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ORIGINAL ARTICLE
Heart Failure

Clinical Characteristics and Outcomes of Heart Failure Patients With Long-Term Care Insurance

— Insights From the Kitakawachi Clinical Background and Outcome of Heart Failure Registry —

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Background: In Japan, the long-term care insurance (LTCI) system has an important role in helping elderly people, but there have been no clinical studies that have examined the relationship between the LTCI and prognosis for patients with acute heart failure (HF).

Methods and Results: This registry was a prospective multicenter cohort, 1,253 patients were enrolled and 965 patients with acute HF aged ≥65 years were comprised the study group. The composite endpoint included all-cause death and hospitalization for HF after discharge. We divided the patients into 4 groups: (i) patients without LTCI, (ii) patients requiring support level 1 or 2, (iii) patients with care level 1 or 2, and (iv) patients with care levels 3–5. The Kaplan-Meier analysis identified a lower rate of the composite endpoint in group (i) than in the other groups. After adjusting for potentially confounding effects using a Cox proportional regression model, the hazard ratio (HR) of the composite endpoint increased significantly in groups (iii) and (iv) (adjusted HR, 1.62; 95% confidence interval [CI], 1.22–1.98 and adjusted HR, 1.62; 95% CI, 1.23–2.14, respectively) when compared with group (i). However, there was no significant difference between groups (i) and (ii).

Conclusions: The level of LTCI was associated with a higher risk of the composite endpoint after discharge in acute HF patients.

Key Words: Acute heart failure; Elderly; Lifestyle; Outcome; Prognosis

In most countries in the world, the elderly population has been increasing rapidly. By 2018, the number of people aged ≥65 years in Japan accounted for 28.1% of the population, giving Japan the highest proportion of elderly people in the world.[1,2] In Japan, the proportion of younger people will continue to decrease, whereas that of the elderly will continue to grow. The proportion of people aged ≥65 years will reach 38.4% by 2065.[1] In such an aging society, heart failure (HF) is a prevalent disease, which causes physical, cognitive, and social problems, as well as many types of comorbidities.[3]

Frailty is one of the most problematic expressions of an aging population.[4] It is a condition of reduced physiological reserves associated with an increased susceptibility to disability.[5,6] Some studies have estimated that a 25–50% of elderly people are frail and are more likely to require long-term care and have a significantly increased risk of falling, disability, and death.[7,8] Patients hospitalized with HF frailty are strongly associated with mortality.[9] Frailty begins prior to long-term care and after loss of independence.[10] In Japan, the frail stage relates to patients with a requirement for support level 1 or 2 in the long-term care

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Refer to **Appendix** for the List of Institutions Participating in the Registry.

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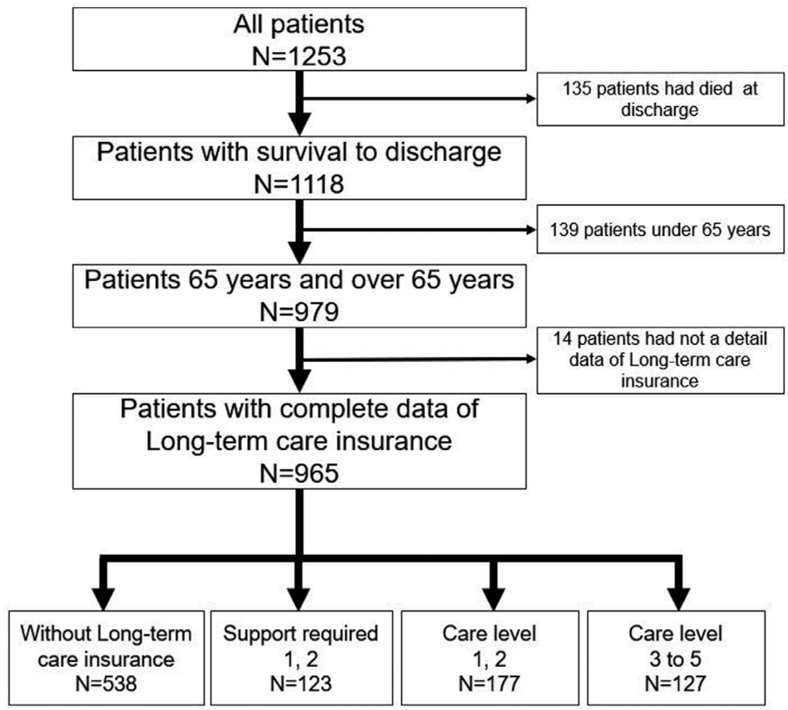

Figure 1. Patient flowchart. We enrolled 1,253 patients with acute heart failure, and 965 patients with follow-up data were available for this study. Of the 965 patients, there were (i) 538 (55.8%) without LTCI, (ii) 123 (12.7%) requiring support level 1 or 2, (iii) 177 with care level 1 or 2 (18.3%), and (iv) 127 patients with care level 3–5 (13.2%). LCTI, long-term care insurance.

insurance (LTCI) system.[11] The existence of frailty is a new risk certification of the LTCI service in Japan.[12] Considering the LTCI is helpful for early intervention in patients affected by physical, psychological, and social problems, understanding their social backgrounds is also important for determining the management of treatment.

In Japan, the LTCI system plays an important role in helping older people lead more independent lives and to relieve the burden of family care.[13] Although the LTCI has the potential to improve the independence and quality of life for older people, there have been no clinical studies examining the relationship between the LTCI and prognosis of patients with acute HF. The Kitakawachi Clinical Background and Outcome of Heart Failure (KICKOFF) Registry was designed as a prospective, multicenter cohort of Japanese patients with acute HF,[14] comprising 13 hospitals in the north of Kitakawachi and Yawata, which are typical satellite communities in Osaka, Japan. Using the database, we assessed the patients' characteristics, including their social background, and examined the difference in outcomes between patients without LTCI support and those in each of the LTCI care levels.

Methods

Study Design

We analyzed the data from the KICKOFF Registry, which registered patients diagnosed with acute HF during hospitalization between April 2015 and August 2017. The institutions participating in the study were 13 hospitals in the north of Kitakawachi (Hirakata City, Neyagawa City, and Katano City) and Yawata. Kitakawachi is located at the eastern end of Osaka Prefecture and Yawata is at the southern end of Kyoto Prefecture. At the time, the northern parts of Kitakawachi and Yawata had a total population of 798,000. The institutions consisted of 1 cardiovascular center and 12 small or medium-sized hospitals.[14] Based on the Framingham criteria,[15] HF was diagnosed when there were ≥2 major criteria, or 1 major and 2 minor criteria. There were no exclusion criteria. The detailed study design of the KICKOFF Registry is described in the UMIN Clinical Trials Registry (UMIN000016850). The clinical data of all patients were collected by an electronic data capture system, and automatically checked by the physicians in charge at each institution for missing or contradictory entries and values not in the normal range. The data were also checked by the general office of the registry. Data from medical record reviews and interviews with patients or other family members were also recorded.

LCTI System of Japan

In order to appropriately deal with long-term care issues in an aging society, the LTCI system was introduced in April 2000, allowing people with long-term care needs from all areas of society in Japan to receive enough support.[16] The LTCI system operates on the principles of social insurance, with benefits provided irrespective of income or family situation. The recipients receive only services, not cash allowances, and can choose their services and providers. People aged ≥65 who satisfy the eligibility criteria (category 1 insured persons), and people aged 40–64 years with an age-related illness (category 2 insured persons) are eligible to receive long-term care services. Questionnaires regarding daily life and activities are used to assess eligibility and create the 7 certification levels of long-term care need: support required 1 or 2, and care levels 1 (least disabled) to 5 (most disabled).[17] The data of LTCI level were collected from both the medical records and interviews with patients or family members.

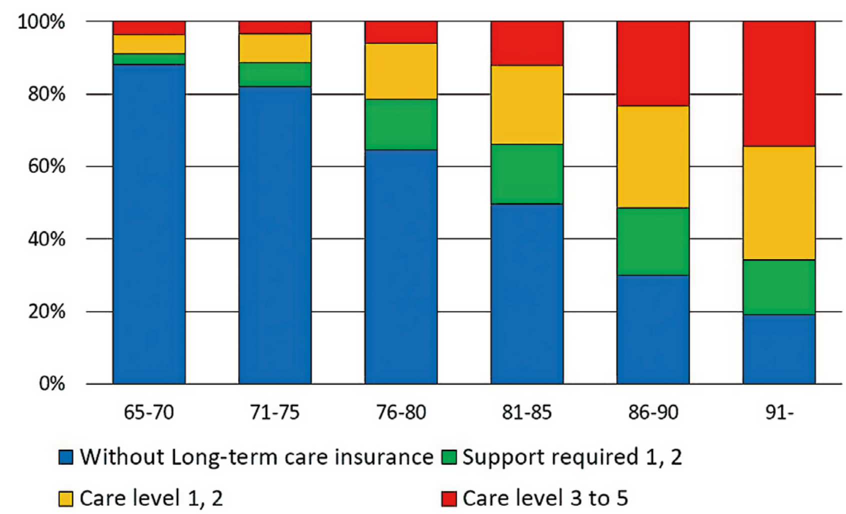

Figure 2. Distribution of LTCI in patients according to age. As patients grew older, they required more, and more intensive, services. LCTI, long-term care insurance.

Patient Data Definitions

In this study, we included only patients aged ≥65 years because patients who had only HF were category 1 insured persons and did not have an eligible of LTCI.[17] Based on their level of LTCI, patients were divided into 4 groups: (i) patients without LTCI, (ii) patients requiring support level 1 and 2, (iii) patients with care level 1 or 2, (iv) patients with care levels 3–5. Patients with care level 1 or 2 are able to perform their own general care with assistance only, but patients with care levels 3–5 are unable to look after themselves without care. The other definitions of each comorbidity are described in our previous paper.[14] We divided the patients into 3 lifestyle groups: (i) living alone or with a partner only; (ii) living with a son or daughter; or (iii) living in a nursing home or hospital. The main dietary manager was defined as the person who most frequently provided the patient with meals (i.e., the patient or partner, a son or daughter, a caretaker, a nursing home or hospital, home-delivery service, or dining out). The main drug therapy manager was defined as the person who most frequently managed the patients' treatments on a daily basis (i.e., the patient or partner, a son or daughter, a caretaker, or a nursing home or hospital).

We performed follow-up at 6 months, 1 year, 2 years, and 3 years after hospital discharge. Follow-up data were collected primarily by a review of hospital records, and additional follow-up information was obtained via telephone or mail contact with the patients or their relatives. The primary endpoint was a composite endpoint that included all-cause death and hospitalization for HF during the follow-up period.[18] The secondary endpoints were the incidence of all-cause death and of hospitalization for HF.

The study protocol complied with the ethical guidelines of the 1975 Declaration of Helsinki and was approved by the Ethics Committee of the Hirakata Kohsai Hospital (Osaka, Japan). Informed consent was given by all participants prior to their enrollment in the study. Direct patient identifiers were not registered, to preserve patient confidentiality. The study did not alter any treatment specified in the protocol or any other method of outpatient care.

Statistical Analysis

The clinical baseline characteristics were compared among the 4 groups using Cochran-Armitage tests for categorical variables, and Dunnet tests for continuous variables. Continuous variables are expressed as mean±standard deviation or interquartile range, and categorical variables are expressed as numbers and percentages. The Kaplan-Meier method was performed to evaluate the cumulative incidences of the composite endpoint, all-cause death and hospitalization for HF. We assessed the differences by performing a log-rank test and the Bonferroni method for multiple comparison. In addition, we performed a multivariate analysis, using a Cox proportional hazard model, to evaluate the association between the 4 groups and the incidence of the composite endpoint. We measured time from discharge to the first outcome (all-cause death or hospitalization for HF) or the completed follow-up until March 2019. All patients were followed at least 6 months. We assumed that the included variables were time independent from discharge.[19,20] We also calculated the hazard ratios (HR) with 95% confidence intervals (CI). We adjusted for potentially confounding effects in the multivariable models that were considered to be associated with the clinical outcomes, including male sex, the age category (65–74, 75–84, 85 and >85 years old), and comorbidities ("yes" or "no"), which included history of HF, coronary artery disease, valvular disease, cardiomyopathy, hypertension, diabetes mellitus, dyslipidemia, atrial fibrillation, chronic kidney disease, and stroke. Furthermore, to evaluate the effect of lifestyle factors, the covariates were selected in another Cox proportional hazard model as follows: male sex, age category, lifestyle factors (yes/no); living style (alone or with partner only), main dietary manager (self or partner), main drug therapy manager (self or partner), history of smoking, drinking every day and dialysis. In addition, to assess the differences between the LTCI patients, we compared the analysis of group (ii) with that of groups (iii) and (iv). All statistical analyses were performed by JMP version 14 (SAS Institute, Cary, NC, USA). We considered $P<0.05$ as statistically significant.

Table 1. Baseline Clinical Characteristics and Social Background

	All patients	Without LTCI	Support required 1, 2	Care level 1, 2	Care level 3–5
n	965	538	123	177	127
Male	465 (48.2)	321 (59.7)†	37 (30.1)	66 (37.3)	41 (32.3)
Age (years)	80.4±7.0	76.9±7.2	83.1±6.3‡	84.2±6.9‡	86.8±7.0‡
65–74	252 (26.1)	214 (39.8)†	12 (9.8)	17 (9.6)	9 (7.1)
75–84	399 (41.4)	241 (44.8)†	59 (47.9)	67 (37.9)	32 (25.2)
85 and >85	314 (32.5)	83 (15.4)†	52 (42.3)	93 (52.5)	86 (67.7)
In hospital (days)	25.7±20.4	23.8±18.5	24.6±19.6	28.5±23.1‡	31.6±24.7‡
Comorbidities					
History of HF	570 (59.1)	293 (54.5)†	72 (58.5)	123 (69.5)	82 (64.6)
History of CAD	286 (29.6)	180 (33.5)†	25 (20.3)	47 (26.6)	34 (26.8)
Valvular disease	305 (31.6)	151 (28.1)†	42 (34.2)	73 (41.2)	39 (30.7)
Cardiomyopathy	130 (11.8)	78 (14.5)	18 (14.6)	19 (10.7)	15 (11.8)
Hypertension	653 (67.7)	385 (71.2)	77 (62.6)	115 (65.0)	78 (61.4)
Diabetes mellitus	328 (34.0)	201 (37.4)	34 (27.6)	52 (29.4)	41 (32.3)
Dyslipidemia	368 (38.1)	218 (40.5)	49 (39.8)	58 (32.8)	43 (33.9)
Atrial fibrillation	432 (44.8)	244 (45.4)	52 (42.3)	77 (43.5)	59 (46.5)
Chronic kidney disease	543 (56.3)	291 (54.1)	68 (55.3)	112 (63.3)	72 (56.7)
History of stroke	129 (13.4)	49 (9.1)†	15 (12.2)	35 (19.8)	30 (23.6)
BNP (pg/dL)	231.0 [106.2–487.9]	225.9 [103.6–466.2]	236.2 [100.2–500.4]	257.8 [102.2–522.5]‡	294.1 [135.4–544.5]
LVEF (%)	53.2±17.2	52.1±17.3	57.5±15.7‡	54.1±17.5	52.8±17.9
<50%	566 (60.0)	304 (58.0)	83 (69.8)	104 (59.8)	75 (59.5)
Lifestyle					
Alone or with partner	472 (48.9)	290 (53.9)†	78 (63.4)	73 (41.2)	31 (24.4)
With son or daughter	377 (39.1)	237 (44.1)†	33 (26.8)	65 (36.7)	42 (33.1)
Institution for aged or hospital	116 (12.0)	11 (2.0)†	12 (9.8)	39 (22.0)	54 (42.5)
Family support (alone or with partner only)	179 (37.9)	101 (34.8)	37 (47.4)	25 (34.3)	16 (51.6)
Main dietary manager					
Self or partner	586 (60.7)	419 (77.9)†	70 (56.9)	71 (40.1)	26 (20.5)
Son or daughter	186 (19.3)	77 (14.3)†	26 (21.1)	48 (27.1)	35 (27.6)
Caretaker, institution for aged or hospital	132 (13.7)	11 (2.0)†	14 (11.4)	48 (27.1)	59 (46.5)
Home-delivery service, Dining out	61 (6.3)	31 (5.8)	13 (10.6)	10 (5.7)	7 (5.5)
Main drug therapy manager					
Self or partner	731 (75.8)	496 (92.2)†	96 (78.1)	102 (57.6)	37 (29.1)
Son or daughter	112 (11.6)	31 (5.8)†	17 (13.8)	33 (18.6)	31 (24.4)
Caretaker, institution for aged or hospital	122 (12.6)	11 (2.0)†	10 (8.1)	42 (23.7)	59 (46.5)
Home-visit medical service	64 (6.6)	–	15 (12.2)	23 (13.0)	25 (19.7)
Day service or day care	161 (16.7)	4 (0.7)†	39 (31.7)	68 (38.4)	50 (39.4)

Categorial data are presented as number (%). Continuous data are presented as mean±standard deviation (SD) or interquartile range. †Significantly different for categorical variables using Cochran-Armitage test, ‡for continuous variables using Dunnet test from without LTCI (P<0.05). BNP, B-type natriuretic peptide; CAD, coronary artery disease; HF, heart failure; LTCI, long-term care insurance; LVEF, left ventricular ejection fraction.

Results

Figure 1 shows the patient flow in this study. We enrolled 1,253 patients with acute HF, and 1,118 patients were discharged from hospital. After excluding 139 patients who were <65 years old and 14 patients who did not have detailed LTCI data, the remaining 965 patients all had follow-up data available as of March 2019. The median follow-up period was 554 days (interquartile range, 230–927 days). Of the 965 patients, there were (i) 538 patients (55.8%) without LTCI, (ii) 123 patients (12.7%) requiring support level 1 or 2, (iii) 177 patients (18.3%) with care level 1 or 2, and (iv) 127 patients (13.2%) with care level 3–5. **Figure 2** shows the distribution of LTCI among the patients according to age. As patients grew older, they required more, and more intensive, LTCI services.

Table 1 shows the baseline clinical characteristics and social background of all eligible patients. Overall, 48.2% of the patients were male and the mean age was 80.4 years. The mean age tended to be higher with increasing level of LTCI: (i) 76.9; (ii) 83.1; (iii) 84.2; and (iv) 86.8 years. The average length of hospital stay was longer in the group with more severe LTCI needs. There was no significant difference in the proportion of HF patients with preserved ejection fraction (left ventricular ejection fraction ≥50%). The patients in group (ii) represented the highest proportion of those living alone or with their partner, and the proportion of patients with family support was also higher

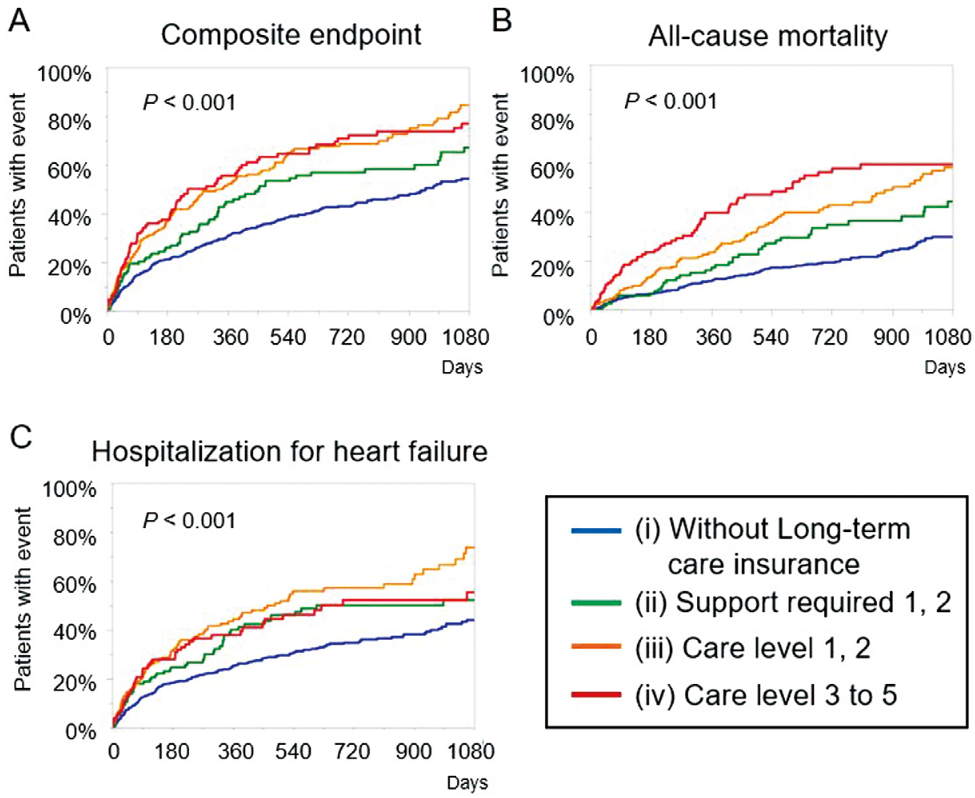

Figure 3. Kaplan-Meier curves for the composite endpoint (**A**), all-cause death (**B**), and the hospitalization for heart failure (HF) (**C**) during the follow-up period among 4 groups of patients: (i) without LTCI, (ii) support level 1 and 2, (iii) care level 1 and 2, and (iv) care level 3–5. In the Kaplan-Meier analysis we obtained a significant lower rate of the composite endpoint in group (i) than in the other groups (**A**). We also obtained a significantly lower rate of all-cause death and hospitalization for HF in group (i) than in the other groups (**B**,**C**).

in group (ii) than in the group of patients without LTCI. The proportion of patients who managed their own diet and drug therapy or whose partner managed them, tended to decrease with increasing LTCI level. The percentage of those using home-visits, day services or the day care system was 43.9% in group (ii), 51.4% in group (iii), and 59.1% in group (iv).

During the follow-up period, the cumulative event rates of all patients were compared among the 4 groups. A total of 502 patients (52.0%) recorded the composite endpoint, and the highest proportion of the composite endpoint was in group (iv): 69.3% (88/127). This was followed by 67.8% (120/177) in group (iii), 55.3% (68/123) in group (ii), and 42.0% (226/538) in group (i). Using the Kaplan-Meier method, we obtained a significantly lower rate of the composite endpoint for group (i) than for the other groups (**Figure 3A**). With regard to the secondary outcomes, increasing the LTCI level significantly increased the proportion of all-cause death, as follows: (i) 20.3% (109/538); (ii) 31.7% (39/123); (iii) 41.8% (74/177); and (iv) 49.6% (63/127). However, with regard to hospitalization for HF, the highest proportion was 51.4% (91/177) in group (iii), followed by 43.1% (53/123) in group (ii), 40.9% (52/127) in group (iv), and 32.2% (173/538) in group (i). Using the Kaplan-Meier method, we also obtained significantly lower rates of all-cause death and hospitalization for HF in group (i), when compared with the other groups (**Figure 3B**,**C**).

In the Cox proportional hazard model (**Table 2**), the composite endpoint HR increased significantly in groups (iii) and (iv), when compared with group (i) (adjusted HR, 1.62; 95% CI, 1.22–1.98, P<0.001 and adjusted HR, 1.62; 95% CI, 1.23–2.14, P<0.001, respectively), but there was no significant difference between groups (i) and (ii) (adjusted HR, 1.22; 95% CI, 0.91–1.64, P=0.165). This trend was also evident for all-cause death. The HR of hospitalization for HF increased significantly only in group (iii), when compared with group (i) (adjusted HR, 1.58; 95% CI, 1.20–2.09, P=0.001). In the other Cox proportional hazard model using lifestyle factors (**Supplementary Table**), we obtained similar results. Finally, the subgroup analysis showed that the composite endpoints in groups (iii) and (iv) had a significantly higher HR than in group (ii) (adjusted HR, 1.34; 95% CI, 1.01–1.79, P=0.040) (**Table 3**).

Discussion

In this prospective registry of HF patients in Japan, among the acute HF patients those with LTCI care level 1–5 had a significantly greater risk of the composite endpoint, including all-cause death and hospitalization for HF, after

Table 2. HRs in All Patients for Each Event, the Composite Endpoint, All-Cause Death and Hospitalization for HF During the Follow-up Period

Events	Composite endpoint				All-cause death				Hospitalization for HF			
	Crude HR (95% CI)	P value	Adjusted HR (95% CI)	P value	Crude HR (95% CI)	P value	Adjusted HR (95% CI)	P value	Crude HR (95% CI)	P value	Adjusted HR (95% CI)	P value
Without LCTI	1 (Ref.)		1 (Ref.)		1 (Ref.)		1 (Ref.)		1 (Ref.)		1 (Ref.)	
Support required 1, 2	1.44 (1.09–1.87)	0.011	1.22 (0.91–1.64)	0.165	1.64 (1.13–2.35)	0.011	1.40 (0.94–2.04)	0.088	1.46 (1.06–1.97)	0.020	1.32 (0.95–1.83)	0.099
Care level 1, 2	2.12 (1.69–2.64)	<0.001	1.62 (1.22–1.98)	<0.001	2.41 (1.79–3.24)	<0.001	1.72 (1.24–2.38)	0.001	2.04 (1.58–2.63)	<0.001	1.58 (1.20–2.09)	0.001
Care level 3–5	2.22 (1.73–2.83)	<0.001	1.62 (1.23–2.14)	<0.001	3.53 (2.58–4.80)	<0.001	2.42 (1.71–3.44)	<0.001	1.68 (1.22–2.28)	0.001	1.34 (0.95–1.89)	0.091

HRs were adjusted for male sex, age category (65–74, 75–84, 85 and >85 years old), comorbidities (yes/no); history of HF, CAD, valvular disease, cardiomyopathy, hypertension, diabetes mellitus, dyslipidemia, atrial fibrillation, chronic kidney disease, and stroke. The composite endpoint included all-cause death and hospitalization for HF. CI, confidence interval; HR, hazard ratio. Other abbreviations as in Table 1.

Table 3. HRs in Patients With Long-Term Care Insurance for Each Event, the Composite Endpoint, All-Cause Death and Hospitalization for HF During the Follow-up Period

Event	Composite endpoint				All-cause death				Hospitalization for HF			
	Crude HR (95% CI)	P value	Adjusted HR (95% CI)	P value	Crude HR (95% CI)	P value	Adjusted HR (95% CI)	P value	Crude HR (95% CI)	P value	Adjusted HR (95% CI)	P value
Support required 1, 2	1 (Ref.)		1 (Ref.)		1 (Ref.)		1 (Ref.)		1 (Ref.)		1 (Ref.)	
Care level 1–5	1.52 (1.16–2.01)	0.002	1.34 (1.01–1.79)	0.040	1.72 (1.22–2.49)	0.002	1.52 (1.06–2.23)	0.021	1.29 (0.95–1.79)	0.105	1.15 (0.83–1.61)	0.394

HRs were adjusted for male sex, age category (65–74, 75–84, 85 and >85 years old), comorbidities (yes/no); history of HF, CAD, valvular disease, cardiomyopathy, hypertension, diabetes mellitus, dyslipidemia, atrial fibrillation, chronic kidney disease, and stroke. The composite endpoint included all-cause death and hospitalization for HF. Abbreviations as in Tables 1,2.

discharge from hospital. However, there was no significant difference between the patients without LTCI and those requiring support only. In the subgroup of patients with LTCI, the patients with care level 1–5 had a greater risk of reaching the composite endpoint than those requiring only support. In addition, these differences were independently maintained despite adjustments for differences in age, sex, and comorbidities. Furthermore, we identified characteristics, including social background, of acute HF patients without LTCI and of those at each level of LTCI. To our knowledge, this is the first report to examine the association between the LTCI system and prognosis, and includes information that is helpful as a social resource for preventative approaches to the management of patients following acute HF.

We found that the worst outcomes after discharge for acute HF patients were more associated with patients in care levels 1–5 than for those without LTCI, and those patients with supportive care only. This suggests that we should prevent a decline in the level of LTCI in patients with HF, in order to improve their outcomes after discharge. The patients with supportive care were still able to live independently and maintain their quality of life. A previous study showed that the need for nursing care was associated with increased mortality, regardless of the stage of HF, in patients with chronic HF.[21] Being in the LTCI system and the level of LTCI have been independently associated with 1-year all-cause death and all-cause readmission in single-center retrospective studies.[11] Similar results were also obtained in our multicenter prospective study with a longer follow-up period. We reported in a previous study that 18.1% of super-elderly patients with acute HF lost the ability to walk independently by the time they were discharged from hospital,[14] and that a decline in the activities of daily living (ADL) was an independent risk factor of hospitalization for HF and death.[22]

In Japan, there was a 3-fold increase in the use of formal services by the frail older population, from 1.49 million people in 2000 to 4.74 million people in 2018, and there was also a 3-fold increase in the number of people with LTCI, from 2.18 million people in 2000 to 6.44 million people in 2018.[23] Previous reports indicate that some people eligible for the LTCI did not use any services, and on average recipients of home-based care chose to use only 40–60% of their entitlement.[13] The northern parts of Kitakawachi (Hirakata City) and Yawata are typical satellite communities in Japan and the rate of people with LTCI in this region is similar to the whole of Japan (18.5% in Hirakata City vs. 18.4% in the whole of Japan in 2015).[24] In our study, the proportion of people using home-visit medical services, day services, or the day care system was 43.9% in patients requiring support, 51.4% in those with care level 1 or 2, and 59.1% in those with care level 3–5. A previous study reported that the use of respite care or day care services was associated with prevention of institutional admission,[25] and another study reported that more frequent use of day care services was associated with lower mortality rates in frail adults.[26] However, in a 2011 report, the results before and after the introduction of LTCI showed no overall favorable effects on either elderly care recipients' subjective health status or their ability to undertake daily tasks.[13] Those results suggested that maintaining, rather than improving, the health and functional status of frail elderly people was an appropriate goal for the LTCI system. Many frail elderly people, with the assistance of an extensive day service or day care system, regularly leave their homes to contact other people and participate in social activities. The contact with other local people in similar situations benefits them both psychologically and socially. These systems should increase the use of formal care to prevent an increase in the level of LTCI and slow the onset of frailty. The government and medical associations should construct systems and institutions to maintain the elderly's self-independent life.

All industrialized countries face an aging population that will require care.[27] In these countries, including Japan, family members undertake most of the caring tasks for the frail elderly people in the community.[28] In our study, the group requiring support had the highest proportion of patients living alone or with their partner (63.4%) and nearly half had family support (47.7%). The proportion of those managing their diet and drug therapy by themselves, or with the help of their partner, tended to be lower with increasing LTCI level. However, 78.0% and >90% of patients in the support-required group managed their daily diet and diet by themselves or with the help of their family, respectively. Of patients with care level 1 or 2, 67.2% and two-thirds managed their daily diet and drug therapy by themselves or with the help of their family, respectively. The availability of care from family members has fallen because the number of children has decreased, and more women now work away from the home.[13] Family care is more stressful and burdensome as a result of long-term care needs. Some reports show that using formal care services reduces the physical and emotional burden of care.[29–31] The official purpose of the LTCI was to help elderly people in need of long-term care to maintain their dignity and independence, subject to each person's level of ability,[17] and to relieve families of the burden of care.[32]

Study Limitations

First, the acute HF diagnosis was defined by physicians using the Framingham criteria; therefore, there was the possibility of selection or referral bias. However, previous major cohort studies of HF in Japan also used Framingham criteria for the diagnosis of HF.[33,34] Second, we did not have detailed data on the implementation of cardiac rehabilitation during hospital admission or after discharge.[3] In patients with HF, cardiac rehabilitation involves the heart team staff and is one of the most important treatments used to improve prognosis. Third, we did not have detailed information to evaluate patients' ADL using quantitative indicators such as the Barthal index or the Functional Independence Measure score.[35,36] Fourth, we had no data on why patients did not have LTCI, but suggest some possible reasons. The patients without LTCI had sufficient physical and cognitive function to live their daily life without help from the LTCI system. Some elderly people or their families refuse interference in their own life. Some patients may not know how to apply for the LTCI and so patients or their families should be informed about the LTCI system as an available option before discharge. Fifth, this registry enrolled consecutive patients with HF in each hospital, but some patients might have been unable to give informed consent. We had no data on them, but we did achieve the targeted number of patients before the cutoff date. We hope that further studies will discover the relationship between these indicators and the level of LTCI. Sixth, the proportional hazard assumption is supported by a non-significant relationship between residuals and time, and refuted by a significant relationship. We analyzed the verification of the Cox proportional hazards model by using EZR software on R commander in this study. In the model shown in **Table 2** and **Table 3**, regarding the composite endpoint, the P value of the main factor was also not statistically significant. Therefore, we believed that the Cox proportional hazards could be assumed in the study. Finally, we did not have any data on the reasons why LTCI was needed by each patient.

Conclusions

In this population of acute HF patients, a higher level of LTCI was associated with a higher the risk of reaching the composite endpoint of all-cause death and hospitalization for HF, after discharge. In the subgroup of patients with LTCI, HF patients with care levels 1–5 had a significantly higher risk of reaching the composite endpoint than those with only support required. We should prevent a decline in the level of LTCI required by patients with HF, and the government and medical associations should construct systems and institutions to maintain patients' independence.

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Data Availability

The deidentified participant data will be shared on a request basis. Please directly contact the corresponding author to request data sharing. The data comprises baseline and follow-up data of patients and the study protocol in Japanese. The data are available immediately. We used Cochran-Armitage tests for categorical variables, and Dunnet tests for continuous variables for the clinical baseline characteristics. The Kaplan-Meier method and a Cox proportional hazard model were performed for outcomes. All statistical analyses were performed by JMP version 14 (SAS Institute, Cary, NC, USA).

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IRB Information

The study protocol complied with the ethical guidelines of the 1975 Declaration of Helsinki and was approved by the Ethics Committee of the Hirakata Kohsai Hospital (reference no. 2015-01-16).

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Appendix

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Supplementary Files

Please find supplementary file(s);
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