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ORIGINAL ARTICLE

Public assistance in patients with acute heart failure: a report from the KCHF registry

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Abstract

Aims There is a scarcity of data on the post-discharge prognosis in acute heart failure (AHF) patients with a low-income but receiving public assistance. The study sought to evaluate the differences in the clinical characteristics and outcomes between AHF patients receiving public assistance and those not receiving public assistance.

Methods and results The Kyoto Congestive Heart Failure registry was a physician-initiated, prospective, observational, multicentre cohort study enrolling 4056 consecutive patients who were hospitalized due to AHF for the first time between October 2014 and March 2016. The present study population consisted of 3728 patients who were discharged alive from the index AHF hospitalization. We divided the patients into two groups, those receiving public assistance and those not receiving public assistance. After assessing the proportional hazard assumption of public assistance as a variable, we constructed multivariable Cox proportional hazard models to estimate the risk of the public assistance group relative to the no public assistance group. There were 218 patients (5.8%) receiving public assistance and 3510 (94%) not receiving public assistance. Patients in the public assistance group were younger, more frequently had chronic coronary artery disease, previous heart failure hospitalizations, current smoking, poor medical adherence, living alone, no occupation, and a lower left ventricular ejection fraction than those in the no public assistance group. During a median follow-up of 470 days, the cumulative 1 year incidences of all-cause death and heart failure hospitalizations after discharge did not differ between the public assistance group and no public assistance group (13.3% vs. 17.4%, $P = 0.10$, and 28.3% vs. 23.8%, $P = 0.25$, respectively). After adjusting for the confounders, the risk of the public assistance group relative to the no public assistance group remained insignificant for all-cause death [hazard ratio (HR), 0.97; 95% confidence interval (CI), 0.69–1.32; $P = 0.84$]. Even after taking into account the competing risk of all-cause death, the adjusted risk within 180 days in the public assistance group relative to the no public assistance group remained insignificant for heart failure hospitalizations (HR, 0.93; 95% CI, 0.64–1.34; $P = 0.69$), while the adjusted risk beyond 180 days was significant (HR, 1.56; 95% CI, 1.07–2.29; $P = 0.02$).

Conclusions The AHF patients receiving public assistance as compared with those not receiving public assistance had no significant excess risk for all-cause death at 1 year after discharge or a heart failure hospitalization within 180 days after discharge, while they did have a significant excess risk for heart failure hospitalizations beyond 180 days after discharge.

Clinical Trial Registration: https://clinicaltrials.gov/ct2/show/NCT02334891 (NCT02334891) and https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000017241 (UMIN000015238)

Keywords Acute heart failure; Public assistance; Mortality

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Introduction

Despite attempts to improve the prognosis of patients with acute heart failure (AHF), the post-discharge mortality in patients with AHF remains high and has not significantly improved over the past decade.[1] In particular, patients with heart failure with a reduced ejection fraction (HFrEF) from low-income countries with a high income inequality have a higher post-discharge mortality, which is strongly associated with the inability to receive guideline-directed medical treatment (GDMT).[2] In Japan, which has adopted a universal health care system, all citizens have access to high-quality medical care at a low cost.[3] Low-income people who meet certain criteria, nearly half of which are due to a disability or illness,[4] can receive public assistance and access to the same quality of medical care for free. In other words, AHF patients receiving public assistance have the opportunity to receive post-discharge GDMT, which may improve the post-discharge mortality. Our hypothesis was that the post-discharge prognosis in AHF patients receiving public assistance would not be poor, but there is a scarcity of data to support this. Thus, we aimed to evaluate the differences in the clinical characteristics and outcomes between AHF patients receiving public assistance and those not receiving public assistance using a large contemporary all-comer registry of patients with AHF hospitalizations in Japan.

Methods

Study design, setting, and population

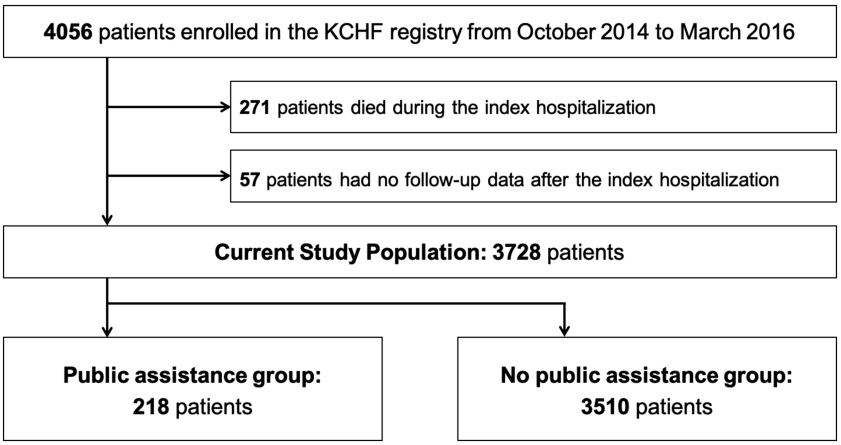
The Kyoto Congestive Heart Failure (KCHF) registry was a physician-initiated, prospective, observational, multicentre cohort study enrolling consecutive patients who were hospitalized due to AHF for the first time between October 2014 and March 2016, including those patients with previous heart failure hospitalizations before October 2014. The participating centres were 19 secondary and tertiary hospitals, including rural and urban, as well as large and small institutions, in Japan. The design and patient enrolment in the KCHF registry were previously reported in detail.[5,6] Briefly, we enrolled consecutive patients with AHF as defined by the modified Framingham criteria, who were admitted to the participating hospitals and underwent a heart failure–specific treatment requiring intravenous drugs within 24 h after presenting to the hospital. The clinical follow-up data were collected in October 2017. The attending physicians or research assistants at each participating hospital collected the clinical event data, including that on death and heart failure hospitalizations, during the follow-up from the hospital medical records or patients, their relatives, or their referring physicians by phone and/or mailed questions.

Among the 4056 patients enrolled in the KCHF registry, 271 died during the index hospitalization (*Figure 1*). After excluding patients without follow-up data after the index hospitalization (N = 57), the present study population consisted of 3728 patients who were discharged alive from the index AHF hospitalization. We divided the patients into two groups, those receiving public assistance and those not receiving public assistance (*Figure 1*).

Public assistance

The purpose of the public assistance system in Japan is to provide a necessary protection according to the income levels of people, to ensure them a minimum standard of living that is healthy and culturally acceptable, and to promote their self-reliance.[7] Conditions for receiving public assistance are briefly summarized as follows: (i) the household monthly income must be less than approximately 130 000 yen (1200 US dollar), (ii) people who are able to receive assistance from their families or relatives are not eligible for public assistance, (iii) people who are unable to work due to illness or injury can receive public assistance regardless of their age, and (iv) it is also important that they do not have any property such as savings or land. Patients receiving public assistance are not enrolled in any social health insurance programme and are exempted from insurance premiums and co-payments. The medical services available to patients receiving public assistance are the same as those available to social health insurance subscribers, and medical institutions are paid on the same fee schedule.[8]

Figure 1 Study flowchart. KCHF, Kyoto Congestive Heart Failure.



Ethics

The investigation conformed to the principles outlined in the Declaration of Helsinki. The study protocol was approved by the ethical committees at Kyoto University Hospital (local identifier: E2311) and at each participating hospital (Supporting Information, *Appendix S1*). A waiver of written informed consent from each patient was approved, because it met the conditions included in the Japanese Ethical Guidelines for Epidemiological Studies.[5,6] No patients refused to participate in the study when contacted for follow-up.

Patient and public involvement

This research was done without any patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or to interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

Definitions

Heart failure was classified according to the baseline left ventricular ejection fraction (LVEF) as that with a reduced LVEF (HFrEF: LVEF $<$ 40%), mildly reduced LVEF (HFmrEF: LVEF 40–49%), or preserved LVEF (HFpEF: LVEF $\geq$ 50%). Anaemia was diagnosed if the value of the haemoglobin was $<$13 g/dL for men and $<$12 g/dL for women. The detailed definitions of other patient characteristics are described in *Appendix S2*.

The primary outcome measure in the present study was all-cause death after discharge from the index hospitalization. Other outcome measures included heart failure hospitalizations, cardiovascular death, and non-cardiovascular death. The causes of death were classified according to the Valve Academic Research Consortium definitions[9] and were adjudicated by a clinical event committee.[5,6,10] Death was regarded as cardiovascular in origin unless obvious non-cardiovascular causes could be identified. Cardiovascular death included death related to heart failure, acute myocardial infarctions, fatal ventricular arrhythmias, sudden cardiac death, other cardiac death, strokes, intracranial haemorrhages, and other vascular death. Sudden cardiac death was defined as unexplained death of a previously stable patient, including fatal ventricular arrhythmias and cardiac arrest. Non-cardiovascular death included malignancy, infections, renal failure, liver failure, respiratory failure, bleeding, and other causes. Heart failure hospitalizations were hospitalizations due to worsening heart failure, requiring intravenous drug therapy.[5]

Statistical analysis

Categorical variables are expressed as numbers and percentages, and continuous variables are expressed as the mean with the standard deviation or median with the interquartile range based on their distribution. As for the patient characteristics, the categorical variables were compared using the χ^2 test when appropriate; otherwise, the Fisher's exact test was used. Continuous variables were compared using the Student's *t*-test or Wilcoxon rank sum test based on their distribution. The baseline characteristics and clinical outcomes including all-cause death, heart failure hospitalizations, cardiovascular death, and non-cardiovascular death were compared between the public assistance group and no public assistance group. We regarded the date of discharge as time zero for the clinical follow-up. The 1 year clinical follow-up

was regarded as completed with an allowance of 1 month. Given that the number of patients without follow-up data after the index hospitalization (N = 57) may have been relatively high for that of patients in the public assistance group, we compared the baseline characteristics of the clinically relevant risk-adjusting variables between the public assistance group and patients receiving public assistance who were lost to follow-up. Cumulative incidences were estimated by the Kaplan–Meier method, and differences were assessed with the log-rank test. Regarding heart failure hospitalizations, to account for the competing risk of all-cause death, we used the Gray's method to estimate and compare the cumulative incidence of the endpoint. After assessing the proportional hazard assumption of public assistance as a variable, we constructed multivariable Cox proportional hazard models to estimate the risk of the public assistance group relative to the no public assistance group, with the results expressed as the hazard ratios (HRs) and 95% confidence intervals (CIs). Because the proportional hazard assumption was not met for heart failure hospitalizations, and the hazards crossed around 6 months after discharge, we separately constructed the multivariable Fine and Gray's models considering the competing risk of all-cause death for the observation period within and beyond 180 days. We included the following 25 clinically relevant risk-adjusting variables into the model: demographical variables (age $\geq$ 80 years, sex, and body mass index $\leq$ 22 kg/m^2), variables related to heart failure (aetiology of heart failure hospitalizations associated with acute coronary syndrome, previous heart failure hospitalizations, and LVEF $<$ 40% by echocardiography), variables related to comorbidities (atrial fibrillation or flutter, hypertension, diabetes mellitus, previous myocardial infarction, previous stroke, current smoking, and chronic lung disease), living status (living alone and ambulatory), vital signs at presentation (systolic blood pressure $<$ 90 mmHg and heart rate $<$ 60 b.p.m.), laboratory tests on admission (estimated glomerular filtration rate $<$ 30 mL/min/1.73 m^2, albumin $<$ 3.0 g/dL, sodium $<$ 135 mEq/L, and anaemia), and medications at discharge [angiotensin converting enzyme inhibitors (ACEIs) or angiotensin II receptor blockers (ARBs), β-blockers, loop diuretics, and tolvaptan] consistent with the previous reports[11–13] as indicated in *Table 1*. The continuous variables were dichotomized by the clinically meaningful reference values. We performed complete case analyses to address any missing values because there was a relatively small number of missing values in the KCHF registry. As sensitivity analyses, we constructed the multivariable Cox proportional hazard models using a multiple imputation by the chained equation method, which replaced each missing value with a set of substituted plausible values by creating 20 filled-in complete data sets. We also constructed multivariable Cox proportional hazard models with an additional risk-adjusting variable of the participating centres dichotomized by the median proportion of patients receiving public assistance. All statistical analyses were performed with EZR software (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria, Version 4.1.2), R package 'mice' version 3.14.0, or JMP version 14.0.0 software (SAS Institute Inc., Cary, NC, USA). Two tailed P values of $<$0.05 were considered statistically significant.

Data sharing statement

All data relevant to the study are included in the article or uploaded as supporting information. The minimal data set is ethically restricted by the Institutional Review Board of Kyoto University Hospital. This is because the secondary use of the data was to be reviewed by the Ethics Commission at the time of the initial application. Data are available from the Ethics Committee (contact via TK) for researchers who meet the criteria for access to confidential data.

Results

Patient characteristics

In the present study population, there were 218 patients (5.8%) in the public assistance group and 3510 patients (94%) in the no public assistance group (*Figure 1*). The proportions of patients receiving public assistance ranged from 0% to 14% across the participating centres (*Figure S1*). The baseline characteristics significantly differed in several aspects between the public assistance group and no public assistance group (*Table 1*). Patients in the public assistance group were younger, more frequently had chronic coronary artery disease, a previous myocardial infarction, a previous heart failure hospitalization, current smoking, chronic lung disease, poor medical adherence, lived alone, no occupation, and a lower LVEF than those in the no public assistance group (*Table 1*). Among the HFrEF patients, the proportion of patients receiving GDMT (ACEIs or ARBs, β-blockers, or mineralocorticoid receptor antagonist) at discharge did not significantly differ between the public assistance group and no public assistance group (*Table S1*). The baseline characteristics of the clinically relevant risk-adjusting variables were almost the same other than the aetiology of the acute coronary syndrome between the public assistance group and patients receiving public assistance who were lost to follow-up (*Table S2*).

Clinical outcomes

The median length of the follow-up was 470 (interquartile range, 357–649) days, with a 95.8% follow-up rate at 1 year. The cumulative 1 year incidence of the primary outcome measure (all-cause death after discharge) did not differ between

Table 1 Patient characteristics

	Total (N = 3728)	Public assistance group (N = 218)	No public assistance group (N = 3510)	P value	Missing values
Clinical characteristics					
Age, years	77.7 ± 12.0	72.3 ± 12.2	78.0 ± 11.9	<0.001	—
≥80 years[a]	1933 (52%)	64 (29%)	1869 (53%)	<0.001	—
Women[a]	1671 (45%)	87 (40%)	1584 (45%)	0.13	—
BMI, kg/m^2	22.9 ± 4.5	23.0 ± 4.4	22.9 ± 4.5	0.71	174 (4.7%)
≤22 kg/m^2[a]	1639 (46%)	101 (47%)	1538 (46%)	0.69	—
Aetiology				0.01	—
Chronic CAD	1003 (27%)	79 (36%)	924 (26%)		
Acute coronary syndrome[a]	206 (5.5%)	7 (3.2%)	199 (5.7%)		
Hypertensive heart disease	929 (25%)	55 (25%)	874 (25%)		
Cardiomyopathy	557 (15%)	34 (16%)	523 (15%)		
Dilated cardiomyopathy	401/557 (72%)	27/34 (71%)	374/523 (72%)		
Valvular heart disease	737 (20%)	31 (14%)	706 (20%)		
Other heart disease	296 (7.9%)	12 (5.5%)	284 (8.1%)		
Medical history					
Previous heart failure hospitalizations[a]	1321 (36%)	94 (44%)	1227 (36%)	0.01	69 (1.9%)
Atrial fibrillation or flutter[a]	1556 (42%)	88 (40%)	1468 (42%)	0.67	—
Hypertension[a]	2699 (72%)	153 (70%)	2546 (73%)	0.45	—
Diabetes mellitus[a]	1397 (37%)	89 (41%)	1308 (37%)	0.29	—
Dyslipidaemia	1455 (39%)	94 (43%)	1361 (39%)	0.20	—
Previous myocardial infarction[a]	838 (22%)	66 (30%)	772 (22%)	0.005	—
Previous stroke[a]	593 (16%)	38 (17%)	555 (16%)	0.53	—
Previous PCI or CABG	956 (26%)	67 (31%)	889 (25%)	0.08	—
Current smoking[a]	453 (12%)	66 (31%)	387 (11%)	<0.001	66 (1.8%)
VT/VF	155 (4.2%)	12 (5.5%)	143 (4.1%)	0.30	—
Device implantation	364 (9.8%)	28 (13%)	336 (9.6%)	0.11	—
Chronic kidney disease	1644 (44%)	85 (39%)	1559 (44%)	0.12	—
Chronic lung disease[a]	489 (13%)	46 (21%)	443 (13%)	<0.001	—
Malignancy	537 (14%)	24 (11%)	513 (15%)	0.14	—
Cognitive dysfunction	658 (18%)	36 (17%)	622 (18%)	0.65	—
Social backgrounds					
Poor medical adherence	629 (17%)	58 (27%)	571 (16%)	<0.001	—
Living alone[a]	796 (21%)	121 (56%)	675 (19%)	<0.001	—
With occupation	494 (13%)	11 (5.1%)	483 (14%)	<0.001	—
Daily life activities				0.19	38 (1.0%)
Ambulatory[a]	2949 (80%)	167 (77%)	2782 (80%)		
Use of wheelchair, outdoor only	275 (7.5%)	13 (6.0%)	262 (7.5%)		
Use of wheelchair, outdoor and indoor	337 (9.1%)	28 (13%)	309 (8.9%)		
Bedridden	129 (3.5%)	9 (4.2%)	120 (3.5%)		
Vital signs at presentation					
BP, mmHg					
Systolic BP	148 ± 35	153 ± 36	148 ± 35	0.06	11 (0.3%)
<90 mmHg[a]	95 (2.6%)	6 (2.8%)	89 (2.5%)	0.85	7 (0.2%)
Diastolic BP	85 ± 24	90 ± 26	85 ± 24	0.003	19 (0.5%)
Heart rate, b.p.m.	96 ± 28	98 ± 29	96 ± 28	0.37	25 (0.7%)
<60 b.p.m.[a]	252 (6.8%)	14 (6.5%)	238 (6.8%)	0.83	25 (0.7%)
Rhythms at presentation				0.06	—
Sinus rhythm	2077 (56%)	121 (56%)	1956 (56%)		
Atrial fibrillation or flutter	1357 (36%)	71 (33%)	1286 (37%)		
Other rhythms	294 (7.9%)	26 (12%)	268 (7.6%)		
NYHA class III or IV	3231 (87%)	192 (88%)	3039 (87%)	0.64	16 (0.4%)
Laboratory tests on admission					
LVEF, %	46 ± 16	43 ± 16	47 ± 16	0.003	90 (2.4%)
HFrEF (LVEF < 40%)[a]	1383 (37%)	100 (46%)	1283 (37%)	0.01	11 (0.3%)
HFmrEF (LVEF 40–49%)	703 (19%)	41 (19%)	662 (19%)		
HFpEF (LVEF ≥ 50%)	1631 (44%)	77 (35%)	1554 (44%)		
BNP, pg/mL	712 [391–1262]	765 [447–1412]	706 [389–1252]	0.052	48 (1.3%)[c]
NT-proBNP, pg/mL	5624 [2661–12 248]	5030 [2520–8899]	5740 [2 661–12 839]	0.30	
Serum creatinine, mg/dL	1.10 [0.82–1.61]	1.10 [0.81–1.61]	1.10 [0.82–1.61]	0.67	6 (0.2%)
eGFR, mL/min/1.73 m^2	46 ± 23	49 ± 25	46 ± 23	0.10	6 (0.2%)
<30 mL/min/1.73 m^2[a]	984 (26%)	48 (22%)	936 (27%)	0.14	6 (0.2%)
Blood urea nitrogen, mg/dL	24 [18–34]	22 [16–30]	24 [18–35]	0.003	11 (0.3%)
Albumin, g/dL	3.5 ± 0.5	3.6 ± 0.5	3.5 ± 0.5	0.005	111 (3.0%)
<3.0 g/dL[a]	482 (13%)	24 (11%)	458 (13%)	0.36	111 (3.0%)

(*Continues*)

Table 1 (continued)

	Total (N = 3728)	Public assistance group (N = 218)	No public assistance group (N = 3510)	P value	Missing values
Sodium, mEq/L	139 ± 4.2	139 ± 4.6	139 ± 4.2	0.75	13 (0.3%)
<135 mEq/L[a]	434 (12%)	28 (13%)	406 (12%)	0.56	13 (0.3%)
Haemoglobin, g/dL	11.6 ± 2.3	11.6 ± 2.2	11.6 ± 2.4	0.83	7 (0.2%)
Anaemia[ab]	2462 (66%)	143 (66%)	2319 (66%)	0.99	7 (0.2%)
CRP, mg/dL	0.60 [0.20–1.97]	0.50 [0.20–1.54]	0.60 [0.20–2.01]	0.29	—
Medications at discharge					
Number of prescribed drugs	8 [6–11]	9 [7–12]	8 [6–11]	0.002	—
ACEIs or ARBs[a]	2142 (57%)	135 (62%)	2007 (57%)	0.17	—
ACEIs	911 (24%)	62 (28%)	849 (24%)	0.16	—
ARBs	1248 (33%)	73 (33%)	1175 (33%)	1.00	—
β-Blockers[a]	2473 (66%)	157 (72%)	2316 (66%)	0.07	—
MRA	1680 (45%)	109 (50%)	1571 (45%)	0.13	—
Loop diuretics[a]	3023 (81%)	178 (82%)	2845 (81%)	0.83	—
Tolvaptan[a]	392 (11%)	22 (10%)	370 (11%)	0.83	—
Length of hospital stay (days)	16 [11–24]	14 [10–23]	16 [11–24]	0.03	—

ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin II receptor blocker; BMI, body mass index; BNP, brain-type natriuretic peptide; BP, blood pressure; b.p.m., beat per minute; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CRP, C-reactive protein; eGFR, estimated glomerular filtration rate; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; NT-proBNP, N-terminal-proBNP; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; VF, ventricular fibrillation; VT, ventricular tachycardia.
Categorical variables are presented as numbers and percentages. Continuous variables are presented as the mean ± standard deviation, or the median (interquartile range) based on their distributions. Categorical variables were compared with the χ^2 test. Continuous variables were compared using the Student's t-test or Wilcoxon's rank sum test based on their distributions.
[a]Risk-adjusting variables selected for the multivariable Cox proportional hazard models.
[b]Anaemia was defined by the World Health Organization criteria (haemoglobin < 12.0 g/dL in women and 13.0 g/dL in men).
[c]BNP values were reported for 3303 patients, and NT-proBNP values were reported for 650 patients.

the public assistance and no public assistance groups (13.3% vs. 17.4%, P = 0.10) (*Figure 2A*). Even after adjusting for the confounders, the risk of the public assistance group relative to the no public assistance group remained insignificant for all-cause death (adjusted HR, 0.97; 95% CI, 0.69–1.32; P = 0.84) (*Table 2*). The adjusted risks of the public assistance group relative to the no public assistance group were also insignificant for cardiovascular death and non-cardiovascular death (adjusted HR, 0.98; 95% CI, 0.63–1.45; P = 0.91, and adjusted HR, 0.95; 95% CI, 0.54–1.57; P = 0.86, respectively) (*Table 2*). The cumulative 1 year incidence of a heart failure hospitalization after discharge did not differ between the public assistance and no public assistance groups (28.3% vs. 23.8%, P = 0.25) (*Figure 2B*). However, the Kaplan–Meier curves for heart failure hospitalizations crossed around 6 months, and the incidence of heart failure hospitalizations after 6 months was numerically higher in the public assistance group than no public assistance group (*Figure 2B*). Even after taking into account the competing risk of all-cause death, the cumulative 1 year incidence of a heart failure hospitalization did not differ between the public assistance and no public assistance groups (25.0% vs. 20.1%, P = 0.25) (*Figure S2*). The adjusted risk within 180 days in the public assistance group relative to the no public assistance group remained insignificant for heart failure hospitalizations (adjusted HR, 0.93; 95% CI, 0.64–1.34; P = 0.69), while the adjusted risk beyond 180 days was significant (adjusted HR, 1.56; 95% CI, 1.07–2.29; P = 0.02) (*Table 3*).

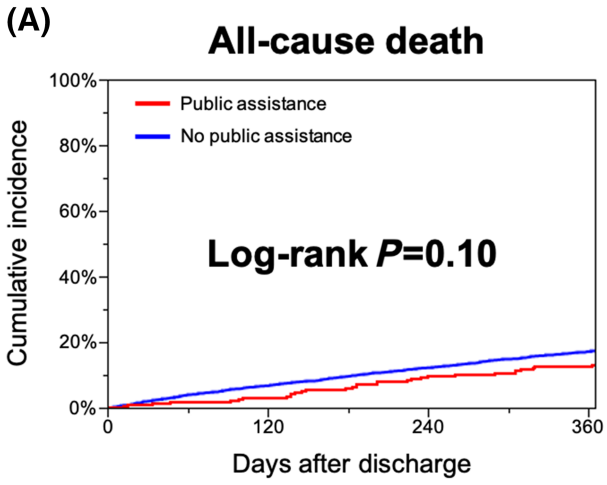
Sensitivity analysis

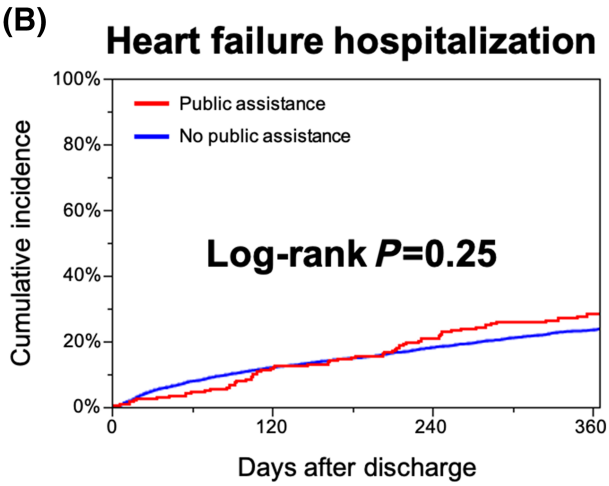
We conducted the multivariable Cox proportional hazard models using the multiple imputation by the chained equation method, and the results were fully consistent with the main analyses (*Tables S3* and *S4*). We also constructed the multivariable Cox proportional hazard models with an additional risk-adjusting variable of the participating centres. The adjusted risks of the public assistance group relative to the no public assistance group remained insignificant for mortality (all-cause death: adjusted HR, 0.98; 95% CI, 0.69–1.35; P = 0.90, cardiovascular death: adjusted HR, 0.99; 95% CI, 0.64–1.48; P = 0.96, and non-cardiovascular death: adjusted HR, 0.96; 95% CI, 0.54–1.59; P = 0.89) (*Table S5*). The adjusted risk within 180 days in the public assistance group relative to the no public assistance group also remained insignificant for heart failure hospitalizations (adjusted HR, 1.07; 95% CI, 0.72–1.54; P = 0.72), while the adjusted risk beyond 180 days was insignificant but tended to be high (adjusted HR, 1.44; 95% CI, 0.96–2.10; P = 0.08) (*Table S6*). These results were almost consistent with the main analyses.

Subgroup analysis

We conducted subgroup analyses stratified by the age, sex, diabetes mellitus, LVEF, previous myocardial infarction,

Figure 2 The Kaplan–Meier curves (*A*) for all-cause death after discharge as compared between the public assistance vs. no public assistance groups, and (*B*) for heart failure hospitalizations after discharge as compared between the public assistance vs. no public assistance groups.





	0-day	30-day	90-day	180-day	365-day
Public assistance					
N of patients with event		2	4	13	28
N of patients at risk	218	217	210	200	165
Cumulative incidence		0.9%	1.8%	6.1%	13.3%
No public assistance					
N of patients with event		72	192	336	597
N of patients at risk	3510	3425	3277	3104	2534
Cumulative incidence		2.1%	5.5%	9.7%	17.4%

	0-day	30-day	90-day	180-day	365-day
Public assistance					
N of patients with event		6	15	32	57
N of patients at risk	218	211	196	172	120
Cumulative incidence		2.8%	7.0%	15.3%	28.3%
No public assistance					
N of patients with event		173	351	506	775
N of patients at risk	3510	3274	2989	2720	2041
Cumulative incidence		5.0%	10.2%	15.0%	23.8%

Table 2 Post-discharge mortality

	Public assistance group (N = 218) N of patients with event (cumulative 1 year incidence)	No public assistance group (N = 3728) N of patients with event (cumulative 1 year incidence)	Crude HR (95% CI)	P value	Adjusted HR (95% CI)	P value
All-cause death	40 (13.3%)	812 (17.4%)	0.77 (0.55–1.04)	0.09	0.97 (0.69–1.32)	0.84
Cardiovascular death	25 (8.2%)	482 (10.7%)	0.81 (0.53–1.19)	0.29	0.98 (0.63–1.45)	0.91
Non-cardiovascular death	15 (5.5%)	330 (7.5%)	0.71 (0.40–1.14)	0.17	0.95 (0.54–1.57)	0.86

CI, confidence interval; HR, hazard ratio.
The number of patients with event was counted throughout the entire follow-up period, while the cumulative incidence was estimated at 1 year. The crude and adjusted HRs and 95% CIs of the public assistance group for the clinical outcome measures were estimated by the Cox proportional hazard models using the no public assistance group as the reference. To adjust for potential confounders, we selected 25 clinically relevant risk-adjusting variables as indicated in *Table 1*.

previous heart failure hospitalizations, current smoking, living alone, use of ACEIs or ARBs at discharge, and use of β-blockers at discharge (*Figure 3*). There were no significant interactions between the subgroup factors except for a positive interaction between current smoking and the effect of the public assistance group relative to the no public assistance group for the primary outcome measure (*Figure 3*).

Discussion

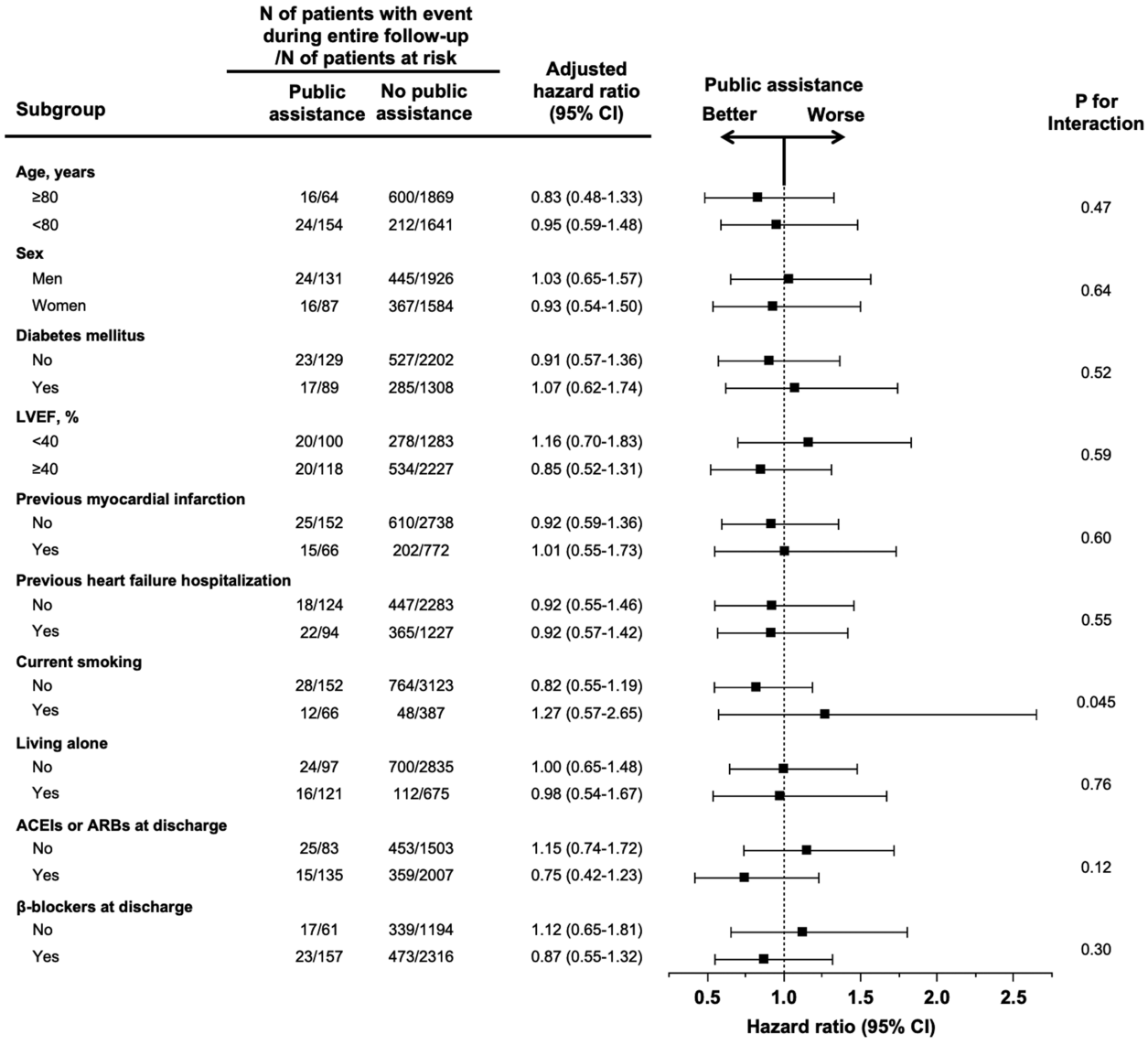
The main findings of the present study were as follows: (i) patients receiving public assistance as compared with those not receiving public assistance were not associated with an increased risk for all-cause death at 1 year after discharge from an AHF hospitalization. (ii) Patients receiving public assistance as compared with those not receiving public assistance were

Table 3 Heart failure hospitalizations after discharge considering competing risk of all-cause death

	Public assistance group (N = 218) N of patients with event/N of patients at risk	No public assistance group (N = 3728) N of patients with event/N of patients at risk	Crude HR (95% CI)	P value	Adjusted HR (95% CI)	P value
Heart failure hospitalization						
Within 180 days	32/218	506/3728	1.01 (0.71–1.43)	0.97	0.93 (0.64–1.34)	0.69
Beyond 180 days	32/186	386/3004	1.35 (0.96–1.98)	0.09	1.56 (1.07–2.29)	0.02

CI, confidence interval; HR, hazard ratio.
Because the proportional hazard assumption was not met for heart failure hospitalizations and the hazards crossed around 6 months after discharge, we separately constructed multivariable Fine and Gray's models considering the competing risk of all-cause death for the observation period within and beyond 180 days. The crude and adjusted HRs and 95% CIs of the public assistance group for the clinical outcome measures were estimated by the Fine and Gray's models using the no public assistance group as the reference. To adjust for the potential confounders, we selected 25 clinically relevant risk-adjusting variables as indicated in *Table 1*.

Figure 3 Subgroup analyses for the risk of the public assistance group relative to the no public assistance group for all-cause death after discharge. ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin II receptor blocker; CI, confidence interval; LVEF, left ventricular ejection fraction.



not associated with an increased risk for a heart failure hospitalization within 180 days after discharge from an AHF hospitalization, while they were associated with an increased risk beyond 180 days.

There was no significant difference in the post-discharge mortality between the public assistance and no public assistance groups even after taking into account the risk-adjusting variables and clinically relevant subgroups. However, the previous studies showed a higher post-discharge mortality in low-income patients with heart failure, even in countries with a universal health care system.[14–16] This discrepancy could be partly because the Japanese public assistance system provides easy access to not only acute medical care but also to post-discharge care including the access to GDMT regardless of the medical institutions, suggesting that the Japanese public assistance system may improve the post-discharge prognosis in low-income patients. The previous study from low-income countries showed a strong association between a high post-discharge mortality and not receiving GDMT in HFrEF patients.[2] In the present study, there was no significant difference in the prevalence of drug prescriptions for heart failure in the entire study population and in the prevalence of GDMT in HFrEF patients between those receiving public assistance and those not receiving public assistance, which might have led to the comparable post-discharge mortality in the two groups.

There was also no significant difference in heart failure hospitalizations within 180 days after discharge between the public assistance and no public assistance groups, which was discordant with the previous studies in other countries.[16,17] On the other hand, the Kaplan–Meier curves for heart failure hospitalization crossed around 6 months, and patients receiving public assistance as compared with those not receiving public assistance were associated with an increased risk for a heart failure hospitalization beyond 180 days. A recent study in Japan showed almost consistent results that AHF patients receiving public assistance had a similar rate of 90 day cardiac events, which were defined as death form cardiovascular disease or heart failure hospitalizations, but had a higher rate of 1 year cardiac events than those not receiving public assistance.[18] That may be at least partly because patients in the public assistance group more frequently had poor medical adherence and were more often living alone. Moreover, hospitalizations due to social but not medical reasons might have been more common in patients receiving public assistance than those not receiving public assistance. Therefore, improving their medical adherence and maintaining their post-discharge care could be quite important to improve outcomes of patients receiving public assistance.

Patients receiving public assistance were more likely to be a current smoker despite a higher rate of a previous myocardial infarction. It might be interesting to note that there was an interaction between current smoking and the mortality risk of those receiving public assistance relative to those not receiving public assistance. It is possible that the health literacy in patients receiving public assistance may be relatively low compared with those not receiving public assistance and that there is room for improvement in the medical adherence and even in the clinical outcomes. Efficient educational programmes for primary or secondary prevention for cardiovascular disease would be needed for those with public assistance, although we did not have data regarding the educational attainment.

Study limitations

The present study had several limitations. First, we had no detailed data on the income level of the individual patients. Thus, the no public assistance group may have included low-income patients who did not meet the criteria for receiving public assistance and might not have had access to the post-discharge GDMT, leading to selection bias. On the other hand, patients in the public assistance group were certain to be low-income unless they were illegal recipients of public assistance. Second, we also had no data on the indications for receiving public assistance. The clinical characteristics and outcomes may have differed according to the indications for receiving public assistance. Third, referring to the five key domains of social determinants of health (economic stability, education access and quality, health care access and quality, neighbourhood and built environment, and social and community context) proposed by Healthy People 2030,[19] we had no data on the education, neighbourhood, or social and community context, which might have been potential residual confounding variables. Fourth, there might have been reginal differences in the prevalence of public assistance and characteristics of those receiving it, although our registry consisted of multicentres in various regions. Fifth, our results increased the generalizability of the significance of receiving public assistance on the post-discharge prognosis to some extent in the Japanese patients with AHF hospitalizations; however, caution should be taken when applying our results to those in other countries because different countries have different social security systems and criteria for receiving public assistance. Finally, several subgroup analyses had the risk of a multiple comparison as well as a small sample size with a low statistical power.

Conclusions

The AHF patients receiving public assistance as compared with those not receiving public assistance had no significant excess risk for all-cause death at 1 year after discharge or a heart failure hospitalization within 180 days after discharge,

while they did have a significant excess risk for a heart failure hospitalization beyond 180 days after discharge.

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Conflict of interest

None declared.

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Conflict of interests

None declared.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Differences in the GDMT between the HFrEF patients receiving public assistance and those not receiving public assistance.
Table S2. Patient Characteristics Between Public Assistance Group and Patients Receiving Public Assistance Who Were Lost to Follow-Up.
Table S3. Post-Discharge Mortality Using the Multiple Imputation Method.
Table S4. Heart Failure Hospitalizations After Discharge Using the Multiple Imputation Method.
Table S5. Post-Discharge Mortality with an Additional Risk-Adjusting Variable of the Participating Centers.
Table S6. Heart Failure Hospitalizations After Discharge with an Additional Risk-Adjusting Variable of the Participating Centers.
Figure S1. The proportions of patients receiving public assistance across the participating centers.
Figure S2. The Kaplan–Meier curves for heart failure hospitalizations after discharge considering the competing risk of all-cause death compared between the public assistance and no public assistance groups.
Appendix S1. List of the participating hospitals.
Appendix S2. Definitions of the patient characteristics.

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