical syndrome that represents the common manifestation of diverse cardiac and non-cardiac pathologies. HF represents a condition with a negative impact on both the individual, because of lost years of life and by altering the quality of life, and on the health system, by raising the financial and social costs. In spite of increased survival, HF prevalence will continue to increase because of the ageing population and the increase in survival following acute conditions (myocardial infarction, acute valvular diseases).

Recent data of the *European Heart Failure Association* has shown that 26 millions of people have been diagnosed with HF, worldwide, and 3,6 million are newly diagnosed each year, only in Europe[1]. In Romania, the picture is even more dramatic - a percentage as high as 4,7% of the general population above 35 years, are diagnosed with HF[2].

Epidemiological data on HF is missing in many countries, because of the absence of relevant observational studies, to capture the incidence, prevalence, prognosis and main causes for HF. The understanding of the epidemiology and the clinical characteristics of HF in a certain population is key issue in improving prognosis. Randomized clinical trials bring important epidemiological information, but its generalization and applicability are limited by the very strict inclusion and exclu-

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sion criteria. Even though registries don't have such limitations and probably reflect the global population with HF in a certain geographical area, there are major differences at both continental and regional level, in regard to the severity, etiology and HF management[3].

There have been several registries and trials in Europe, in acute or chronic HF patients, but with several limitations, regard to the representatives for each country, the degree of data completion and especially, to 1-year follow-up[4-6].

The European HF-Long Term Registry is a permanent registry of the *European Society of Cardiology* (ESC)[7]. Its main objective was to describe the clinical epidemiology of ambulatory and hospitalized HF patients and the diagnostic and therapeutic procedures applied to these patients in Europe, including the HF management programs organization[7].

The present paper aims to characterize in terms of demography, clinical presentation, biology, and treatments, the subset of patients with HF enrolled in Romanian centers. Furthermore, other important objective of the study is to evaluate the 1-year prognosis of acute and chronic HF patients, in the subgroup of Romanian patients and to compare them with the rest of patients, enrolled in the registry.

METHODOLOGY

Study characteristics

The ESC HF-LT Registry is a prospective, multicenter, observational study, which enrolled patients with HF in 211 cardiology centers from 21 countries affiliated to the (ESC). Center selection was made based on geographic representatives and accounting for medical facilities available at national level. In each country, for every 2 million inhabitants, one investigational center was assigned. At the moment of the present analysis, a total number of 12440 patients were enrolled, starting with May 2011, and of these, 380 patients had been enrolled in Romania.

Inclusion criteria

All ambulatory patients with HF evaluated in clinics and those hospitalized for acute HF (either previously diagnosed, or de novo HF), for which intravenous therapy was required, were included. To facilitate consecutive enrolment, patients were enrolled in the registry on a one-day-per-week basis. One 12 months follow up visit was mandatory to collect morbidity and mortality data (death, re-hospitalization). A telephone call visit was accepted to replace the clinical visit, if the patient was unable to arrive at the reference centers. During the course of the year patients were followed-up according to the usual practice of each center.

There were no specific exclusion criteria, except age (which had to be above 18 years). The study was approved by each local Ethics Committee, according to the local rules of each participating country. The data on the study were not collected before detailed information was given to the patient and the informed consent form was signed.

At 1-year follow-up, the data of the patients enrolled during the main part (data of study patients from the best 12 consecutive months, for each country) was analyzed.

Participating centers

The patients were enrolled in the following countries and regions: Lithuania and Sweden (Northern countries); Bosnia & Herzegovina, Bulgaria, Czech Republic, Hungary, Latvia, Poland, Romania and Slovakia (Eastern countries); Austria and France (Western countries); Greece, Italy, Portugal, Serbia, Slovenia, and Spain (Southern countries).

There were 10 centers in Romania: 3 in Bucharest, 1 in Timisoara, 1 in Galati, 1 in Brasov, 1 in Slobozia, 1 in Iasi, 1 in Targoviste and 1 center in Focsani. (Appendix 1).

Statistical analysis

Categorical variables were expressed as numbers and proportions (N, %) and continuous variables as mean or median, based on distribution (mean, SD, median, interquartile ranges). All results were presented for regions (Romania vs. other countries in EU) and for subgroups (acute vs. chronic HF).

Categorical variables were compared by the X2 test and continuous variables by a non-parametric test (Kruskal-Wallis test). Demographical and clinical characteristics and type of treatments were also compared between the HF cohort of Romania (RO) and the rest of the participating countries (other EU).

Plots of Kaplan-Meier curves for time to all-cause death, time to admission to hospital for HF and time to all-cause death or HF hospitalization were performed. In addition, these plots were divided into outpatients with chronic HF and in patients with acute HF.

A p-value <0.05 was considered statistically significant. All test were two-sided. Analyses were performed with program R (Vienna University of Economics and Business Administration, Vienna, Austria) and the package Hmisc (Vanderbilt University, Nashville, Tennessee).

RESULTS

During the enrolment period 12440 patients were enrolled in the registry. Of these, 380 patients were enrolled in Romania, representing 3.7% of the total number of patients. With regard to the clinical form of HF, 51 patients had chronic HF and 329 patients had hospitalized HF.

The differences in demographic, clinical, biological characteristics between the two populations are presented in Table 1. Compared to patient with chronic HF, hospitalized HF patients have lower SBP, lower EF and more frequent ischemic etiology. Also, patients with acute HF are more frequently in NYHA classes III and IV (91.2% vs 52.9%; p<0.0001). In-hospital mortality of acute HF patients was 4.9%.

1-year follow-up analysis revealed significant differences regarding the adverse event rate (death, HF hospitalization, death or hospitalization) between the chronic HF and hospitalized HF patients, enrolled in Romania. 1-year mortality in patients hospitalized for acute HF was 24.4% and 6% in chronic HF. A percentage of 15.2% of acute HF patients are readmitted at 1 year because of HF and 8.9% of patients with chronic HF have a readmission due to HF, when analyzed at 1-year follow-up (Table 2).

The Kaplan-Meyer curves show that these differences become larger as the duration of patient' follow-up increases (Figures 1, 2 and 3).

Regarding the comparison between patients enrolled in Romania and those in other participating countries, this is differentially presented for patients with acute HF (Table 3) and those with chronic HF (Table 4).

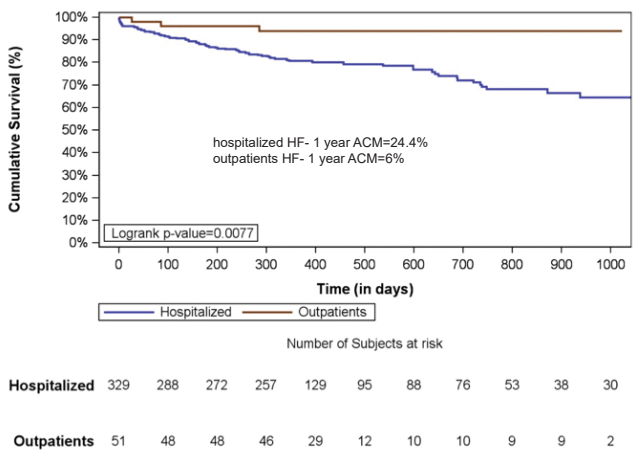

Figure 1. Kaplan-Meyer survival curves for all-cause mortality in patients with acute hospitalized HF and chronic ambulatory HF; data from Romanian subgroup.

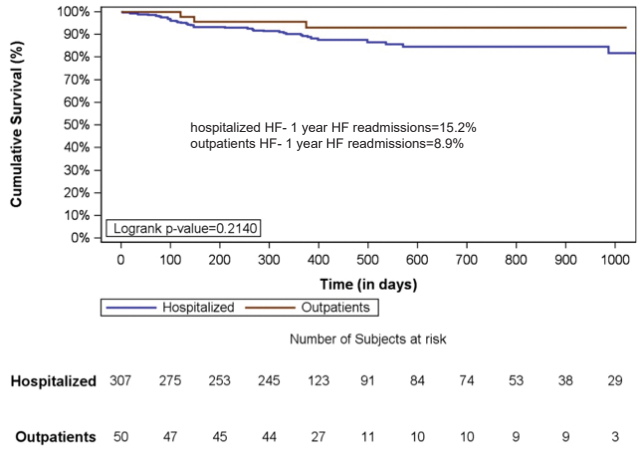

Figure 2. Kaplan-Meyer survival curves for HF readmissions in patients with acute hospitalized HF and chronic ambulatory HF; data from Romanian subgroup.

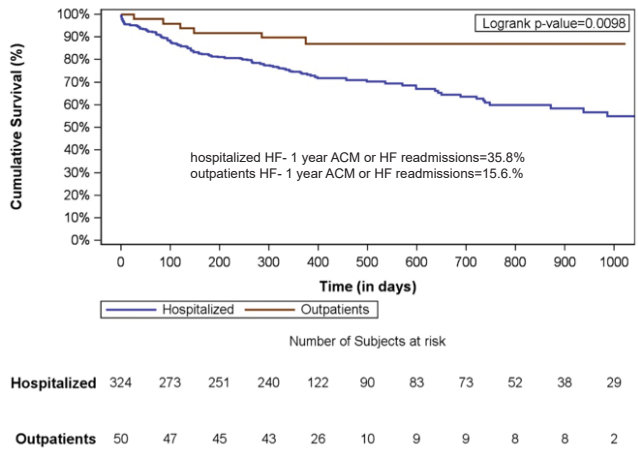

Figure 3. Kaplan-Meyer survival curves for all-cause mortality or HF readmissions in patients with acute hospitalized HF and chronic ambulatory HF; data from Romanian subgroup.

Generally, the clinical characteristics at presentation are similar between patients with acute HF enrolled in Romania and patients enrolled in the rest of the participating countries. There are differences on female sex prevalence (Table 1) and the proportion of comorbidities, anemia, respiratory disease, less frequent in the Romanian population. The frequency of clinical forms of acute HF is also similar. In-hospital mortality was identical (4.9%). Significant differences exist between the rate of device treatment, which is considerably lower in Romania. Also, for the neurohormonal medication at discharge, o smaller proportion of Romanian patients received beta-blockers (BB) and angiotensin conversion enzyme inhibitors (ACEI) as compared to other European countries. Digoxin use at discharge is more frequent in Romania.

Table 1. Heart Failure Long-Term analyses for Country Romania; baseline characteristics - Country Romania

	Acute HF (n=329)	Chronic HF (n=51)	p
Demographics			
age >=70 years	55.6%	56.9%	0.8683
Female (%)	48.9%	51.0%	0.7858
BMI >=30 kg/sqm	25.8%	9.8%	0.0122
Initial symptoms and evaluation			
NYHA class III/IV	91.2%	52.9%	<0.0001
SBP (mmHg) median (IQR)	135 (120-160)	141.0 (130.0-157.0)	0.0430
HR (bpm)median	84.0 (71.0-102.0)	75.0 (66.0-90.0)	0.0055
EF% median (IQR)	40.0 (35.0-50.0)	42.5 (30.0-55.0)	0.5217
EF >45%	33.3%	42.9%	0.5546
Atrial fibrilation	46.8%	64.7%	0.0174
Hemoglobine (g/dl)median (IQR)	13.2 (11.9-14.5)	12.7 (11.6-14.2)	0.3270
Hb <=12g/dl	27.8%	29.0%	0.8817
Medical history			
Prior HF without previous hospitalizations	50.6%	94.1%	<0.0001
MI/angina	50.9%	29.4%	0.0042
DM	33.1%	19.6%	0.0527
Hypertension treatment	62.4%	82.0%	0.0068
Chronic renal dysfunction	22.0%	15.7%	0.3078
COPD	13.1%	3.9%	0.0584
Prior Stroke/TIA	12.8%	11.8%	0.8354
Peripheral vascular disease	9.1%	3.9%	0.2843
Hepatic dysfunction	7.3%	2.0%	0.2256
Primary etiology			
Ischemic heart disease	55.3%	5.9%	<0.0001
Dilated cardiomyopathy	9.1%	19.6%	
Valvular heart disease	13.7%	47.1%	
Hypertension	13.1%	21.6%	

HHF, hospitalized heart failure; CHF, chronic heart failure; DM, diabetes mellitus; IQR, interquartile range; BMI, body mass index. SBP, systolic blood pressure; HR, heart rate; EF, ejection fraction; MI, myocardial infarction; COPD, chronic obstructive pulmonary disease; TIA, transient ischemic attack; SBP, systolic blood pressure

1-year mortality is similar (24.4% vs 28.1%; p=0.157), but the number of patients readmitted because of HF is smaller in Romania, as compared to other participating countries (15.2% vs 27.1%; p<0.0001).

As regard to chronic HF patients, the Romanian population is older and female sex is more prevalent. As compared to other countries, chronic HF patients enrolled in Romania have o higher prevalence of atrial fibrillation (64.7% vs 37.4%; p<0.0001) and valvular etiology (47.1% vs 8%; p<0.0001). No significant difference was found between the neurohormonal medication between patients with chronic HF in Romania and patients in other countries. Also, the adverse event rate at one year was similar for patients enrolled in Romania, as compared to other countries. 1-year mortality in chronic HF Romanian patients was 6%, while in other countries was 8% (p=0.757).

DISCUSSION

This data represents the most recent epidemiological European experience as regard to observational studies. The ESC HF LT registry is one of the few observational studies with 1-year follow-up for both patients with acute HF and those with chronic HF. Importantly, the response rate at 1 year follow-up was above 95%. Although Romania has a good coverage and a good epidemiological knowledge of population of acute HF patients, there hasn't been so far a national registry with rigorous follow-up after hospitalization[2,8,9].

Similar to other European countries and to the previous registry of the *European Society of Cardiology,* the classification of patients with HF in two types - chronic (in ambulatory practice) and acute HF (that requires hospitalization) has clinical and prognostic value[6]. There are significant differences regarding 1-year mortality and the readmission rate between the two categories, regardless of geographical area, observational study or year of enrollment.

For a population of about 20 million inhabitants, Romania had a medium enrollment rate, with 380 HF patients, representing 3.7% from the total number of enrolled patients.

Interestingly, most Romanian patients had acute HF, which may be explained by the type of ambulatory

Table 2. 1-year FU Outcomes - Heart Failure Long-Term analyses for Country Romania

	Total (n=12440)	Romania (n=380)	Other countries (n=12060)	p
Hospitalized patients				
All-cause of death	27.9%	24.4%	28.1%	0.1587
CV death	51.7%	49.4%	51.8%	0.0664
Non CV death	13.7%	6.5%	14.1%	
Unknown	34.7%	44.2%	34.1%	
All-cause of hospitalization	44.8%	26.0%	46.3%	<0.0001
HF hospitalization	26.2%	15.2%	27.1%	<0.0001
All-cause of hospitalization and HF hospitalization	47.2%	35.8%	48.1%	<0.0001
Outpatients				
All cause death	8.5%	6.0%	8.5%	0.7976
CV death	49.8%	33.3%	49.9%	0.3219
Non-CV deaths	23.2%		23.3%	
Unknown	27.0%	66.7%	26.8%	
All cause hospitalization	27.4%	22.2%	27.4%	0.4341
HF hospitalization	12.0%	8.9%	12.0%	0.5199
All-cause of hospitalization and HF hospitalization	18.7%	15.6%	18.8%	0.5820

CV, cardio vascular; HF heart failure

Table 3. Comparison between hospitalized patients with heart failure in Country Romania and other countries participating in ESC-HF Long Term registry - Country Romania

	Romania (N=329)	Other countries (N=4710)	p
Demography			
Female	48.9%	36.4%	<0.0001
age >=70 years	55.6%	53.0%	0.3554
Clinical presentation			
SBP (mmHg)median (IQR)	135.0 (120.0-160.0)	130.0 (110.0-150.0)	0.0002
BMI >=30 kg/sqm	25.8%	33.9%	0.0029
EF (%)Median (IQR)	40.0 (35.0-50.0)	38.0 (30.0-52.0)	0.4444
EF >45%	33.3%	32.8%	0.9073
Medical history			
Atrial fibrillation	46.8%	43.8%	0.2948
DM	33.1%	39.3%	0.0265
Hypertension treatment	62.4%	64.7%	0.4069
Chronic renal dysfunction	22.0%	26.7%	0.0614
Hepatic dysfunction	7.3%	8.5%	0.4663
COPD	13.1%	20.7%	0.0010
Prior stroke/TIA	12.8%	13.0%	0.9205
Peripheral vascular disease	9.1%	14.6%	0.0063
Smokers	38.3%	52.5%	<0.0001
Hemoglobine <=12g/dl	27.8%	40.9%	<0.0001
Primary etiology			
Ischemic heart disease	55.3%	53.9%	0.0087
Dilated cardiomiopathy	9.1%	14.2%	
Valvular heart disease	13.7%	11.9%	
Hypertension	13.1%	9.0%	
other	8.8%	10.9%	
Hospital presentation			
Pulmonary edema	12.5%	12.6%	0.0614
Cardiogenic shock	4.3%	2.4%	
IC decompensata	59.9%	63.4%	
Hypertensive HF	6.1%	5.1%	
Right HF	1.8%	3.8%	
ACS/HF	15.5%	12.8%	

Table 3. Comparison between hospitalized patients with heart failure in Country Romania and other countries participating in ESC-HF Long Term registry - Country Romania

	Romania (N=329)	Other countries (N=4710)	p
In-hospital mortality	4.9%	4.9%	0.9453
Devices			
No	93.2%	84.8%	<0.0001
PM	5.0%	6.3%	
CRT-P	1.2%	0.6%	
CRT-D		3.3%	
ICD	0.6%	5.1%	
Acute treatment			
IV Diuretics	73.7%	82.1%	0.0002
IV Nitrates	16.7%	20.7%	0.0897
Inotropic support	13.9%	11.5%	0.1863
Medications at discharge			
ACEI/ARBs	64.8%	77.6%	0.0001
Beta-blockers	66.3%	73.1%	0.0075
MRAs	52.9%	53.9%	0.7100
Diuretics	78.7%	84.2%	0.0088
Digitalis	38.3%	25.0%	<0.0001

IQR, interquartile range; SBP, systolic blood pressure; BMI, body mass index; EF, ejection fraction. COPD, chronic obstructive pulmonary disease; TIA, transient ischemic attack; ACS, acute coronary syndrome. HF, heart failure; PM, Pacemaker; CRT, cardiac resynchronization therapy; D, defibrillator; ICD, implantable cardioverter defibrillator; ACE, angiotensin enzyme inhibitor; ARB, angiotensin receptor blocker; MRA, Mineralocorticoid receptor antagonists. Kruskal-Wallis test is used for quantitative data. Chi-2 or Fisher exact test [a] is used for binary variables. For qualitative variables with more than 2 possibilities; the Monte Carlo estimates of the exact p-values are used.

Table 4. Comparison between CHF patients in Country Romania and other countries participating in ESC-HF long term registry - Country Romania

	Romania (N=329)	Other countries (N=4710)	p
Demography			
Age >=70 years	56.9%	39.4%	0.0110
Female	51.0%	28.6%	0.0004
Clinical presentation			
Systolic BP (mmHg) median	141.0	120.0	<0.0001
BMI (Kg/sqm) >=30 kg/sqm	9.8%	31.1%	0.0010
EF(%)Median	42.5	35.0	0.1184
EF>45%	42.9%	23.1%	0.1066
Medical History			
Atrial fibrillation	64.7%	37.4%	<0.0001
DM	19.6%	31.9%	0.0608
Hypertension treatment	82.0%	58.1%	0.0006
Chronic renal dysfunction	15.7%	18.2%	0.6366
Hepatic dysfunction	2.0%	3.4%	>0.999
COPD	3.9%	13.9%	0.0395
Prior stroke/AIT	11.8%	9.4%	0.4770
Peripheral vascular disease	3.9%	12.3%	0.0679
Smokers	35.3%	52.9%	0.0119
Hemoglobine <=12g/dl	29.0%	23.5%	0.4698
Primary ethiology			
Ischemic coronary disease	5.9%	43.2%	<0.0001
Dilative cardiomiopathy	19.6%	29.8%	
Valvular heart disease	47.1%	8.0%	
Hypertension	21.6%	7.8%	
Other	5.9%	11.1%	
Devices			
No	88.2%	64.8%	0.0001
PM	11.8%	5.8%	
CRT-P		2.3%	

Table 4 (CTD). Comparison between CHF patients in Country Romania and other countries participating in ESC-HF long term registry - Country Romania

	Romania (N=329)	Other countries (N=4710)	p
CRT-D		11.1%	
ICD		16.0%	
Medication at out-patient visit			
ACEI/ARBs	84.3%	89.2%	0.2642
Beta-blockers	88.2%	88.9%	0.8740
MRAs	56.9%	59.3%	0.7216
Diuretics	90.2%	83.0%	0.1729
Digitalis	39.2%	22.8%	0.0056
Statins	39.2%	61.0%	0.0015
Anti-platelets	52.9%	48.6%	0.5382
Nitrates	3.9%	19.5%	0.0050
CCBs	17.6%	11.2%	0.1489
Anticoagulants	47.1%	42.3%	0.4946
Amiodarone		13.9%	0.0042
Ivabradine		8.5%	0.0201

IQR, interquartile range; SBP, systolic blood pressure; BMI, body mass index; EF, ejection fraction; COPD, chronic obstructive. pulmonary disease; TIA, transient ischemic attack; PM, Pacemaker; CRT, cardiac resynchronization therapy. D, defibrillator; ICD, implantable cardioverter defibrillator; ACE, angiotensin enzyme inhibitor; ARB, angiotensin receptor blocker; - MRA, Mineralocorticoid receptor antagonists; - CCBs, Calcium channel blocker

practice of the affiliated hospitals in Romania. Importantly, there were no significant differences for 1-year mortality between HF patients in Romania and those enrolled in other countries. Like in other countries, 1-year mortality was different between patients with acute HF and those with chronic HF (22.4% vs 6%). Also, as for the number of patients requiring hospitalization for any cause during the 1-year follow-up, there were differences between patients with acute and chronic HF (26% vs 22%). It is worth to note that regardless of region or the type of HF patients, more than half of re-admissions are not related to worsening HF. This should be carefully noticed when strategies to lower re-hospitalisation ratse are considered. Many of re-admissions are non-cardiac in origin and are due to worsening of non-cardiac comorbidities, as theese are very frequent both in patients with acute and chronic HF. Thus, identification and treating comorbidities remain an important target during hospitalization and represent a component of comprehensive management directed to decrease post-discharge outcomes.

Although, no substantial differences in 1-year mortality have been detected between patients enrolled in Romania and in other counties, the rate of 1-year re admissions was considerably lower in Romania compared to other countries. This may be explained by the absence of universally accepted criteria for HF admission, as well as by different pshychological and social thresholds for hospital admission influenced by the differences in cultural perception of severity.

For the patients hospitalized in Romania, the frequency of which received the guideline recommended therapy at discharge, was lower than in other European countries[10]. Although in Romania, there has been a continuous increase in prescription of evidence based therapies[2], there probably still exist a large number of patients that are eligible to receiving such medication. From a Romanian perspective, by analyzing

Table 5. Comparison between two registries for use of oral therapies and procedures during hospitalization

	RO-AHFS study (2007-2009) n=3224	ESC HF LT Registry (2011-2014) n=329
Beta-blockers (%)	55.9	66.3
ACE/ARBs (%)	61.2	64.8
MRAs (%)	54.3	52.9
Digitalis (%)	40	38.3
Diuretics (%)	81.2	78.7
VVI-P (%)	1.9%	5%
CRT/ICD (%)	0.27	1.8%

ACE, angiotensin enzyme inhibitor; ARB, angiotensin receptor blocker; MRA, Mineralocorticoid receptor antagonists; VVI-P VVI pacemaker, CRT, cardiac resynchronization therapy, ICD, implantable cardioverter defibrillator

two epidemiological studies that took place at 5 years apart (Table 5), an increase in the prescription of oral medications at discharge can be noticed. This is mainly true for beta-blockers, for which there has been an absolute increase of 10%. By using this percentage to the proportion of HF patients hospitalized in Romania and by knowing that the number needed to treat with BB to save a life is 15, we can estimate that approximately 1400 HF patients had a survival benefit by increasing the rate of BB use in this 5-year interval[11].

Unfortunately, the rate of use of HF related devices and interventional procedures, although is increasing, is still unacceptably low, and reflect lack of these facilities and probably overall economic development. National programs to implement larger in-hospital utilization of these procedures are needed.

LIMITATIONS

ESC HF LT registry has enrolled patients capable of understanding and signing the informed consent. This fact, limited the enrollment of patients that are in a critical state at admission, who not have the capacity to sign. Also, patients who died in the first 24 hours (criteria used to define hospitalization) were not enrolled, fact which may underestimate in-hospital mortality. Another methodological request of the registry was the ability to be contacted and to be willing to participate in a follow-up visit. All these limitations, which actually represent very rigorous methodological criteria, may contributed to a lower proportion of severe patients, and to an adverse event rate smaller than expected.

Another important limitation is that the enrollment rate varied significantly between participating centers.

CONCLUSIONS

Rigorous epidemiological research represents the mainstay for precise knowledge of a certain pathology at national and regional level. HF is a multi-event disease and accurate characterization of these patients is critical for improving long-term outcomes. The ESC-HF-LT registry confirms that patients with acute HF have a worse prognosis than patients with chronic HF, regardless of geographical region, and for the hospitalized HF patients, risk to die extends beyond the period of hospitalization. In Romania, HF represents a severe clinical condition that is associated to a high rate of death and re-hospitalizations, which is particularly dramatic for acute HF patients, meaning that 36% of patients either die or are re-hospitalized during 1-year follow-up.

Conflict of interest: none declared.

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APPENDIX 1

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