Clinical Characteristics and Outcome of Hospitalized Patients With Heart Failure in Japan

Rationale and Design of Japanese Cardiac Registry of Heart Failure in Cardiology (JCARE-CARD)

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Background  Heart failure (HF), defined as a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood, is a leading cause of mortality and hospitalization for adults older than 65 years in the industrialized countries. The characteristics and outcome of patients with HF have been described by several epidemiological studies and large scale clinical trials, performed mainly in the United States and Europe. Very little information is available on this issue in Japan.

Methods and Results  The Japanese Cardiac Registry of Heart Failure in Cardiology (JCARE-CARD) is designed to prospectively study the characteristics, treatment, and outcomes of a broad sample of patients hospitalized with HF at teaching hospitals throughout Japan between January 2004 to June 2005 and the outcomes, including death and hospital readmission, will be followed through 2006 (mean follow-up at least 1 year). Participating cardiologists identify patients admitted for worsening of HF symptoms. Demographics, medical history, severity, treatment, and outcome data are collected and entered into a database via secure web browser technology. As of June 2005, baseline data for 2,676 patients with HF have been registered from 164 participating hospitals.

Conclusions  The JCARE-CARD will provide important insights into the management of patients with HF in routine clinical practice in Japan, thus providing the framework for improved management strategies for these patients. (Circ J 2006; 70: 1617–1623)

Key Words:  Heart failure; Management; Outcome; Registry

Heart failure (HF) is defined as a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood, according to the guidelines for the diagnosis and treatment of chronic heart failure of American College of Cardiology/American Heart Association and European Society of Cardiology (ESC).1,2 The manifestations of HF are dyspnea and fatigue, which may limit exercise tolerance, and fluid retention, which may lead to pulmonary congestion and peripheral edema.1,2 HF is a leading cause of morbidity and mortality in the industrialized countries3 and is a growing public health problem, mainly because of the aging of the population and the increased prevalence of HF in the elderly.4 The clinical characteristics, treatment, and outcome of these patients have been well described by a number of both community-based5–7 and hospital-based studies,8–11 as well as by clinical trials of HF treatment.12–14 However, information derived from clinical trials is not necessarily representative of “real world” patients with HF and, moreover, these studies have been performed mainly in the United States and Europe. Very limited information is available on the characteristics and outcome of patients with HF in Japan.15–17 Our previous studies were the first detailed analysis of the clinical characteristics, management, and outcome data of patients hospitalized for worsening of HF symptoms. As many as 35% of hospitalized patients with HF were readmitted within 1 year of hospital discharge. These characteristics are consistent with those of patient populations in community-based studies reported previously.21,22

The Japanese Cardiac Registry of Heart Failure in Cardiology (JCARE-CARD) has been developed to provide a national prospective registry database describing the clinical characteristics, treatment, and outcomes of patients hospitalized for worsening of HF symptoms. It will also establish the framework for future initiatives to improve the outcomes of these patients. Specifically, this study aimed to determine the influence of clinical characteristics on patient outcomes and further identify the predictive risk of adverse outcomes. This report presents a detailed de-
scription of the rationale and design of JCARE-CARD.

Methods

Study Design

JCARE-CARD is a multicenter registry designed to compile a large clinical database on the characteristics, management, and outcomes of patients hospitalized for the worsening of HF in Japan. Baseline data are collected during the episode of index hospitalization from January 2004 to June 2005. Follow-up data will be collected at least 1 year after the index admission.

Study Objectives

The specific objectives of the JCARE-CARD include the following: (1) to describe the demographic and clinical characteristics of patients hospitalized with HF in Japan; (2) to describe the in-hospital and long-term outcomes; and (3) to identify the factors, including specific treatments, associated with improved or worsened outcomes.

Study Hospitals

The study hospitals include the cardiology units serving as primary, secondary, and tertiary referral medical centers for cardiovascular patients across Japan. They are authorized as teaching hospitals by the Japanese Circulation Society.

Study Patients

For this registry, HF is defined as a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood. The presence of HF is confirmed by using the Framingham criteria (Table 1).

Patients readmitted to hospital during the study period are included only by the first hospitalization (index admission). Patients must be at least 15 years old at the time of hospital admission. Eligibility is not contingent on the use of any particular therapeutic agent or regimen.

<table>
<thead>
<tr>
<th>Major criteria</th>
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<tbody>
<tr>
<td>Paroxysmal nocturnal dyspnea</td>
</tr>
<tr>
<td>Neck vein distension</td>
</tr>
<tr>
<td>Rales</td>
</tr>
<tr>
<td>Radiographic cardiomegaly</td>
</tr>
<tr>
<td>Acute pulmonary edema</td>
</tr>
<tr>
<td>S3 gallop</td>
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<tr>
<td>Increased central venous pressure (&gt;16cm water at right atrium)</td>
</tr>
<tr>
<td>Circulation time ≥25 s</td>
</tr>
<tr>
<td>Hepatojugular reflux</td>
</tr>
<tr>
<td>Pulmonary edema, visceral congestion, or cardiomegaly at autopsy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minor criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilateral ankle edema</td>
</tr>
<tr>
<td>Nocturnal cough</td>
</tr>
<tr>
<td>Dyspnea on ordinary exertion</td>
</tr>
<tr>
<td>Hepatomegaly</td>
</tr>
<tr>
<td>Pleural effusion</td>
</tr>
<tr>
<td>Decrease in vital capacity by one-third from maximum value recorded</td>
</tr>
<tr>
<td>Tachycardia (rate ≥120 beats/min)</td>
</tr>
</tbody>
</table>

Table 1 Framingham Criteria for Heart Failure (HF)

The diagnosis of HF was established by the simultaneous presence of at least 2 major criteria or 1 major criterion in conjunction with 2 minor criteria.

Data Collection and Processing

Data are entered using a web-based electronic data capture (EDC) system licensed by the JCARE-CARD. The EDC system was chosen because of perceived advantages over the traditional, paper-based data entry process, including the ability to inform participating hospitals of missing or illogical data fields at the time of data submission. A study web site has been created with a public area providing general information regarding this study and a registry-site-only area that provides information concerning data registry (Figs 1, 2). The study hospitals are encouraged to register the patients as consecutively as possible. The diagnosis of HF is established by the simultaneous presence of at least 2 major criteria or 1 major criterion in conjunction with 2 minor criteria of the Framingham criteria (Table 1). Compliance with these
methods of registry is not strictly monitored.

For each case, baseline data recorded on the form include (1) demography; (2) cause of HF; (3) precipitating cause; (4) comorbidities; (5) complications; (6) clinical status; (7) electrocardiographic and echocardiographic findings; and (8) treatment including discharge medications.

The status of all patients is surveyed at least 1 year after admission and the following information is obtained: (1) survival, (2) cause of death, and (3) hospital readmission because of exacerbation of HF that required more than continuation of the usual therapy on prior admission.

Patient Confidentiality

The JCARE-CARD protocol was organized to ensure compliance with the Guidelines for the Epidemiological Research published by the Japanese Ministry of Health, Labour and Welfare. The original study protocol was approved by the Institutional review board (IRB) at Kyushu University. IRB approval from each participating hospital is also required for participation in this registry. Informed consent is given by each patient. The study does not include any protocol-specified alteration of treatment or any other aspect of hospital care. Patient confidentiality is preserved because direct patient identifiers, such as name, address, and identification number, are not collected. Access to the EDC system at each hospital is carefully controlled by the data management office.

Statistical Analysis

Descriptive statistics are used to summarize baseline characteristics, treatment, and outcomes for the patients and for specific subgroups of interest.

Results

The JCARE-CARD enrolled HF patients from January 2004 to June 2005. As of June 2005, baseline data on 2,676 patients with HF have been registered from 164 participating hospitals (Fig 3, Table 2).

Discussion

The characteristics and outcomes of Japanese patients with HF are poorly defined despite the public health impor-

tance of this disease. The JCARE-CARD, which aimed to better characterize this population, is the first diverse, large-scale, prospective multicenter database of patients hospitalized for HF in Japan.

We have previously reported the characteristics and outcomes of patients admitted to urban cardiology departments in Fukuoka, Japan. Those studies highlighted several important features of Japanese patients with HF. One key feature was their advanced age: the mean age of HF patients was 69 years (70% were ≥ 65 years of age). In particular, women were mostly over 70 years of age, which is consistent with results from previous community-based studies. Another important feature was the high proportion of patients with relatively preserved EF; that is, half of the patients with definite HF who had echocardiography had normal EF (≥50 %), indicating the contribution of diastolic dysfunction in the pathogenesis of HF. A most interesting and important finding was a relatively good survival prognosis for the study patients; the 1-year mortality rate was 8.3 %. Survival prognosis for patients with decreased EF (<40 %) was still good; their 1-year mortality rate was 9.1 %. At the first glance, this finding appears to contradict the generally held notion that advanced age and more comorbidity are related to poor survival. In contrast to the relatively low mortality, rates of readmission for HF were as high as 40 % within 1 year after discharge. This is comparable to the rates found in prior studies (3–6-month readmission rate of 30–50 %) and the most commonly identified cause for hospital readmission was lack of compliance with
medical and dietary treatment (48%);\(^9\)

Even though our previous studies gave a valuable insight into the clinical characteristics, outcomes, and the potential effective treatment strategies for HF patients in Japan\(^8\)–\(^10\)\(^–\)\(^20\)\(^–\)\(^24\)\(^–\)\(^29\) generalization of these results is questioned because our investigation involved a small number of patients (n=230). Therefore, it is of critical importance to analyze the data of HF patients in routine clinical practice on a national basis and to form a database for future investigations. For this purpose, JCARE-CARD is designed to focus on the demographic and clinical characteristics, treatment strategies, and outcomes of patients admitted to hospitals throughout Japan. It is important to consider the JCARE-CARD in the context of other large-scale databases such as the Acute Decompensated Heart Failure National Registry (ADHERE) or EuroHeart that have been established to evaluate epidemiologic and clinical aspects of HF\(^8\),\(^10\),\(^11\). These administrative data sets have provided important insights concerning the prognostic and public health role of a number of classic epidemiologic factors, as well as information on medication use. The JCARE-CARD is expected to provide us with important information regarding the characteristics, treatment, and outcomes of HF patients in Japan, which may be complementary to that gathered from the studies in Europe and the USA. This information is often critical to our understanding of the clinical characteristics of HF, including independent prognostic predictors.

There have been 2 large-scale registries of HF reported: the EuroHeart Failure Survey from Europe and ADHERE from the USA. The EuroHeart Failure Survey registered 11,304 HF patients in departments of cardiology, cardiovascular surgery, general internal medicine and geriatrics at 115 hospitals, including both general hospitals and university centers from 24 ESC member countries over a 6-week period during March 2000 and May 2001.\(^9\)–\(^11\) Patients were enrolled as HF if they fulfilled at least 1 of the following criteria: (1) clinical diagnosis of HF during the admission; (2) diagnosis of HF recorded at any time in the last 3 years; (3) administration of a loop diuretic for any reason other than renal failure during the 24 h prior to death or discharge; (4) pharmacological treatment for HF or ventricular dysfunction within 24 h of death or discharge. The Euro Heart Failure Survey described the quality of care, and the diagnostic and therapeutic management of patients with HF in Europe. Outcome was further assessed by repeat interviews in 6–12 months\(^25\),\(^26\).

The ADHERE is a registry designed to study the characteristics, management, and outcomes in a broad sample of patients hospitalized with acute decompensated HF throughout the USA.\(^8\) Participating hospitals identify patients with a primary or secondary discharge diagnosis of HF. Medical history, management, treatment, and outcome data are collected through review of medical records and entered into a database via secure web browser technology. Of available data (105,388 patients from 274 hospitals), the mean age was 72.4 years old, and 52% were women. The most common comorbid conditions were hypertension (73%), coronary artery disease (57%), and diabetes (44%). Evidence of mild or no impairment of systolic function was found in 46% of patients. In-hospital mortality was 4.0%. The ADHERE data provided important insights into the clinical characteristics and patterns of care of these patients. Similar to our previous studies\(^29\) the ADHERE demonstrated that many patients hospitalized with HF had mild or no impairment of systolic ventricular function.\(^27\) These registry data demonstrate significant differences in the definition of HF between patients hospitalized for HF and those enrolled in randomized clinical trials\(^29\). Even though JCARE-CARD and ADHERE share many similarities in their design and rationale, there are several important differences between them. Follow-up data were not obtained in the ADHERE, so the subsequent clinical outcomes, including death and readmission of patients after the index hospitalization, are unknown. Data are gathered retrospectively after hospital discharge in the ADHERE, which may preclude prospective analysis of particular treatments in these patients.

Study Limitations

Several crucial limitations inherent in the design of the JCARE-CARD should be considered. First, the data are based on the decisions made by the participating cardiologists. The lack of a precise, universal definition of HF makes this type of registry open to many criticisms. However, it is not the objective of this survey to restrict enrollment to the narrowly defined population of HF usually included in clinical trials, but rather to include a broad range of patients reflecting the current reality of clinical practice. All participating hospitals are authorized as teaching hospitals by the Japanese Circulation Society. In addition, the information regarding the study protocol was regularly provided at national as well as local meetings and also via monthly e-mail notice. Second, this survey relies on the hospitals to volunteer their support, which almost certainly biased the study towards larger centers that can support research staff. In addition, we excluded specialist wards other than cardiology from this survey.

Conclusions

The JCARE-CARD will be the first survey to provide valuable information on current patient characteristics, management, and outcomes in a broad sample of Japanese patients who are hospitalized with HF as routine clinical practice. These data may indicate that there are substantial opportunities to improve the management of these patients. By helping to better characterize this disease state, it will ultimately have a significant impact on public health at the national level in Japan.

Acknowledgments

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References

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Heart Failure Registry in Japan


Appendix 1

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Appendix 2

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Patient Data Form for JCARE-CARD

1. Date of registry
2. Date of admission
3. Date of birth
4. Age
5. Sex
6. Race
7. Marital status
8. Body weight
9. Body mass index
10. Pulmonary circulation
11. Diastolic blood pressure
12. Systolic blood pressure
13. Heart rate
14. Body temperature
15. Hematocrit
16. Hemoglobin
17. Urea nitrogen
18. Creatinine
19. Sodium
20. Potassium
21. Chloride
22. Total protein
23. Albumin
24. Total cholesterol
25. Triglycerides
26. Glucose
27. Lipase
28. Amylase
29. Uric acid
30. Alkaline phosphatase
31. γ-Glutamyl transpeptidase
32. Aspartate aminotransferase
33. Alanine aminotransferase
34. Creatine kinase
35. Cardiac troponin I
36. Cardiac troponin T
37. Myoglobin
38. Procalcitonin
39. Prothrombin time
40. Activated partial thromboplastin time
41. D-dimer
42. N-terminal pro brain natriuretic peptide (NT-proBNP)
43. B-type natriuretic peptide (BNP)
44. C-reactive protein
45. Iron
46. Iron saturation
47. Ferritin
48. Total iron binding capacity
49. Lactate dehydrogenase
50. Adenosine deaminase
51. Carbonic anhydrase
52. C1 esterase inhibitor
53. Anti-neutrophil cytoplasmic antibody (ANCA)
54. Anti-neutrophil cytoplasmic antibody (c-ANCA)
55. Anti-neutrophil cytoplasmic antibody (p-ANCA)
56. Anti-myeloperoxidase (MPO) antibody
57. Anti-proteinase 3 (PR-3) antibody
58. Anti-glomerular basement membrane (GBM) antibody
59. Anti-endothelial cell antibodies (ACE)
60. Anti-endothelial liver antibodies (ALMA)
61. Anti-thrombin antibodies
62. Anti-factor X antibodies
63. Anti-factor II antibodies
64. Anti-factor VIII antibodies
65. Anti-factor IX antibodies
66. Anti-factor X antibodies
67. Anti-factor XII antibodies
68. Anti-factor XIII antibodies
69. Anti-factor XIV antibodies
70. Anti-factor XV antibodies
71. Anti-factor XVI antibodies
72. Anti-factor VII antibodies
73. Anti-factor VIII antibodies
74. Anti-factor IX antibodies
75. Anti-factor X antibodies
76. Anti-factor XII antibodies
77. Anti-factor XIII antibodies
78. Anti-factor XIV antibodies
79. Anti-factor XV antibodies
80. Anti-factor XVI antibodies
81. Anti-factor VII antibodies
82. Anti-factor VIII antibodies
83. Anti-factor IX antibodies
84. Anti-factor X antibodies
85. Anti-factor XII antibodies
86. Anti-factor XIII antibodies
87. Anti-factor XIV antibodies
88. Anti-factor XV antibodies
89. Anti-factor XVI antibodies
90. Anti-factor VII antibodies
91. Anti-factor VIII antibodies
92. Anti-factor IX antibodies
93. Anti-factor X antibodies
94. Anti-factor XII antibodies
95. Anti-factor XIII antibodies
96. Anti-factor XIV antibodies
97. Anti-factor XV antibodies
98. Anti-factor XVI antibodies
99. Anti-factor VII antibodies
100. Anti-factor VIII antibodies
101. Anti-factor IX antibodies
102. Anti-factor X antibodies
103. Anti-factor XII antibodies
104. Anti-factor XIII antibodies
105. Anti-factor XIV antibodies
106. Anti-factor XV antibodies
107. Anti-factor XVI antibodies

Appendix 3

Step 1. Demographic Data

**Step 2. Clinical Data (Medical History)**

1. Causes of heart failure
   1. Ischemic
   2. Hypertensive
   3. Cardiomyopathic, dilated
   4. Cardiomyopathic, hypertrophic
   5. Cardiomyopathic, dilated phase of hypertrophic cardiomyopathy
   6. Valvular heart disease
   7. Congenital heart disease
   8. Others
   9. Unknown

2. Precipitating causes of heart failure
   1. Lack of compliance with sodium and fluid restriction
   2. Lack of compliance with drugs
   3. Overactivity
   4. Infection
   5. Arrhythmias
   6. Ischemia
   7. Uncontrolled hypertension
   8. Other
   9. Unknown

3. Comorbidity
   1. Hypertension (Blood pressure >140/90 mmHg)
   2. Diabetes mellitus (Fasting blood sugar ≥125 mg/dl or 2-h blood sugar ≥200 mg/dl)
   3. Renal failure (Serum creatinine 2.5 mg/dl or dialysis)
   4. Hyperlipidemia (Total cholesterol ≥220mg/dl or LDL ≥140mg/dl)
   5. Hyperuricemia (Serum uric acid >7.0 mg/dl)
   6. Cerebrovascular disease (Brain infarction, brain hemorrhage, transient ischemic attack)
   7. Anemia (Hemoglobin ≤10 g/dl)
   8. COPD
   9. Smoking

4. Complications
   1. Prior myocardial infarction
   2. Atrial fibrillation or flutter
   3. Sustained ventricular tachycardia or ventricular fibrillation

5. Medical history
   1. First-time diagnosis of HF
   2. Interval after the initial diagnosis of HF (months)
   3. Prior hospitalization for heart failure
   4. Percutaneous coronary intervention
   5. Coronary artery bypass surgery
   6. Valve surgery

**Step 3. Clinical Data (Medical Status)**

1. New York Heart Association (NYHA) functional class on admission and at discharge
2. Heart rate (beats/min)
3. Blood pressure (mmHg)
4. Left bundle branch block
5. Left ventricular hypertrophy (SV1 + RV5 or V5 ≥2.5 mV or RV5 or V6 ≥2.6 mV)
6. Echocardiographic data on admission and at discharge
7. Serum BNP levels at admission and discharge

**Step 4. Discharge Status and Treatment**

1. Discharge status
   1. In-hospital death
   2. Autopsy
   3. Discharge to home

2. Discharge medications
   1. Angiotensin-converting enzyme inhibitors
   2. Angiotensin II receptor blockers
   3. Beta-blockers
   4. Diuretics
   5. Digitalis
   6. Oral inotropic agents
   7. Calcium channel blockers
   8. Alpha-blockers
   9. Nitrites
   10. Antiarrhythmic agents
   11. Aspirin
   12. Antiplatelet agents
   13. Warfarin
   14. Statins
   15. Participation in clinical trial

3. Non-pharmacological therapy
   1. Permanent pacemaker
   2. Cardiac resynchronization therapy
   3. Implantable cardioverter defibrillator
   4. Left ventricular assist device
   5. Cardiac transplantation

**Step 5. Long-Term Outcomes**

1. Date of survey
2. Death
   1. Date of death
   2. All-cause death
   3. Cause of death
      1. Cardiac death
      2. Non-cardiac death
      3. Unknown
   4. Autopsy
   5. Hospital readmission because of exacerbation of heart failure
      1. Date of readmission
      2. Date of discharge
   3. Sustained ventricular tachycardia or ventricular fibrillation