EURObservational Research Programme: The Heart Failure Pilot Survey (ESC-HF Pilot)

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The ESC-HF Pilot study is a prospective, multicentre, observational survey conducted in 136 cardiology centres from 12 European countries selected to represent the different health systems and care attitudes across Europe. All outpatients with HF and patients admitted for acute HF were included during the enrolment period (1 day per week for 8 consecutive months). From October 2009 to May 2010, 5118 patients were included in this pilot survey, of which 1892 (37%) were admitted for acute HF and 3226 (63%) for chronic HF. Ischaemic aetiology was reported in about half of the patients. In patients admitted for acute HF, the most frequent clinical profile was compensated HF (75% of cases), whereas pulmonary oedema and cardiogenic shock were reported, respectively, in 13.3 and 2.3% of the cases. The total in-hospital mortality rate was 3.8% and was cardiovascular in 90.1% of the cases. Lowest and highest mortality rates were observed in hypertensive HF and in cardiogenic shock, respectively. More than 80% of patients with chronic HF were treated with renin–angiotensin–aldosterone system blockers and β-adrenergic blockers. However, target doses of such drugs were reached in one-third to one-fourth of the patients only.

The ESC-HF Pilot Survey was an example of the possibility of utilizing an observational methodology to get insights into the current clinical practice in Europe, whose picture will be completed by the 1-year follow-up. Moreover, this study offered the opportunity to refine the organizational structure of a long-term, extended European network.

Aims

The primary objective of the new ESC-HF Pilot Survey was to describe the clinical epidemiology of outpatients and inpatients with heart failure (HF) and the diagnostic/therapeutic processes applied across 12 participating European countries. This pilot study was specifically aimed at validating the structure, performance, and quality of the data set, for continuing the survey into a permanent registry.

Methods and results

The ESC-HF Pilot study is a prospective, multicentre, observational survey conducted in 136 cardiology centres from 12 European countries selected to represent the different health systems and care attitudes across Europe. All outpatients with HF and patients admitted for acute HF were included during the enrolment period (1 day per week for 8 consecutive months). From October 2009 to May 2010, 5118 patients were included in this pilot survey, of which 1892 (37%) were admitted for acute HF and 3226 (63%) for chronic HF. Ischaemic aetiology was reported in about half of the patients. In patients admitted for acute HF, the most frequent clinical profile was compensated HF (75% of cases), whereas pulmonary oedema and cardiogenic shock were reported, respectively, in 13.3 and 2.3% of the cases. The total in-hospital mortality rate was 3.8% and was cardiovascular in 90.1% of the cases. Lowest and highest mortality rates were observed in hypertensive HF and in cardiogenic shock, respectively. More than 80% of patients with chronic HF were treated with renin–angiotensin–aldosterone system blockers and β-adrenergic blockers. However, target doses of such drugs were reached in one-third to one-fourth of the patients only.

Conclusion

The ESC-HF Pilot Survey was an example of the possibility of utilizing an observational methodology to get insights into the current clinical practice in Europe, whose picture will be completed by the 1-year follow-up. Moreover, this study offered the opportunity to refine the organizational structure of a long-term, extended European network.

Keywords

Acute heart failure • Chronic heart failure • Prognosis • Observational studies • Pharmacological treatments

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Introduction

Chronic heart failure (HF) is associated with a high burden of mortality and morbidity, reduced quality of life, and increasing healthcare costs in Europe as well as across the world.\(^1\)\(^-\)\(^4\) Although the incidence of HF seems to show a plateau after three decades of marked increase,\(^5\)\(^,\)\(^6\) age-related prevalence is still increasing with a concomitant increase in the number of related hospitalizations for worsening or acute HF episodes.

Acute HF is a complex, heterogeneous, clinical syndrome characterized by a rapid onset of signs and symptoms of cardiovascular failure, and it is often life-threatening, requiring urgent therapy.\(^7\)\(^-\)\(^10\) In the USA, a primary diagnosis of acute HF accounts for more than 1 million hospitalizations every year, with similar numbers suggested also for Europe.\(^2\)\(^,\)\(^7\)\(^,\)\(^8\) Advances in diagnosis and therapy are limited, and so patients with acute HF continue to have a poor short- and long-term prognosis.\(^8\)\(^-\)\(^13\)

Registries and surveys have been conducted in patients with either chronic or acute HF, but a description of the entire clinical history of patients with HF, including the acute episodes, and the consequent changes in clinical conditions and in the management strategies are not available.

A survey able to capture all the relevant clinical information of patients with chronic HF, including their acute episodes of decompensation, could allow us to improve our knowledge on the epidemiology and outcomes of real-world patients with this clinical condition. The ESC-HF Pilot study has been planned in this line. The primary objective of the ESC-HF Pilot study has been planned in this line. The primary objective of the ESC-HF Pilot study was to describe the clinical epidemiology of outpatients and inpatients with HF and their diagnostic/therapeutic processes applied in the 12 participating European countries. The ESC-HF Pilot phase was specifically aimed at validating the structure, performance, feasibility, and quality of the data set, with the intention of continuing the survey into a permanent registry.

Methods

Study design and clinical setting

The principles of the new EURObservational Research Programme (EORP) of the ESC have been previously published.\(^14\)

The ESC-HF Pilot study is a prospective, multicentre, observational survey of patients presenting to 136 cardiology centres from 12 European countries. These countries were selected on the basis of (i) previous performances in the Euro Heart Surveys and (ii) geographical distribution subdivided as follows:

(i) four Western European countries (Austria, France, Germany, and The Netherlands);
(ii) two Eastern European countries (Romania and Poland);
(iii) three Southern European countries (Greece, Italy, and Spain), and
(iv) three Northern European countries (Denmark, Norway, and Sweden).

The National Cardiology Societies of each country agreed to participate in the programme and were asked to select hospitals of different levels of complexity from which patients would be recruited. The aim was to involve a broad spectrum of cardiology and/or HF units following outpatients with HF and admitting patients with acute, pre-existing, or new onset HF to build up a network of centres representative of European reality.

The number of participating centres for each country was decided according to the number of inhabitants from that country, i.e. one centre per 2 million people, but no more than 25 and no less than 6 per country. As far as possible, the centres were to also fulfil geographical criteria within each country. This included a balanced proportion of centres with a different range of facilities for cardiology. For example, the ratio for a country contributing 25 centres was as follows:

(i) 5 centres with cardiac surgery,
(ii) 8 centres with interventional cardiology [percutaneous coronary intervention/cardiac resynchronization therapy (CRT)/implantable cardioverter defibrillator (ICD)], and
(iii) 12 community centres with no surgery or interventional cardiology.

The EORP Department at the European Heart House was appointed to operationally coordinate the project, provide support to the Committees, National Coordinators, and participating centres, and to guard the methodological concepts of the survey. The database was set up at the European Heart House, according to the requirements defined by the appointed Executive Committee with the support of the EORP Department.

The statistical analysis was performed at the ANMCO Research Center, Florence, Italy.

Inclusion criteria

All outpatients with HF seen at the clinics and those admitted for acute, pre-existing, or new onset HF were included during the enrolment period (1 day per week for 8 consecutive months). Therefore, during the course of the screening day, the following patients were entered in the survey:

- all outpatients with chronic HF diagnosed according to the clinical judgement of the responsible cardiologist at the participating centres;
- patients admitted to hospital for acute HF, for whom an intravenous therapy (inotropes, vasodilators, or diuretics) was needed.

There were no specific exclusion criteria, with the exception that all patients had to be aged over 18 years.

The survey was approved by each local Institutional Review Board according to the rules of each participating country. No data were collected before detailed information was provided to the patient, and a signed informed consent was obtained.

Statistical analysis

Continuous variables are reported as mean ± standard deviation or as median and inter-quartile range (IQR). Categorical variables are reported as percentages and compared by the \(x^2\) test. Continuous variables are compared by the t-test or the Mann–Whitney U-test. A P-value of <0.05 was considered statistically significant. All tests were two-sided. Analyses were performed with SAS system software (SAS Institute, Inc., Cary, NC, USA).

Results

From October 2009 to May 2010, 5118 patients were included in this ESC-HF Pilot Survey. Figure 1 shows the number of centres and patients stratified by (i) areas of recruitment and (ii) inpatients with acute HF and outpatients with chronic HF.
In-hospital patients were generally older than ambulatory patients with chronic HF and were more often female (Table 1). As expected, co-morbidities were more frequent in patients admitted for acute HF, whereas the rate of implanted devices was more common in patients with chronic HF. More than half of the patients with acute HF had an ischaemic aetiology, confirmed by coronary angiography in 64% of the cases. In patients with chronic HF, an ischaemic aetiology accounted for just 40% of the cases, but angiographic confirmation was available for 85% of the cases.

### Specific features of the in-hospital patient population

At hospital entry, clinical signs of pulmonary congestion were detected in 62% of the cases, peripheral congestion was detected in 65%, and either pulmonary or peripheral congestion was detected in 82% of the cases. Clinical signs of peripheral hypoperfusion were reported in 8.6% of the patients; 10.5% of admitted patients were described as somnolent or confused.

Intravenous diuretics were used in 84.6% of the cases. The median dose of furosemide used during the hospital stay was 60 mg per day (IQR 40–100). Nitrates and inotropes were administered in 18.5 and 10.5% of the patients, respectively. Among inotropes, the most used was dobutamine (in 4.6% of the patients) followed by levosimendan (in 2.4% of the patients).

At the electrocardiogram performed at hospital entry, atrial fibrillation was diagnosed in 35% of the cases and a large QRS (≥120 ms) was detected in 35.5% of the patients. Left ventricular hypertrophy was reported in 16.1% of the cases. An echocardiographic examination was performed in 75% of the patients. The median ejection fraction was 38% (IQR 27–52); 39.1% of the patients had a preserved ejection fraction, defined as >40%. A moderate-to-severe mitral regurgitation was diagnosed in 43.4% of the patients.
Anaemia, defined as a haemoglobin level <12 g/dL, was detected in 31.4% of the patients; an estimated glomerular filtration rate (eGFR) 50 and 30 mL/min/1.73 m² was reported, respectively, in 32.9 and 9.8% of the patients. N-terminal pro-brain natriuretic peptide and brain natriuretic peptide (BNP) were measured at entry in 489 and 204 patients only, respectively. The median values were 4007 pg/mL (IQR 2043–9487) and 870 pg/mL (IQR 423–1950), documenting the severity of the clinical conditions at hospital admission. Troponin (I or T) was measured in 987 patients with a median value of 0.04 ng/mL (IQR 0.01–0.29).

Figure 2A shows the stratification of in-hospital patients according to the clinical profiles of the ESC guidelines.5 Decompensated HF (75% of the cases) was most frequent, whilst pulmonary oedema and cardiogenic shock were reported in 13.3 and 2.3% of the patients, respectively. Figure 2B shows the overall rate of in-hospital mortality and that stratified by clinical profiles. Overall, 71 patients died during the hospital stay; the highest mortality rate being observed in patients with cardiogenic shock and the lowest in those with hypertensive HF. The cause of death was cardiovascular in 90.1% of the cases. Owing to the nature of this pilot experience, only a relatively small number of deaths was observed. For this reason, an adjusted model to identify the independent predictors of death was not performed. However, when the three major well-known independent determinants of death (systolic blood pressure, older age, and reduced renal function) were considered, we observed that 93% of deaths could be explained by the presence of at least one of these factors (Figure 3).

Figure 4 reports the rate of use of pharmacological treatments before hospital admission, during the hospital stay, and at discharge. All evidence-based treatments were used more frequently after hospital admission than at entry. The median length of stay was 8 days (IQR 5–11), and 48% of the patients were managed in the intensive care unit for a median period of 4 days (IQR 2–7). At discharge, pulmonary congestion, peripheral congestion, or both were still present in 9.8, 18.1, and 24.0% of the cases, respectively. The median body weight reduction during the hospital stay was 2 kg (IQR 2–4 to 0), whereas the creatinine level did not increase (the median change from admission to discharge being 0.0 mg dL, IQR 0.1 to 0.1).

Specific features of the ambulatory patient population

The rates of moderate (NYHA class I–II) and severe HF (NYHA class III or IV) were 72 and 28%, respectively. Ejection fraction was available in 2857 patients (89% of the outpatients): its median value was 36% (IQR 30–46) and preserved ejection fraction was reported in 36.1% of the cases. A haemoglobin level <12 g/dL was reported in 18.8% of the cases, and an eGFR <60 and <30 mL/min/1.73 m² was reported in 40.7 and 5.1% of the
patients, respectively. N-terminal pro-brain natriuretic peptide and BNP were measured in a minority of cases (747 and 285 patients, respectively). Median values were 1387 pg/mL (IQR 485–3381) and 390 pg/mL (IQR 133–870), respectively.

The use of pharmacological treatments is reported in Table 2. A blocker of the renin–angiotensin system, β-adrenergic blockers, and aldosterone blockers were prescribed in 88.5, 86.7, and 43.7% of the cases, respectively. Table 3 reports the dose prescriptions of evidence-based treatments. The combination of renin–angiotensin system blockers, β-adrenergic blockers, and aldosterone blockers was prescribed in 35% of the patients, whereas the combination of β-adrenergic blockers, angiotensin-converting enzyme (ACE)-inhibitors, and angiotensin receptor blockers was reported in just 3% of the patients. Ramipril and enalapril were the most prescribed ACE-inhibitors; the target dose of these drugs was achieved in 38.2 and 46.2% of the cases, respectively. With respect to angiotensin receptor blockers, the target dose of candesartan, losartan, and valsartan was reached in 28.0, 19.7, and 16.7% of the cases, respectively. The target dose of carvedilol, bisoprolol, and metoprolol was reached in 37.3, 20.7, and 21.4% of patients, whereas the target dose of spironolactone, canrenone, and eplerenone was prescribed in 22.2, 61.3, and 32.7% of patients, respectively.

Figure 5 reports the number of patients with the clinical characteristics that suggest, according to current guidelines, a device implantation with ICD, CRT, or both. Of these patients with a theoretical indication for the implant, only 32.7% were implanted with an ICD and 22.5% with CRT.

Discussion

In August 2008, the ESC Board decided to start a new registry/survey programme that was named EURObservational Research Programme (EORP). The first aim of this programme was to provide a better understanding of cardiology practised in Europe collecting data with a robust methodology. The second aim was to establish a professional research centre located at the European Heart House.14

The ESC-HF Pilot is the first experience of the new EORP. The study has been conducted by the Heart Failure Association in association with the National Cardiology Societies of the participating Countries.

The primary objective of the HF survey was to describe the clinical epidemiology of outpatients and inpatients with HF and the diagnostic/therapeutic processes applied in these patients across Europe. The pilot phase also aimed (i) to create and validate a data set that is useful to collect information on patients with HF,
(ii) to test the feasibility of the implementation of a network of hospitals representing the real European world (by including adequate proportions of hospitals at any level of complexity), and (iii) to answer relevant clinical questions using an observational methodology. With respect to the last objective, the analysis of the database of the ESC-HF Pilot Registry allowed one to answer some relevant clinical questions.

What are the prevalence and outcome rates of different clinical profiles of acute heart failure?

One of the most important reasons for the failures in the development of drugs in the setting of acute HF is that, frequently, the controlled trials adopt an ‘all comers’ approach, including in the study very heterogeneous and unselected populations of patients. The current European guidelines for the diagnosis and treatment of HF\(^5\) propose a stratification of patients admitted for acute HF, but a validation in a real clinical setting has never been performed. The ESC-HF Pilot Survey, performed in a representative sample of 12 European countries, provides a contribution defining the prevalence of the different clinical profiles and their related outcomes. For example, the physicians admitting patients with worsening/acute HF classified 75% of them as ‘decompensated HF’. Whether this represents a homogeneous group of patients is difficult to envisage. There is the need, in the future, to better clarify the relationship between clinical pictures and the definition of guideline profiles to reach a patient’s categorization that could allow both individual decision-making and the identification of a patient population appropriate for testing specific new drugs. As expected, and as described in previous registries,\(^7,9,15–18\) patients with cardiogenic shock have the worst short-term prognosis. For this reason, patients presenting with this clinical profile should be managed with specific aggressive approaches. Patients with hypertensive HF are at the other extreme, showing the most favourable in-hospital survival. It is unlikely that the inclusion of both these

<table>
<thead>
<tr>
<th>Table 3 Target doses of evidence-based treatments</th>
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<tr>
<td>Rate of use (%)</td>
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<tr>
<td>Prescribed ACE-i and doses (n = 2078 patients)</td>
</tr>
<tr>
<td>Ramipril</td>
</tr>
<tr>
<td>Enalapril</td>
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<tr>
<td>Other ACE-i</td>
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<tr>
<td>Prescribed ARBs and doses (n = 864 patients)</td>
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<tr>
<td>Candesartan</td>
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<tr>
<td>Losartan</td>
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<tr>
<td>Valsartan</td>
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<tr>
<td>Other ARBs</td>
</tr>
<tr>
<td>Prescribed (\beta)-blockers and doses (n = 2774 patients)</td>
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<tr>
<td>Carvedilol</td>
</tr>
<tr>
<td>Bisoprolol</td>
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<tr>
<td>Metoprolol</td>
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<tr>
<td>Other (\beta)-blockers</td>
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<tr>
<td>Prescribed aldosterone antagonists and doses (n = 1396 patients)</td>
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<tr>
<td>Spironolactone</td>
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<td>Canrenone</td>
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<tr>
<td>Eplerenone</td>
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<td>Other aldosterone antagonists</td>
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</table>

IQR, inter-quartile range; ACE-i, angiotensin-converting enzyme-inhibitor; ARBs, angiotensin II receptor blockers.

**Figure 5** Rate of actual device implantation in patients with the clinical profile suitable for ICD or CRT implantation according to the guidelines. ICD, implantable cardioverter defibrillator; CRT, cardiac resynchronization therapy; EF, ejection fraction. \(^a\)NYHA II–III, EF \(\leq\) 35%, at least two neurohormonal blockers. \(^b\)NYHA III–IV, EF \(\leq\) 35%, QRS \(\geq\) 120, at least two neurohormonal blockers.
patient categories in the same trial, testing the same drug, could lead to meaningful and applicable results.

The relatively small dimension of the ESC-HF Pilot Survey does not allow us to provide a risk stratification tool more reliable than the existing ones. The methodology, however, has been tested, and reliable information will become available in the future when participation in the registry will be offered to all the 52 ESC countries, and not limited only to the 12 selected participating countries. This preliminary ESC-HF Pilot study just confirms that the most impacting factors such as blood pressure, age, and renal function can explain more than 90% of the deaths occurring during hospital admission.

When are the patients discharged and how?

The length of stay of patients admitted for acute HF seems to be reduced with respect to the prior European survey (from 9 to 8 days), despite the fact that half of the patients were managed for a median period of 4 days in an intensive care unit. The median body weight reduction during the hospital stay was 2 kg, whereas the creatinine level did not increase. Signs/symptoms of peripheral and/or pulmonary congestion were still present at discharge in about one-fourth of the patients. These findings are similar to those reported by a registry on patients with acute HF conducted in the USA. This suggests that the management of patients with acute HF should be improved. The evaluation of the rate of deaths and re-hospitalizations in the course of the follow-up will allow us to evaluate the impact of a longer hospital stay and of the clinical status at discharge.

What is the rate of adherence to evidence-based treatments in patients with chronic heart failure?

The ESC-HF Pilot Survey provides a clear picture on the rate of use of guideline recommended, evidence-based treatments, and detailed data on the proportion of patients in whom the target suggested dose was reached as well as the adherence to recommendation on device implantation.

As expected, the rate of use of renin–angiotensin–aldosterone system blockers (ACE-inhibitors, angiotensin receptor blockers, and aldosterone blockers) and β-adrenergic blockers is satisfactory. However, the number of patients treated with appropriate doses is, at best, suboptimal. Thus, there is a need to develop strategies to improve the management of patients with chronic HF through specific, focused management programmes. This is a common finding of all registries on HF, confirming the gap between the information generated by randomized controlled trials, performed in selected populations carefully monitored over time, and those provided by observational research reflecting routine clinical practice.

With respect to the rate of implantation of devices (CRT and/or ICD), the identification of patients with a clinical profile theoretically corresponding to the indication for the device implantation was performed using the database of the ESC-HF Pilot Survey. According to the current guidelines, nearly 38% of the ambulatory patients qualified for ICD implantation and 6.2% for CRT. Only one-third of patients with the ICD characteristics were actually implanted and one-fifth with CRT. This is clearly another gap between recommendations and the actual clinical practice that should be considered in the future. Along the same line, the EUROMED Registry showed that the implantation rates of ICD and CRT have increased significantly from 2004 to 2008, but an underutilization is still present with major differences across countries.

Limitations

Surveys based on voluntary participation and recruitment of patients have obvious limitations that have to be acknowledged. First, policies of patient hospital care differ between countries and centres, and the study population may not represent the general population. We tried to balance the methodological need of consecutiveness of enrolment with the practical feasibility by dumping the workload for centres with a limitation of recruitment to 1 day per week for 8 months. Secondly, representativeness is often a limitation in observational studies. For this reason, the participating centres were selected proportionally to the size of the population of the participating countries, taking into account the different technological levels of the invited cardiology centres.

Conclusions

The ESC-HF Pilot Survey tried to overcome some of the limitations of previous heart failure surveys by creating a more representative setting of centres and countries. In this context, the contribution of all investigators was invaluable in improving the quality of the data set which will now be refined and utilized in the implementation of a pan-European permanent registry. Further, even if the size of the study was relatively small, this pilot survey can be considered a useful example of how it is possible to utilize an observational methodology to answer relevant clinical questions and to identify some unsolved issues that can lead to future strategic programmes implemented at the national level or by a common policy of the ESC-HF Association. Evaluation of the data of the 1-year follow-up and further analysis stratified by geographical areas or specific countries will further improve our knowledge and put in evidence some local or generalized unmet needs.

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Conflict of interest: none declared.
Appendix

Executive Committee

A.P.M. (Chairman), Italy; U.D., Sweden; G.F., Greece; L.T., Italy; and F.Z., France.

Steering Committee (National Coordinators)

Austria, F.F.; Denmark, O.W.N.; France, D.L.; Germany, M.R.; Greece, J.P.; Italy, M.M.; The Netherlands, A.V.; Norway, L.G.; Poland, J.D.; Romania, O.C.; Spain, M.C.L.; and Sweden, U.D.H.P.

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Donata Lucci and Lucio Gonzini.

Participating centres, investigators, and data collection officers


References