D A T A B A S E

新規患者登録は次のステップ1から4で入力して下さい。

STEP 1
患者基礎データ

STEP 2
患者背景データ(診断)

STEP 3
患者背景データ(重症度)

STEP 4
退院時状況および治療

登録へすすむ
go

D A T A B A S E

STEP 1 患者基礎データ

登録日	2003 年 2 月 5 日
入院日	年 月 日
退院日	年 月 日
施設名	EnMedix
施設ID	
医師名	All Mighty
患者ID	先生が患者を特定できるもの。半角英数字の組み合せで最大12文字まで。"-" "/" は入力不可。ただし氏名は不可。
生年月日	年 月 日 年号の換算: 明治 年 換算 西暦 年
性別	
身長/体重	cm (□不明)/ kg (□不明)

次のステップ 次のステップに進むには左のボタンを押してください。

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保存しないでこのままやめる場合はQUITを押してください。

STEP1 STEP2 STEP3 STEP4 QUIT

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確認 中断して登録する

D A T A B A S E

STEP 2 患者背景データ(診断)

慢性心不全の基礎疾患 (主たるもの。 ただし複数選択可)	□虚血 □高血圧 心筋症(□拡張型 □肥大型 □肥大型の拡張相) □弁膜症 □先天性 □その他 □不明
心不全増悪の誘因 (主たるもの。 ただし複数選択可)	□塩分、水分制限不徹底 □治療薬服用不徹底 □過労、安静不徹底 □感染症 □不整脈 □虚血 □コントロール不良高血圧 □その他 □不明
合併疾患 (各主治医の診断による。治療中はありとする)	高血圧 (□有 □無 □不明) (診断基準)BP>140/90mmHg
	糖尿病 (□有 □無 □不明) (診断基準)FBS≧126mg/dLまたは2hrBS≧200mg/dL インスリン治療 (□有 □無 □不明) (必須記入事項ではありません)
	高脂血症 (□有 □無 □不明) (診断基準)TC≧220mg/dLまたはLDL≧140mg/dL
	腎不全 (□有 □無 □不明) (診断基準)Cr≧2.5mg/dLまたは透析中 血液透析(維持透析) (□有 □無 □不明) 血清クレアチニン [ ] mg/dL (必須記入事項ではありません)
	高尿酸血症 (□有 □無 □不明) (診断基準)尿酸>7.0mg/dL 尿酸値 [ ] mg/dL(必須記入事項ではありません)
	脳血管障害 (□有 □無 □不明) (診断基準)脳梗塞、脳出血、TIA
	貧血 (□有 □無 □不明) (診断基準)Hb10g/dL以下 Hb [ ] g/dL(必須記入事項ではありません)
	慢性閉塞性肺疾患 (□有 □無 □不明)
	喫煙歴 (□有 □無 □不明)
陳旧性心筋梗塞	□有 □無 □不明
陳旧性心筋梗塞	□有 □無 □不明
慢性心房細動 または粗動	□有 □無 □不明
持続性心室頻拍または 心室細動の既往	□有 □無 □不明 (診断基準)30秒以上持続または、血行動態の悪化を伴うもの
慢性心不全の 診断	□今回初めて □以前より診断
慢性心不全の罹病期間 (診断から登録までの期間)	[ ] か月 □不明
慢性心不全の増悪 による入院歴	□有 □無 □不明
冠動脈インターベンション (既往・入院中も含む)	□有 □無 □不明
冠動脈バイパス (既往・入院中も含む)	□有 □無 □不明
弁手術(弁置換・弁形成術)(既往・入院中も含む)	□有 □無 □不明

次のステップ 次のステップに進むには左のボタンを押してください。

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STEP1 STEP2 STEP3 STEP4 QUIT

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確認 中断して登録する

JCARE CARD
Japanese CArdiac REgistry in CHF-CARDiology

▼TOPへはこちらから

■
[研究計画書]
■
[研究組織]
■
[事務局]
■
[会議議事録]
■
[会議室]
■
[リンク集]
■
[DATA BASE]
■
[お問合わせ]

PDF
患者様へ
■
同意文書
■
研究計画書
word圧縮ファイル

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証明書の内容を
ご確認ください。

STEP 3　患者背景データ(重症度)

(入院時・退院時それぞれ1週間以内を原則とする)

入院時自覚症状(NYHA分類)	□I □II □III □IV (NYHA分類の定義)
退院時自覚症状(NYHA分類)	□I □II □III □IV
安静時心拍数(退院時)	bpm
安静時血圧(退院時)	/ mmHg
心電図左脚ブロック	□有 □無 □ペーシング波形 QRS幅 msec (必須記入事項ではありません)
心電図左室肥大	□有 □無 □判定不能(ペースメーカ調律等) (診断基準)SV_1+RV_5 or $V_6 \geq 35$ または RV_5 or $V_6 > 26$
入院時心エコー所見 □ 未施行	左室拡張末期径 mm □不明 左室収縮末期径 mm □不明 左室駆出率 % □不明 (断層法から計測。ただし壁運動異常なければMモード法からの算出も可) 中隔壁厚 mm □不明 後壁壁厚 mm □不明 僧帽弁逆流(ドップラー) □不明 □無 □1-2度 □3-4度 左室流入血流速波形(必須記入事項ではありません) E/A DecT msec
退院時心エコー 入力する	
入院時BNP	pg/mL □不明
退院時BNP	pg/mL □不明

次のステップ　次のステップに進むには左のボタンを押してください。

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STEP1　STEP2　STEP3　STEP4　QUIT

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確認　中断して登録する

STEP 4　退院時状況および治療

退院時状況

退院時状況	☐ 入院中死亡　患者予後調査も入力下さい。 剖検: ☐有 ☐無 ☐不明 ☐ 外来治療 ☐ 転科または転院入院/心不全治療目的(心臓外科など) ☐ 転科または転院入院/上記以外目的(他疾患治療など)

薬物治療

注意:後発品(ゼネリック)は該当する薬剤を選択して下さい。(例:レニメック錠レニベース)

ACE阻害薬	☐ レニベース ☐ ロングスまたはゼストリル ☐ コバシル ☐ タナトリルまたはノバロック ☐ カプトリル ☐ インヒベース ☐ エースコール ☐ 標記以外ACE阻害薬 ☐ 無
アンジオテンシン受容体拮抗薬(ARB)	☐ ニューロタン ☐ ディオバン ☐ ブロプレス ☐ ミカルデイス ☐ 標記以外ARB ☐ 無
β遮断薬	☐ アーチスト [ ] mg/日 ☐ メインテート [ ] mg/日 ☐ セロケンまたはロプレソール(徐放錠含む) [ ] mg/日 ☐ 標記以外β遮断薬 [ ] mg/日 ☐ 無
利尿剤	☐ サイアザイド系利尿薬 ☐ ラシックス ☐ ダイアート ☐ アルダクトンA ☐ エプレレノン ☐ 標記以外利尿薬 ☐ 無
ジギタリス	☐有 ☐無
経口強心薬(ジギタリス以外)	☐ アカルディ ☐ タナドーパ ☐ その他 ☐ 無
Ca拮抗薬	☐ ノルバスクまたはアムロジン ☐ アダラート(徐放錠含む) ☐ ヘルベッサー(徐放錠含む) ☐ 標記以外Ca拮抗薬 ☐ 無
α遮断薬	☐ カルデナリン ☐ 標記以外α遮断薬 ☐ 無
亜硝酸薬	☐有 ☐無
抗不整脈薬(β遮断薬・Ca拮抗薬除く)	☐ アンカロン ☐ ソタコール ☐ ベプリコール ☐ リスモダン ☐ アスペノン ☐ メキシチール ☐ タンボコール ☐ サンリズム ☐ シベノール ☐ 標記以外抗不整脈薬 ☐ 無
アスピリン	☐有 ☐無
抗血小板薬(アスピリン以外)	☐ パナルジン ☐ プレタール ☐ 標記以外の抗血小板薬 ☐ 無
ワーファリン	☐有 ☐無
スタチン	☐ メバロチン ☐ ローコール ☐ リピトール ☐ リポバス ☐ 標記以外のスタチン ☐ 無
薬剤治験	☐ J-CHF ☐ ビソプロロール治験 ☐ その他 治験名を入力して下さい [ ] ☐ 無

非薬物療法

永久ペースメーカ植え込み	☐有 ☐無
両心室ペーシング	☐有 ☐無
植え込み型除細動器(ICD)	☐有 ☐無
左心補助装置	☐有 ☐無
心臓移植	☐有 ☐無

次のステップ　次のステップ(確認画面)に進むには左のボタンを押してください。

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STEP1　STEP2　STEP3　STEP4　QUIT

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確認　中断して登録する

認証が完了しました。

D A T A B A S E

施設名	EnMedix
施設ID	
氏名	All Mighty
氏名ID	10000001
E-mail	admin@jcare-card.jp

新規患者登録

登録患者データ 修正

登録患者データ 予後調査

医師別全症例
データベース作成(Excel形式)

施設代表医師用 施設別全症例
データベース作成(Excel形式)

「全症例データベース作成」をご利用の際には、事務局での登録が必要です。
登録がお済みでない施設代表の先生は、事務局までご連絡下さい。

D A T A B A S E

登録患者予後調査

戻る

ID	1111	登録	◉
ID	2222	登録	○
ID	12345	仮登録	○

予後調査を記入するには「選択」ボタンを押してください。 選択

患者予後調査　リストに戻る

記入(修正)日	2006 年 2 月 5 日
調査日	2005 年 3 月 3 日
死亡状況	全ての原因による死亡(□有 □無)
	死亡年月日 年 月 日
	心臓死 (□有 □無 □不明)
	突然死 (□有 □無 □不明) (突然死の定義)
	剖検 (□有 □無 □不明)
心不全増悪による再入院	入院期間 入院期間の追加
	1回目: 2005 年 4 月 3 日～ 2005 年 4 月 5 日
	2回目: 2005 年 4 月 5 日～ 2004 年 4 月 6 日
	3回目: 2005 年 2 月 1 日～ 2005 年 6 月 3 日
	4回目: 2005 年 5 月 2 日～ 2005 年 5 月 5 日
	5回目: 2005 年 5 月 6 日～ 2005 年 5 月 8 日
	6回目: 2005 年 5 月 10 日～ 2005 年 5 月 15 日
	7回目: 2006 年 2 月 2 日～ 2006 年 5 月 4 日
	8回目: 2006 年 2 月 5 日～ 2005 年 7 月 25 日
	9回目: 2005 年 2 月 5 日～ 2005 年 2 月 6 日
	10回目: 年 月 日～ 年 月 日
	11回目: 年 月 日～ 年 月 日
	12回目: 年 月 日～ 年 月 日
	13回目: 年 月 日～ 年 月 日
	14回目: 年 月 日～ 年 月 日
不整脈イベント	持続性心室頻拍または心室細動 ☑有 □無

「心不全増悪による再入院」は観察期間中(最低1年以上)に発生したものすべてを記入して下さい。
1回目の再入院で予後調査が終了するのではありませんのでご注意下さい。

V. 発 表 論 文

Circ J 2006; **70:** 1617–1623

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) —

Hiroyuki Tsutsui, MD; Miyuki Tsuchihashi-Makaya, PhD*;
Shintaro Kinugawa, MD; Daisuke Goto, MD; Akira Takeshita, MD**;
for the JCARE-CARD Investigators

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 countries[3] 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-based[5–7] 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, including mortality and HF-related readmission, in Japan[18–20] They demonstrated that HF patients were elderly, comprised more women, especially at higher ages, and had a higher incidence of overt HF despite a relatively normal ejection fraction (EF). 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-

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Table 1 Framingham Criteria for Heart Failure (HF)

Major criteria
Paroxysmal nocturnal dyspnea
Neck vein distension
Rales
Radiographic cardiomegaly (increased heart size on chest X-ray)
Acute pulmonary edema
S3 gallop
Increased central venous pressure (>16cm water at right atrium)
Circulation time ≥25 s
Hepatojugular reflux
Pulmonary edema, visceral congestion, or cardiomegaly at autopsy
Minor criteria
Bilateral ankle edema
Nocturnal cough
Dyspnea on ordinary exertion
Hepatomegaly
Pleural effusion
Decrease in vital capacity by one-third from maximum value recorded
Tachycardia (rate ≥120 beats/min)
Major or minor criteria
Weight loss ≥4.5 kg in 5 days in response to treatment

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.

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).[5] 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.

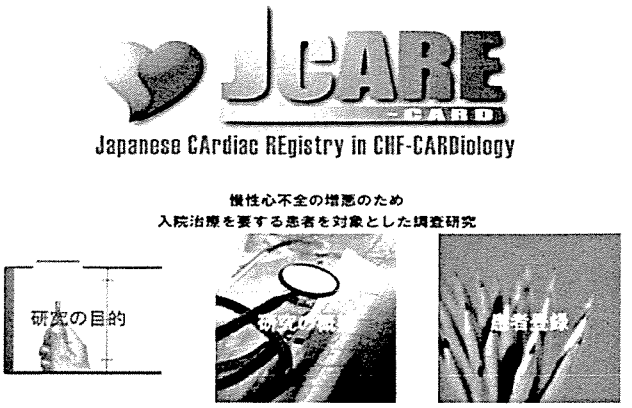

Fig 1. Screen-shot of the top page of the Japanese Cardiac Registry of Heart Failure in Cardiology (JCARE-CARD) web site (www.jcare-card.jp).

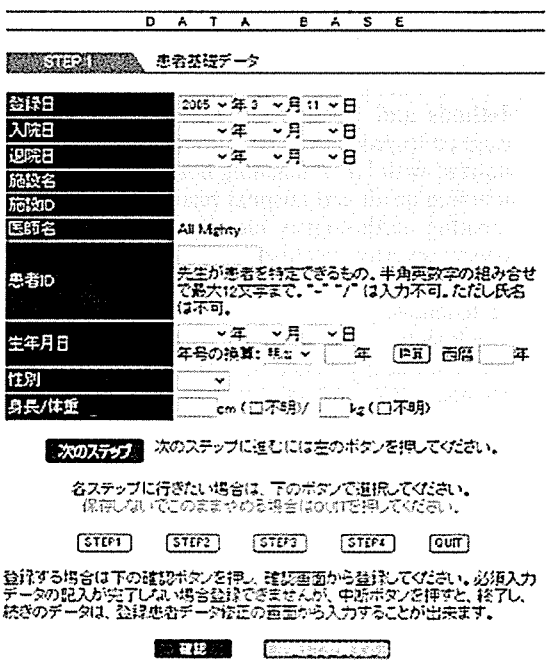

Fig 2. Sample screen-shot of a page of the electronic case report form with sample pull-down menus from the Japanese Cardiac Registry of Heart Failure in Cardiology web site (www.jcare-card.jp).

Data Collection and Processing

Data are entered using a web-based electronic data capture (EDC) system licensed by the JCARE-CARD (www.jcare-card.jp). 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

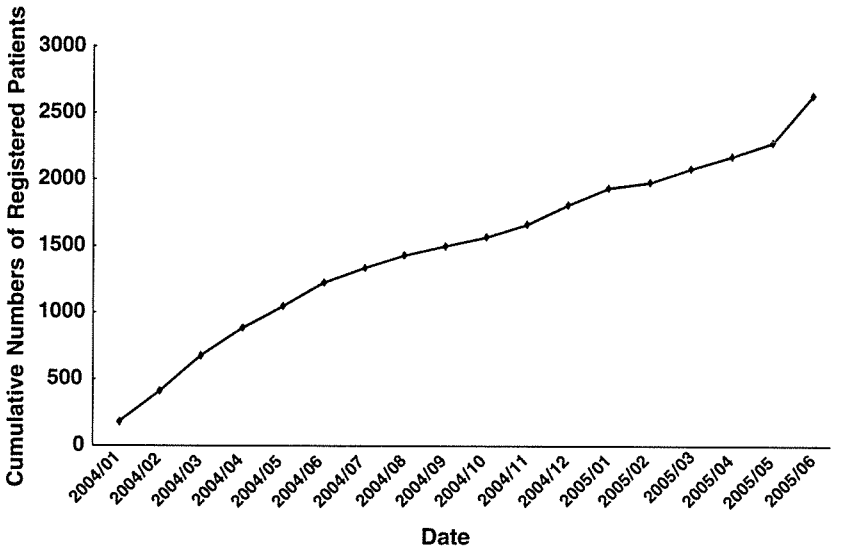

Fig 3. The Japanese Cardiac Registry of Heart Failure in Cardiology cumulative number of registered patients from January 2004 to June 2005.

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).

Table 2 Number of Participating Hospitals and Registered Patients Among 8 Regions in Japan

Region	*No. of participating hospitals*	*No. of registered patients*
Hokkaido	*8*	*143*
Tohoku	*7*	*140*
Kanto	*44*	*728*
Hokuriku	*10*	*55*
Tokai	*20*	*499*
Kinki	*31*	*491*
Chugoku · Shikoku	*18*	*239*
Kyushu	*26*	*381*
Total	*164*	*2,676*

Discussion

The characteristics and outcomes of Japanese patients with HF are poorly defined despite the public health importance 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.[18–20] 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.[21,22] 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.[20] 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.[18] 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%),[23,24] and the most commonly identified cause for hospital readmission was lack of compliance with

medical and dietary treatment (48%)[19]

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,[8–20] 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,[20] 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.[28]

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.

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Appendix 1

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Appendix 3

Patient Data Form for JCARE-CARD

Step 1. Demographic Data

1. Date of registry
2. Date of admission
3. Date of discharge
4. Date of birth
5. Age
6. Sex
7. Height
8. Body weight
9. Body mass index

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)
      Insulin treatment
   3. Hyperlipidemia (Total cholesterol ≥220 mg/dl or LDL ≥140 mg/dl)
   4. Renal failure (Serum creatinine 2.5 mg/dl or dialysis)
      Serum creatinine: [ ] mg/dl
      Hemodialysis
   5. Hyperuricemia (Serum uric acid >7.0 mg/dl)
      Serum uric acid: [ ] mg/dl
   6. Cerebrovascular disease
      (Brain infarction, brain hemorrhage, transient ischemic attack)
   7. Anemia (Hemoglobin ≤10 g/dl)
      Hemoglobin: [ ] 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
   QRS duration: [ ] ms
5. Left ventricular hypertrophy (SV_1+RV_5 or V_6 ≥3.5 mV or RV_5 or V_6 >2.6 mV)
6. Echocardiographic data on admission and at discharge
   1. Left ventricular end-diastolic and end-systolic diameters (mm)
   2. Left ventricular ejection fraction (%)
   3. Left ventricular wall thickness (mm)
   4. Mitral regurgitation
   5. Transmitral velocity (E/A ratio, deceleration time of E wave)
7. Serum BNP levels at admission and discharge

Step 4. Discharge Status and Treatment

1. Discharge status
   1. In-hospital death
      Autopsy
   2. Discharge to home
   3. Transfer to another ward for heart failure treatment
   4. Transfer to another ward to treat other diseases
2. Discharge medications
   1. Angiotensin-converting enzyme inhibitors
      [ ] Enalapril [ ] Lisinopril [ ] Perindopril
      [ ] Imidapril [ ] Captopril [ ] Cilazapril
      [ ] Temocapril [ ] Other [ ] No
   2. Angiotensin II receptor blockers
      [ ] Losartan [ ] Valsartan [ ] Candesartan
      [ ] Telmisartan [ ] Other [ ] No
   3. Beta-blockers
      [ ] Carvedilol: daily dosage [ ] mg/dl
      [ ] Bisoprolol: daily dosage [ ] mg/dl
      [ ] Metoprolol: daily dosage [ ] mg/dl
      [ ] Others: daily dosage [ ] mg/dl
      [ ] No
   4. Diuretics
      [ ] Thiazide [ ] Furosemide [ ] Azosemide
      [ ] Spironolactone [ ] Eplerenone [ ] Other
      [ ] No
   5. Digitalis
      [ ] Yes [ ] No
   6. Oral inotropic agents
      [ ] Pimobendan [ ] Docarpamine [ ] Other
      [ ] No
   7. Calcium channel blockers
      [ ] Amlodipine [ ] Nefedipine [ ] Diltiazem
      [ ] Other [ ] No
   8. Alpha-blockers
      [ ] Doxazosin [ ] Other [ ] No
   9. Nitrates
      [ ] Yes [ ] No
   10. Antiarrhythmic agents
      [ ] Amiodarone [ ] Sotalol [ ] Bepridil
      [ ] Disopyramide [ ] Aprindine [ ] Mexiletine
      [ ] Flecainide [ ] Pilsicainide [ ] Cibenzoline
      [ ] Other [ ] No
   11. Aspirin
      [ ] Yes [ ] No
   12. Antiplatelet agents
      [ ] Ticlopidine [ ] Cilostazol [ ] Other
      [ ] No
   13. Warfarin
      [ ] Yes [ ] No
   14. Statins
      [ ] Pravastatin [ ] Fluvastatin [ ] Atorvastatin
      [ ] Simvastatin [ ] Other [ ] No
   15. Participation in clinical trial
      [ ] J-CHF [ ] Bisoprolol
      [ ] Other
      [ ] No
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
      [ ] Cardiac death [ ] Non-cardiac death [ ] Unknown
   4. Autopsy
3. Hospital readmission because of exacerbation of heart failure
   1. Date of readmission
   2. Date of discharge
4. Sustained ventricular tachycardia or ventricular fibrillation

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Characteristics and Outcomes of Patients With Heart Failure in General Practices and Hospitals

— Japanese Cardiac Registry of Heart Failure in General Practice (JCARE-GENERAL) —

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for the JCARE-GENERAL Investigators

Background The characteristics and outcomes of patients discharged from hospitals with a diagnosis of heart failure (HF) have been described by a number of previous epidemiological studies. However, very little information is available on this issue in general practice in Japan.

Methods and Results The Japanese Cardiac Registry of Heart Failure in General Practice (JCARE-GENERAL) is designed to study the characteristics, treatment and outcomes prospectively in a broad sample of outpatients with HF who were managed by cardiologists in hospital (Hospital-HF) and primary care physicians in general practice (GP-HF). Out of 2,685 patients with HF, 1,280 patients were Hospital-HF and 1,405 GP-HF. Compared to the Hospital-HF patients, GP-HF patients were more likely to be elderly and female, and they had a higher prevalence of hypertensive heart disease as a cause of HF. Angiotensin-converting enzyme inhibitors, angiotensin receptor blockers and β-blockers were more prescribed to Hospital-HF than GP-HF patients. At the follow-up of 1.2 year, after adjustment, the mortality was comparable between the Hospital-HF and GP-HF groups, whereas HF-related admission was higher in the Hospital-HF group than in in the GP-HF group.

Conclusions Based on the JCARE-GENERAL, the characteristics, treatment and outcomes of GP-HF patients differed from those of Hospital-HFpatients in Japan. (*Circ J* 2007; **71:** 000–000)

Key Words: General practice; Heart failure; Hospital; Outcome; Registry

Heart failure (HF) is 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 cardiac manifestations of HF are dyspnea and fatigue, which may limit exercise tolerance, and fluid retention, which may lead to pulmonary congestion and peripheral edema. HF is a leading cause of morbidity and mortality in industrialized countries[1] It is also a growing public health problem, mainly because of aging populations and the increase in the prevalence of HF in the elderly[2] The clinical characteristics, treatment and outcomes of these patients have been well described by a number of hospital-based registries performed in the United States of America[3] Europe[4–6] and Japan[7–11] However, most patients with HF are managed not only by hospital cardiologists but also by primary healthcare physicians in the community (general practitioners). Accordingly, primary care physicians must play a key role in the identification and management for these patients. Nevertheless, much less is known of HF in general practice. There have been no studies reported that provide information on the characteristics, treatment and outcomes in this setting in Japan.

The Japanese Cardiac Registry of Heart Failure in General Practice (JCARE-GENERAL) was developed to provide a large, national prospective registry database describing the clinical characteristics, treatment and outcomes of outpatients with HF. The main aim of the present study was to compare the characteristics and outcomes between patients managed by hospital cardiologists with those managed by primary care physicians in general practice.

Methods

The JCARE-GENERAL is a prospective multicenter registry designed to compile a large clinical database on the characteristics, treatment and outcomes of the outpatients with HF in Japan. Baseline data were collected during November 2004. Follow-up data were collected 1 year after the enrollment.

Study Patients

Eleven participating areas, Hakodate, Shiogama, Mishima, Kahoku in Ishikawa; Motosu in Gifu, Ibaraki, Kasai, Hata in Kochi; Ube, Higashi in Fukuoka; and Kurume, have been selected throughout Japan (Fig 1). In

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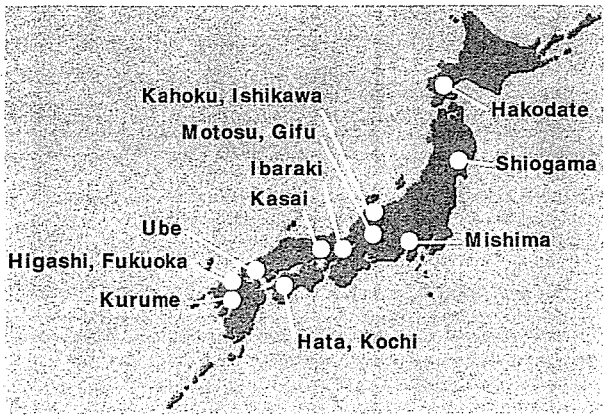

Fig 1. The Japanese Cardiac Registry of Heart Failure in General Practice (JCARE-GENERAL) study areas in Japan.

each participating area, hospital cardiologists and primary healthcare physicians enrolled HF outpatients into the present study. HF patients managed by the hospital cardiologists were categorized as "Hospital-HF" and those managed by primary care physicians in general practice as "GP-HF".

HF was 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. For this registry, patients with current HF symptoms as well prior HF were enrolled. The presence of HF was confirmed by the simultaneous presence of at least 2 major criteria or 1 major criterion in conjunction with 2 minor criteria according to the Framingham criteria (Table 1)[12] Patients must have been at least 15 years old at the time of enrollment. Eligibility is not contingent on the use of any particular therapeutic agent or regimen.

Data Collection and Processing

The study protocol, study procedures and data-collection forms were reviewed by the co-investigators at each study area during the central meetings and also presented to all participating physicians during training sessions before commencing the present study. The participating physicians were encouraged to register all patients meeting the entry criteria as consecutively as possible. Duplicated registry of the same patient at different institutions was avoided by checking for their prior enrollment to this registry. Compliance with these methods of registry was not strictly monitored. For each case, baseline data recorded on the form included: (1) demography including age and sex; (2) underlying causes of HF; (3) atrial fibrillation; (4) prior history of HF; and (5) medication. The status of all patients was surveyed and the following information was obtained: (1) whether they survived to the follow up; (2) their cause of death; and (3) hospital admissions due to an exacerbation of HF that required more than continuation of their usual therapy on admission. The cause of death was classified as cardiac or non-cardiac death by the participating physician in each patient based on the clinical information. Death from cardiac causes was defined as death due to cardiac events including sudden cardiac death, fatal myocardial infarction and HF death. Death from causes other than cardiac diseases such as cancer was defined as non-cardiac death.

Ischemic heart disease was considered an etiology of HF if the patient had one of the following: (1) a documented history of myocardial infarction, angina or prior coronary revascularization; (2) pathologic Q waves on the electrocardiogram; or (3) greater than 75% stenosis in one or more coronary arteries on coronary angiograms. Valvular heart disease was determined on the basis of the presence of long standing mitral or aortic valve involvement documented by physical examination and echocardiography or angiography. Hypertensive heart disease was considered present if there was a history of hypertension in the medical records or sustained hypertension and left ventricular (LV) hypertrophy confirmed by electrocardiogram or echocardiogram. Dilated cardiomyopathy was diagnosed by the presence of global LV dilatation with impaired systolic function occurring in the absence of known cardiac or systemic causes.

Table 1 Framingham Criteria for HF

Major criteria
Paroxysmal nocturnal dyspnea
Neck vein distension
Rales
Radiographic cardiomegaly (increasing heart size on chest X-ray)
Acute pulmonary edema
S3 gallop
Increased central venous pressure (>16 cm water at right atrium)
Circulation time ≥25 s
Hepatojugular reflux
Pulmonary edema, visceral congestion, or cardiomegaly at autopsy
Minor criteria
Bilateral ankle edema
Nocturnal cough
Dyspnea on ordinary exertion
Hepatomegaly
Pleural effusion
Decrease in vital capacity by one-third from maximum value recorded
Tachycardia (rate ≥120/min)
Major or minor criteria
Weight loss ≥4.5 kg in 5 days in response to treatment

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.
HF, heart failure.

Patient Confidentiality

The JCARE-GENERAL 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 at Kyushu University. Informed consent was attained for each patient. The present study did not include any protocol-specified alterations of treatment or any other aspects of hospital care. Patient confidentiality was preserved because direct patient identifiers, such as name, address and identification number, were not collected.

Statistical Analysis

Data are expressed as means±SD. Differences in clinical characteristics, treatment and outcomes were evaluated using the chi-square test or Student's t-test. Survival was estimated with the Kaplan and Meier methods. Differences in survival between the groups were evaluated using the log rank test. After the adjustment for age, sex, etiology of HF, atrial fibrillation and prior history of HF, the relative risk for outcomes including all-cause death, cardiac death and HF-related admission was estimated for the Hospital-HF and GP-HF groups. They were adjusted as categorical

Table 2 Patient Characteristics

	All (n=2,685)	Hospital-HF (n=1,280)	GP-HF (n=1,405)	p value
Age, year (mean±SE)	74±12	71±13	77±10	<0.01
≥75 years, %	56	46	64	<0.01
Male, %	46	55	38	<0.01
Underlying causes of HF, %				
Ischemic	30	27	32	<0.05
Hypertensive	35	22	47	<0.05
Valvular	26	27	25	NS
Cardiomyopathic	15	22	9	<0.05
Others	12	12	12	NS
Unknown	5	4	5	NS
Atrial fibrillation, %	40	42	37	<0.01
Prior history of HF, %	83	90	77	<0.01

GP, general practice. Other abbreviation see in Table 1.

Table 3 Medication Use

	All (n=2,685)	Hospital-HF (n=1,280)	GP-HF (n=1,405)	p value
ACEIs, %	31.5	40.4	23.5	<0.01
ARBs, %	30.9	32.7	29.4	NS
ACEIs or ARBs, %	59.2	68.7	50.6	<0.01
ACEIs and ARBs, %	3.3	4.4	2.3	<0.01
β-blockers, %	27.4	38.3	17.5	<0.01
Diuretics, %	62.0	66.1	58.2	<0.01
Digitalis, %	43.0	45.4	40.8	<0.05
Calcium antagonists, %	37.1	33.4	40.5	<0.01

ACEIs, angiotensin-converting enzyme inhibitors; ARBs, angiotensin receptor blockers. Other abbreviations see in Tables 1,2.

Table 4 Death and HF-Related Admission Rate

	No. of patients		All cause death (%)		Cardiac death (%)		HF-related admission (%)	
	Hospital-HF	GP-HF	Hospital-HF	GP-HF	Hospital-HF	GP-HF	Hospital-HF	GP-HF
Crude rate	1,251	1,377	6.7	5.9	2.9	1.7	11.3	6.8
Age-adjusted rate (95%CI)			7.6 (2.7–12.5)	5.3 (1.9–8.7)	3.0 (0.2–6.1)	1.5 (0.3–3.3)	12.1 (6.0–18.3)	6.8 (2.3–11.3)
Age groups								
–39 years	36	4	11.1	0	5.6	0	8.3	0
40–49 years	52	16	1.9	0	1.9	0	13.5	6.3
50–59 years	132	72	3.0	0	3.0	0	8.3	5.6
60–69 years	237	200	3.4	1.5	1.7	0.5	10.1	4.0
70–79 years	439	503	6.6	3.8	2.7	1.4	11.8	7.2
80–89 years	314	472	10.5	8.3	3.8	2.8	13.1	6.4
90– years	38	108	13.2	18.5	2.6	1.9	7.9	13.9
Sex groups								
Male								
Crude rate	685	508	8.7	7.3	2.9	1.8	12.0	6.9
Age-adjusted rate (95%CI)			10.2 (4.9–15.6)	6.4 (2.7–10.0)	3.1 (0.2–5.9)	1.5 (0.5–3.5)	13.0 (7.4–18.6)	6.8 (1.3–12.3)
Female								
Crude rate	563	858	4.4	5.1	2.8	1.6	10.5	6.9
Age-adjusted rate (95%CI)			4.9 (0.8–8.9)	4.9 (2.3–7.5)	2.9 (0.2–6.1)	1.6 (0.5–2.8)	11.4 (5.2–17.6)	6.9 (3.3–10.5)

The mean follow-up periods for HP-HF and GP-HF were 431±93 days and 424±91 days, respectively.
CI, confidence interval; Other abbreviations see in Tables 1,2.

variables, except for age, which was a numerical variable. Two tailed tests of significance are reported. $p<0.05$ was considered to be statistically significant.

Results

Patient Characteristics

The present study included 2,685 outpatients with HF from 11 areas in Japan; 1,280 patients from 55 hospitals as Hospital-HF and 1,405 patients from 180 general practitioners as GP-HF. The mean number of patients at each hospital and GP was 23±27 and 8±9, respectively. The mean age was 74±12 years (range 15 to 101), and 56% of patients were >75 years of age (Table 2). The mean age and the proportion of aged patients were greater in GP-HF patients compared to Hospital-HF patients (Table 2). Overall, 46% were men and 54% women. The GP-HF patients were more often women (45% vs 62%, $p<0.01$).

Ischemic heart disease was the predominant cause of HF in both groups, but this was more prevalent in the GP-HF group. Hypertensive heart disease was more common in the GP-HF group than in the Hospital-HF group and it was the leading cause of HF in this group of patients. In contrast, cardiomyopathy was less common in GP-HP patients.

The prevalence of atrial fibrillation was greater and the prior history of HF was more frequent in Hospital-HF patients than in the GP-HF group (Table 2).

Medication Use

Angiotensin-converting enzyme (ACE) inhibitors were administered to 32% of the patients, angiotensin receptor blockers (ARBs) to 31%, β-blockers to 27%, diuretics to 62% and digitalis to 43% (Table 3). ACE inhibitors and ARBs were more prescribed to Hospital-HF than GP-HF patients (Table 3). Beta-blockers were prescribed to approximately 38% of Hospital-HF patients whereas they were prescribed to only 18% of GP-HF patients. Prescription rates of diuretics and digitalis were also higher in Hospital-HF patients. In contrast, calcium antagonists were prescribed more often to GP-HF patients.

Mortality and HF-Related Admission

Among 2,685 patients, 57 patients were lost during the follow up (2.1%). The mean follow-up periods for patients with HP-HF and GP-HF were 431±93 and 424±91 days, respectively, which were not significantly different.

During the follow-up, 165 patients (6.3%) died; 59 (36%) from cardiac causes, 53 (32%) from non-cardiac causes and 53 (32%) from unknown causes. The rates of all-cause death as well as cardiac death tended to be greater in Hospital-HF

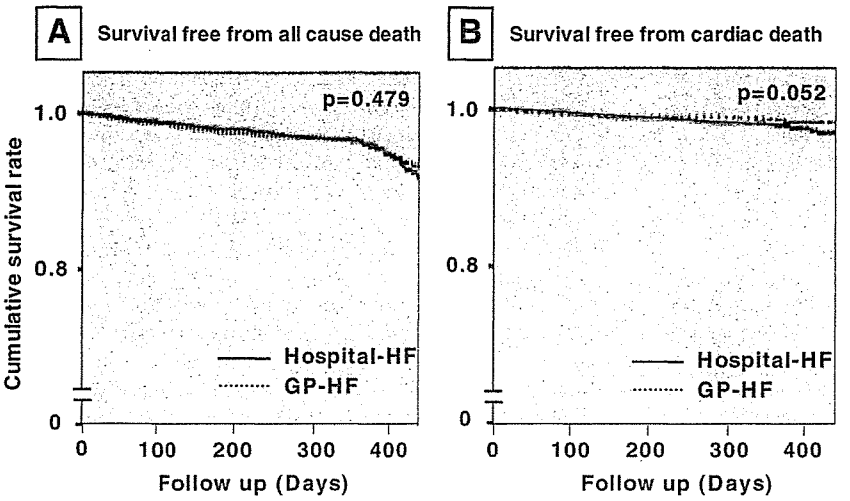

Fig 2. Cumulative survival rates. Survival estimates free from all-cause death (A) and cardiac death (B) during the follow up were derived from the Kaplan and Meier methods. HF, heart failure; GP, general practice.

Table 5 Adjusted Relative Risk for Outcomes by Hospital-HF and GP-HF

	Relative risk (95%CI)	*p value*
All cause death		
Hospital-HF	*1*	
GP-HF	*0.83 (0.59–1.18)*	*0.30*
Cardiac death		
Hospital-HF	*1*	
GP-HF	*0.69 (0.39–1.22)*	*0.20*
HF-related admission		
Hospital-HF	*1*	
GP-HF	*0.62 (0.47–0.82)*	*<0.01*

Adjusted for age, sex, etiology of HF, atrial fibrillation, and prior history of HF.
Abbreviations see in Tables 1,2,4.

patients than GP-HF (Table 4, Fig 2). For the age and sex categories studied, these rates were higher in Hospital-HF patients than in GP-HF, except for all-cause death in female patients (Table 4). However, after adjusting for age or variables including age, sex, causes of HF, atrial fibrillation and prior history of HF, the rates of all-cause death and cardiac death did not differ between Hospital-HF and GP-HF patients (Tables 4, 5).

During the same study period, 235 patients (9%) had a hospital admission due to an exacerbation of HF. The HF-related hospital admission rate was significantly higher in Hospital-HF than in GP-HF patients ($p<0.01$; Table 4), which did not alter even after adjustment (Table 5).

Discussion

The characteristics and outcomes of outpatients with HF in general practice have been poorly described, despite the importance of this disease to public health. The JCARE-GENERAL is the first diverse, large-scale, prospective multicenter database of this population in Japan. An important finding is that HF outpatients in the general practice were more likely to be elderly and women with hypertension as a predominant cause of HF. Evidence-based medications for HF, including ACE inhibitors, ARBs and β-blockers, were less prescribed to GP-HF patients compared to Hospital-HF patients. In contrast, calcium antagonists were prescribed more often to GP-HF patients. At the follow-up of 1.2 years after adjustment, the mortality was comparable between Hospital-HF and GP-HF patients, whereas HF-related admission was higher in Hospital-HF than in GP-HF patients, which might be caused by them having more definite and severe HF.

We have previously reported the characteristics and outcomes of patients hospitalized to the cardiology departments in Fukuoka, Japan[9–11] These studies highlighted several important features of "real world" patients with HF, which were not found in large-scale clinical trials. One key feature was the old age of HF patients. The mean age of the patients was 69 years; 70% were ≥65 years of age. Women especially were mostly over 70 years of age. This is consistent with previous community-based studies![13,14] Another important feature was a relatively good survival prognosis; the 1-year mortality rate being 8.3%. A prognosis of patients with decreased ejection fraction (<40%) was still good; the 1-year mortality rate being 9.1%. At the first glance, this finding appears to be contradicted by the generally held notion that advanced age and more comorbidity may be related to poor survival. In contrast to the relatively low mortality, rates of readmission due to worsening HF were as high as 40% within 1 year after discharge. This value was comparable to those in prior studies (a 3- to 6-month readmission rate 30 to 50%)[15,16] The most commonly identified precipitating cause for hospital readmission was lack of compliance with medical and dietary treatment (48%).[10]

Even though our previous studies have provided a valuable insight into the clinical characteristics, outcomes and the potential effective treatment strategies for HF patients, the generality of these results is questioned because our previous studies were conducted in hospitalized patients with HF[9–11] Outpatients with HF are managed mostly in the community by primary care physicians. Nevertheless, few studies provide objective information about these patients. Therefore, it is of critical importance to analyze the realistic data for HF outpatients in general practice, and to form a database on a national basis for future investigations. For this purpose, JCARE-GENERAL was designed to focus on the demographic and clinical characteristics, treatment strategies and outcomes in "real-world" outpatients managed by primary care physicians in general practice.

The present study demonstrated that, compared to Hospital-HF patients, GP-HF patients were more often elderly and female, and had a higher prevalence of hypertensive heart disease as a cause of HF. In concordance with the