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Association of Diastolic Dysfunction and Outcomes in Ambulatory Older Adults with Chronic Heart Failure

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Abstract

Background—Studies of patients with heart failure and preserved systolic function report variable outcomes compared with those with impaired systolic function.

Objective—To study outcomes of diastolic (versus systolic) heart failure in older adults with chronic heart failure.

Methods—Patients were ambulatory chronic heart failure patients 65 years and older (N=3,984) who participated in the Digitalis Investigation Group trial. Of these, 3,405 had systolic heart failure (SHF) (ejection fraction ≤45%) and 579 had diastolic heart failure (DHF) (ejection fraction >45%). Using a 1:1 match by age, sex and race, 571 DHF patients were matched with 571 SHF patients. Kaplan Meier survival analyses and multivariable Cox proportional hazard analyses were used to estimate the risk of various outcomes between the groups.

Results—During the 1,044 mean days of follow up, compared with 41% of SHF patients, 27% of DHF patients died (p<0.001). Presence of DHF was independently associated with a 27% decreased risk of all cause death (adjusted hazard ratio {HR} = 0.73; 95% confidence interval {CI} = 0.58 - 0.91) and a 32% reduction in risk of hospitalization due to heart failure (adjusted HR = 0.68; 95% CI = 0.52 - 0.88). There was no difference in overall hospitalization between the groups. However, compared with SHF patients, DHF patients were more likely to be hospitalized due to non-cardiovascular causes (adjusted HR = 1.38; (95% CI = 1.02 - 1.88).

Conclusions—Older adults with DHF had lower risk of all-cause mortality and heart failure related hospitalizations, but higher risk on non-cardiovascular hospitalization.

Keywords

Diastolic heart failure; mortality; hospitalization; older adults

Heart failure with preserved left ventricular systolic function, also known as diastolic heart failure is relatively common among older adults.[1-8] Most studies of outcomes of diastolic heart failure in older adults involved hospitalized patients.[1, 8-11] These studies involve all-cause mortality and heart failure hospitalization and are limited by selection bias. Community based studies, most of which include patients of all age groups, are limited by their small sample size.[4, 6, 7] The purpose of this study was determine various outcomes in older adults with diastolic heart failure compared with a age-, sex-, and race-matched cohort with systolic heart failure.

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METHODS

Study Design

Digitalis Investigation Group (DIG) trial was a randomized controlled trial of patients with heart failure. The purpose of the DIG trial was to determine the effects of digoxin on mortality and hospitalizations in chronic systolic heart failure patients with normal sinus rhythm. The trial was conducted at 302 centers in the United States and Canada and details of the study design, baseline characteristics of the patients, and results are published elsewhere.[12, 13]. The DIG dataset was obtained from the National Heart, Lung and Blood Institute of the National Institutes of Health. All patients signed informed consent forms and the protocol was approved by the Institutional Review Boards of all the participating centers. DIG trial enrolled 7,788 ambulatory patients with chronic heart failure. The Institutional Review Board of the University of Alabama at Birmingham approved the use of the dataset.

Study Patients

In the original DIG trial, 7,788 heart failure patients were randomized to either digoxin or placebo group.[5] Of these, 6,800 had systolic heart failure and 988 had diastolic heart failure. Patients were recruited irrespective of their heart failure etiology or New York Heart Association (NYHA) functional class. Patients with non-sinus rhythm were excluded and all patients were encouraged to be on ACE inhibitors. For the present study, we excluded 3,804 patients younger than 65 years. Of the 3,984 patients in this study, 579 had diastolic heart failure and 3,405 had systolic heart failure. Of the 579 patients with diastolic heart failure, 571 were matched by age, sex, and race with 571 patients with systolic heart failure.

Diagnosis of Heart Failure and Evaluation of Systolic Function

In the DIG trial, the diagnosis of heart failure was established based on current or past clinical symptoms or signs or radiographic evidence of pulmonary congestion. Left ventricular systolic function was evaluated by two-dimensional echocardiography, radionuclide ventriculography and contrast left ventriculography. In the original trial, 6,800 patients with left ventricular ejection fraction ≤45% (systolic heart failure) and were randomized in the main trial, and 988 patients with left ventricular ejection fraction >45% (preserved systolic function or “probable” diastolic heart failure)[14] were randomized in the ancillary trial. For the purpose of this study, we used the same ejection fraction cutoff to define systolic and diastolic heart failure.

Study Outcomes

Patients in the DIG trial were followed for a mean of 37 months, with range from 28 to 58 months.[13] The primary outcome of the main DIG trial was all-cause mortality. For the purpose of this study, we studied all-cause death, death due to heart failure, heart failure hospitalization, combined end point of heart failure hospitalization or all-cause mortality, all-cause hospitalization, and hospitalizations due to cardiovascular and non-cardiovascular causes.

Statistical Analysis

Baseline characteristics of 579 diastolic heart failure and 3,405 systolic heart failure patients were compared at first. Then, we compared the baseline characteristics of 571 diastolic heart failure patients with 571 age, sex, and race-matched systolic heart failure patients. Pearson Chi-square tests and Student’s t tests were used as appropriate to test for statistical significance.

Then, we used Kaplan-Meier survival analyses to compare various outcomes between the two groups and tested statistical significance using log rank t est. Bivariate and multivariable Cox proportional hazards models were used to compare various outcomes between the two groups of heart failure patients. Covariates used in the multivariable models included duration and

etiology of heart failure, comorbidities (myocardial infarction, angina, hypertension, diabetes, and chronic kidney disease (defined by estimated glomerular filtration rate of 60 ml/min/ 1.73m^2 "body surface area"), medications (digoxin, non-potassium sparing diuretics, and angiotensin-converting enzyme inhibitors), New York Heart Association functional class, clinical features vital signs (heart rate, systolic and diastolic blood pressure), and signs of heart failure (jugular venous distention, third heart sound, pulmonary râles, lower extremity edema, and pulmonary congestion by chest x-ray). All statistical tests were evaluated using a two-tailed 95% confidence level. Analyses were performed using SPSS for Windows (Release 12).[15]

RESULTS

Patient Characteristics

In the pre-match cohort, older adults with heart failure and diastolic heart failure were more likely to be older and female. In the matched cohort, patients had a mean (±SD) age of 72.6 (±5.6) years, 42.7% female and 11.2% were non-whites (Table 1). Patients with diastolic heart failure were more likely to have hypertension and hypertensive cardiomyopathy, and less likely to have a history of acute myocardial infarction and ischemic cardiomyopathy. They were also less likely to have chronic kidney disease. Diastolic heart failure patients were more likely to present with lower extremity edema and less likely to have a third heart sound, jugular venous distension, or pulmonary congestion by chest x-ray. However, there were no significant differences in the prevalence of dyspnea and activity limitations between the groups.

Mortality due to All Causes and Worsening Heart Failure

Three hundred eighty six patients (33.8%) died from all causes during the study. Compared with 41.0% (234/571) systolic heart failure patients, 26.6% (152/571) diastolic heart failure patients died during the study ($p < 0.001$). The Kaplan Meier survival curves for all-cause mortality are displayed in Figure 1 (a). Mean survival in diastolic heart failure patients was over 6 months longer in patients with diastolic heart failure (mean survival of 1,426 days compared with 1,230 days for systolic heart failure patients; log rank test $p < 0.001$). Compared with systolic heart failure patients, those with diastolic heart failure had a 41% lower risk of death from any cause (unadjusted hazard ratio {HR} = 0.59; 95% confidence interval {CI} = 0.48 - 0.72). After adjustment for covariates, presence of diastolic heart failure was independently associated with a significant 27% lower risk of death (adjusted HR = 0.73; 95% CI = 0.58 - 0.91).

One hundred twenty one patients (10.6%) died due to worsening heart failure during the study. Compared with 14.2% (81/571) deaths in systolic heart failure patients, 7.0% (40/571) diastolic heart failure patients died from worsening heart failure during the study ($p < 0.001$). The Kaplan Meier survival curves for heart failure related deaths between the groups are displayed in Figure 1 (b). Diastolic heart failure patients had 114 days of longer mean survival free of heart failure related death (1,650 vs. 1,536 days for systolic heart failure patients; $p < 0.001$). Compared with systolic heart failure patients, those with diastolic heart failure had a 46% lower risk of death from worsening heart failure (adjusted HR = 0.73; 95%CI = 0.58 - 0.91).

Hospitalizations

Seven hundred sixty nine (67.3%) were hospitalized due to all causes during the study. There were no differences in the overall hospitalization between the groups. Hospitalizations due to worsening heart failure was significantly lower in diastolic heart failure patients (20.0% vs. 31.3% in systolic heart failure patients; $p < 0.001$). The Kaplan Meier survival curves for all-cause and heart failure hospitalizations are displayed in Figures 2 (a) and (b) respectively. Diastolic heart failure was associated with a 28% independent reduction in hospitalization due

to worsening heart failure (adjusted HR = 0.68; 95%CI = 0.52 - 0.88). The risk of combined end point of hospitalization due to worsening heart failure or all-cause death was lower in older adults with diastolic heart failure (Table 2). While the risk of hospitalization due to cardiovascular causes were lower (adjusted HR = 0.83; 95%CI = 0.69 - 0.99) in diastolic heart failure patients, they were more likely to be hospitalized due to non-cardiovascular causes (Figure 3 a and b, Table 2). There were no differences between the two groups in risks of hospitalization due to acute myocardial infarction, unstable angina, supraventricular arrhythmias, coronary revascularization or stroke.

DISCUSSION

The results of this study are important for several reasons. This is the first study that reports various outcomes in community dwelling older adults with diastolic heart failure compared with systolic heart failure. The results of this study demonstrate that compared with systolic heart failure patients, diastolic heart failure patients had overall lower risks of death. However, there were no differences in overall hospitalizations between the groups. Even though, diastolic heart failure patients were less likely to have hospitalizations due to cardiovascular causes, they had higher risk for non-cardiovascular hospitalizations suggesting significant burden of morbidity in these patients.

In a recent review of literature, Hogg et al. identified 12 studies of hospitalized diastolic heart failure patients published since January 2000.[9] While some of these studies were restricted to patients 65 years and older, as most hospitalized heart failure patients are older adults, all of these studies involved older adults.[1, 11, 16-25] Nine of these studies reported mortality (all-cause) as an outcome.[1, 16, 18-21, 23-25] Results from seven of these studies suggest that older adults with diastolic heart failure have better survival compared with systolic heart failure patients.[1, 16, 18-20, 23, 24] In one study, mortality rates between diastolic and systolic heart failure patients were similar.[21] Several other previous studies have also observed no difference in morality between patients with systolic and diastolic heart failure.[26-28] In one study of hospitalized veterans, presence of diastolic heart failure was associated with increased risk of death.[25] However, in that study heart failure patients were identified using an electronic search of computerized medical record for administrative coding of heart failure as the primary discharge diagnosis. In one study of older adults with heart failure associated with prior myocardial infarction living in long-term care facilities, patients with impaired systolic function had higher mortality rate than those with preserved systolic function.[29]

Most population based studies of diastolic heart failure suffer from small numbers of diastolic heart failure patients.[6, 7, 30-32] Most of these studies are also not restricted to patients 65 years and older. In the Cardiovascular Health Study that involved 5,532 community-dwelling persons 65 years and older, 249 (4.9%) had heart failure.[6] One hundred seventy (63%) of them diastolic heart failure based on left ventricular ejection fraction >55%. Thirty nine patients (15%) had ejection fraction between 45 and 54% and 60 (22%) had systolic heart failure (ejection fraction <45%). In that study, respective annual mortality rates for diastolic, borderline and systolic heart failure patients were 8.7%, 11.5% and 15.4%.[6] Compared with healthy cohorts with normal systolic function, presence of diastolic, borderline and systolic heart failure were independently associated with respectively 48%, 140% and 88% higher risk of death from any cause.[6] Several other community based studies did not observe any mortality differences between diastolic and systolic heart failure.[6, 7, 30] In all these studies, the number of diastolic heart failure patients was relatively low: 20 in Helsinki Aging Study,[30] 37 in the Framingham Heart Study,[7] and 59 in the Mayo Clinic Olmsted County study.[31] To our knowledge, the current study is the first to demonstrate significant lower risk of all-cause mortality and mortality due to worsening heart failure in a large cohort of ambulatory older adults with diastolic heart failure. Using the Veterans Administration Cooperative Study trial dataset, Cohn

et al. demonstrated a similar survival benefit associated with diastolic heart failure (ejection fraction ≥45%).[33] However, patients in that study were younger (mean age 60 years).

Data on hospitalization among patients with diastolic heart failure is relatively scarce in the literature. In the Olmsted County study, of 51% (30/59) patients with diastolic heart failure had one hospitalization due to heart failure and 25% (15/59) had 2 or more hospitalizations due to heart failure. On the other hand, in that study 41% (32/78) patients with systolic heart failure had one and 49% (38/78) had 2 or more hospitalizations due to heart failure.[31] There is no reports on hospitalization in patients with diastolic heart failure from the Framingham Heart Study or Cardiovascular Heart Study.[6, 7] In hospitalized heart failure patients, the risk of heart failure-related hospitalization has been variously reported to be lower than[1] or similar to that of systolic heart failure.[18, 23] Several of these studies reported all-cause hospitalization and did not find any difference between the two groups.[16-18] We too observed a similar all-cause hospitalization between patients with systolic and diastolic heart failure. However, we noted that while hospitalizations due to all cardiovascular causes were lower in diastolic heart failure patients, except for those due to worsening heart failure, there were no differences between the two groups in terms of hospitalizations due to other major cardiovascular reasons. On the other hand, risk of hospitalizations due to non-cardiovascular causes was higher in patients with diastolic heart failure.

One of the limitations of our study is patients in our study were in normal sinus rhythm. Atrial fibrillation is common in older adults with heart failure and is associated with poor outcomes.[34, 35] In addition, we did not exclude patients with valvular heart disease. Only 56 of the 3,984 patients 65 years and older (1.4%) patients had valvular heart disease identified as primary cause of heart failure. A subgroup analysis excluding these patients demonstrated similar results on key outcomes.

In conclusion, the results of our study suggest that among community dwelling older adults compared with an age-sex-race matched cohort of systolic heart failure patients those with diastolic heart failure have better survival. However, despite a lower risk for hospitalization due to heart failure, hospitalizations due to other cardiovascular causes were similar and those due to non-cardiovascular hospitalizations were higher. With the population aging, this might impose burden on older adults and the health care system. Future studies should examine if more aggressive evaluation and management of comorbidities such as coronary artery disease or hypertension would reduce this burden.

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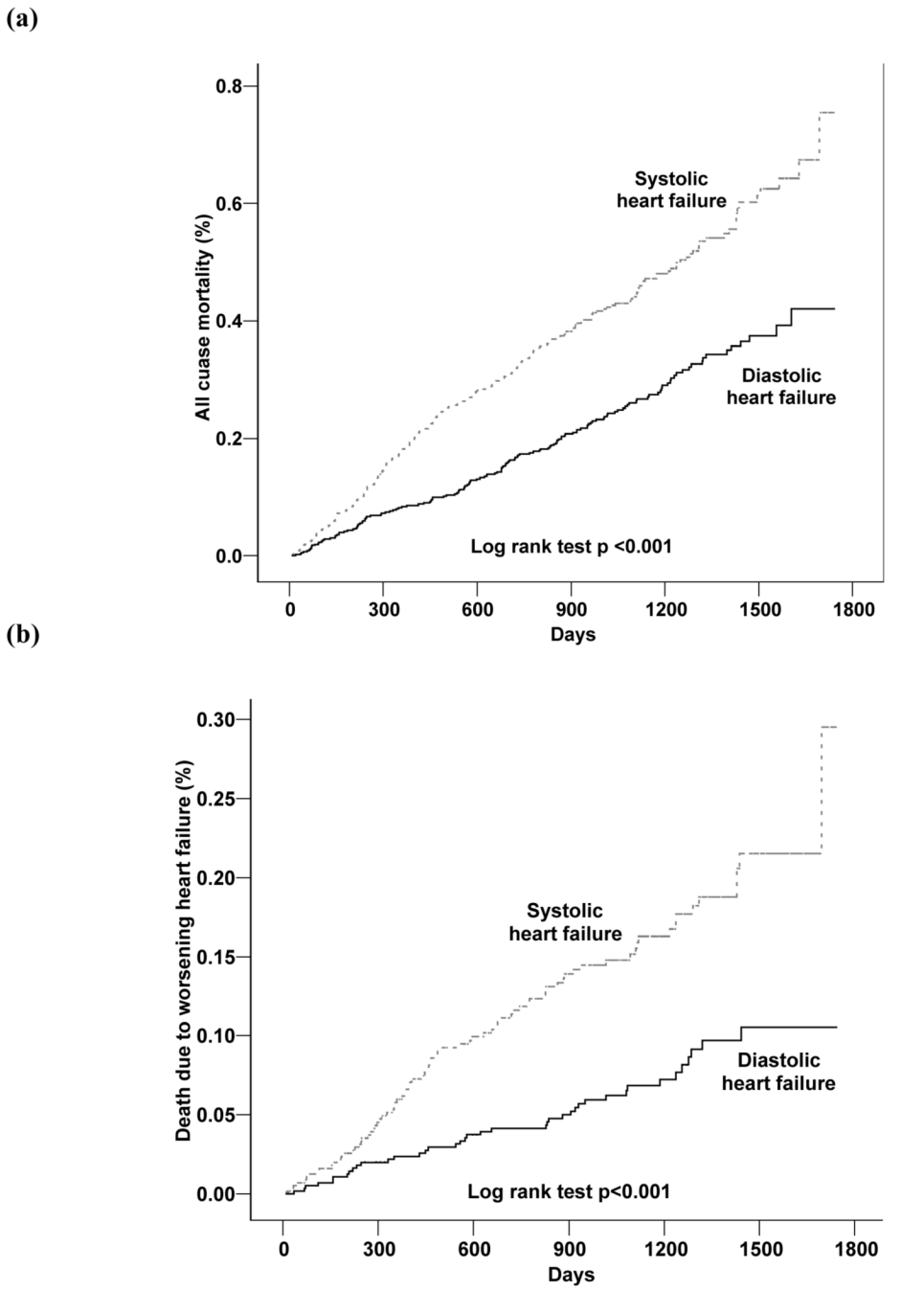

Figure 1.
Kaplan-Meier plots for (a) all cause mortality and (b) heart failure related mortality for heart failure patients with systolic vs. diastolic dysfunction.

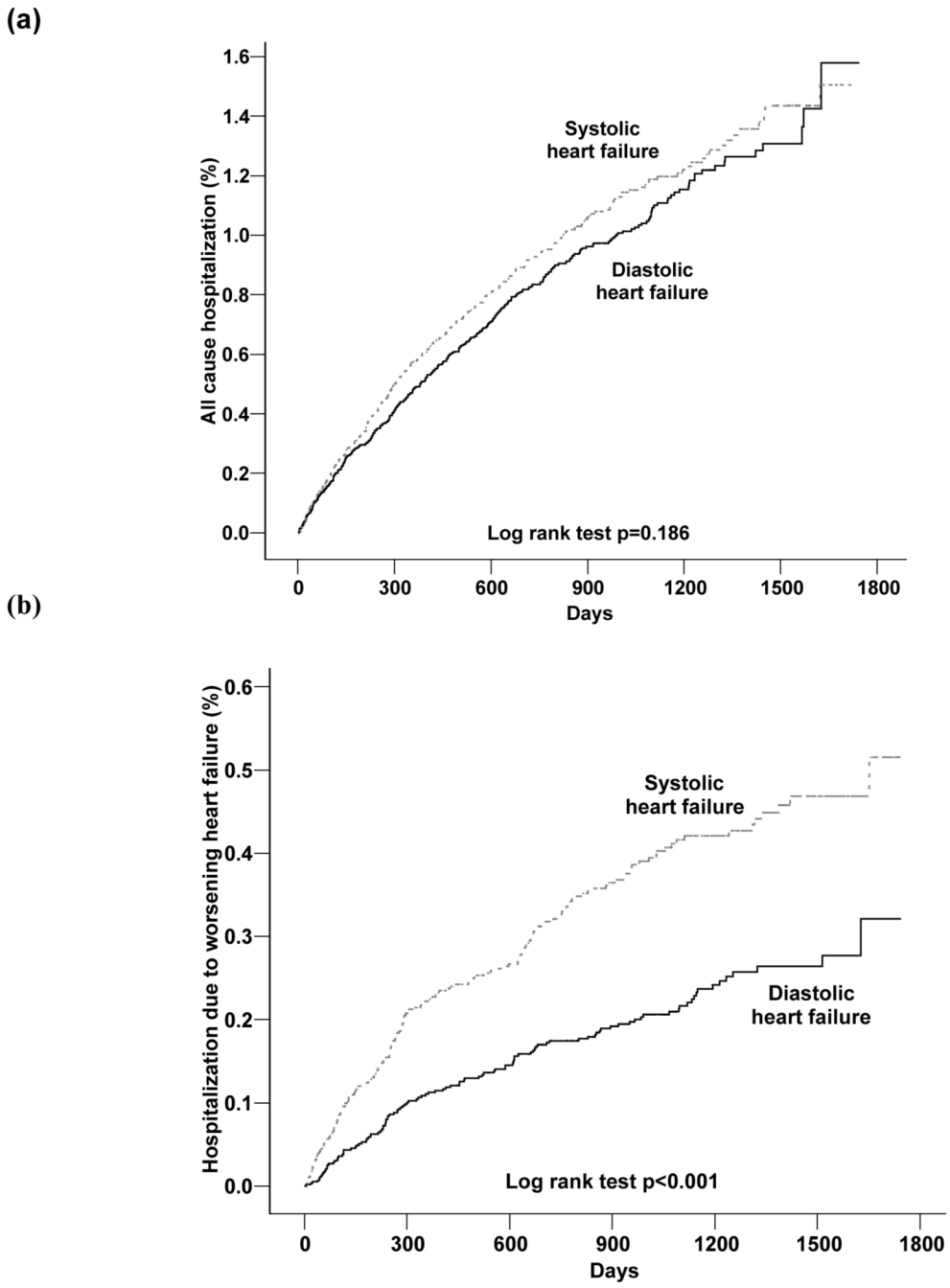

Figure 2.
Kaplan-Meier plots for hospitalization due to (a) all cause and (b) worsening heart failure in patients with systolic vs. diastolic dysfunction.

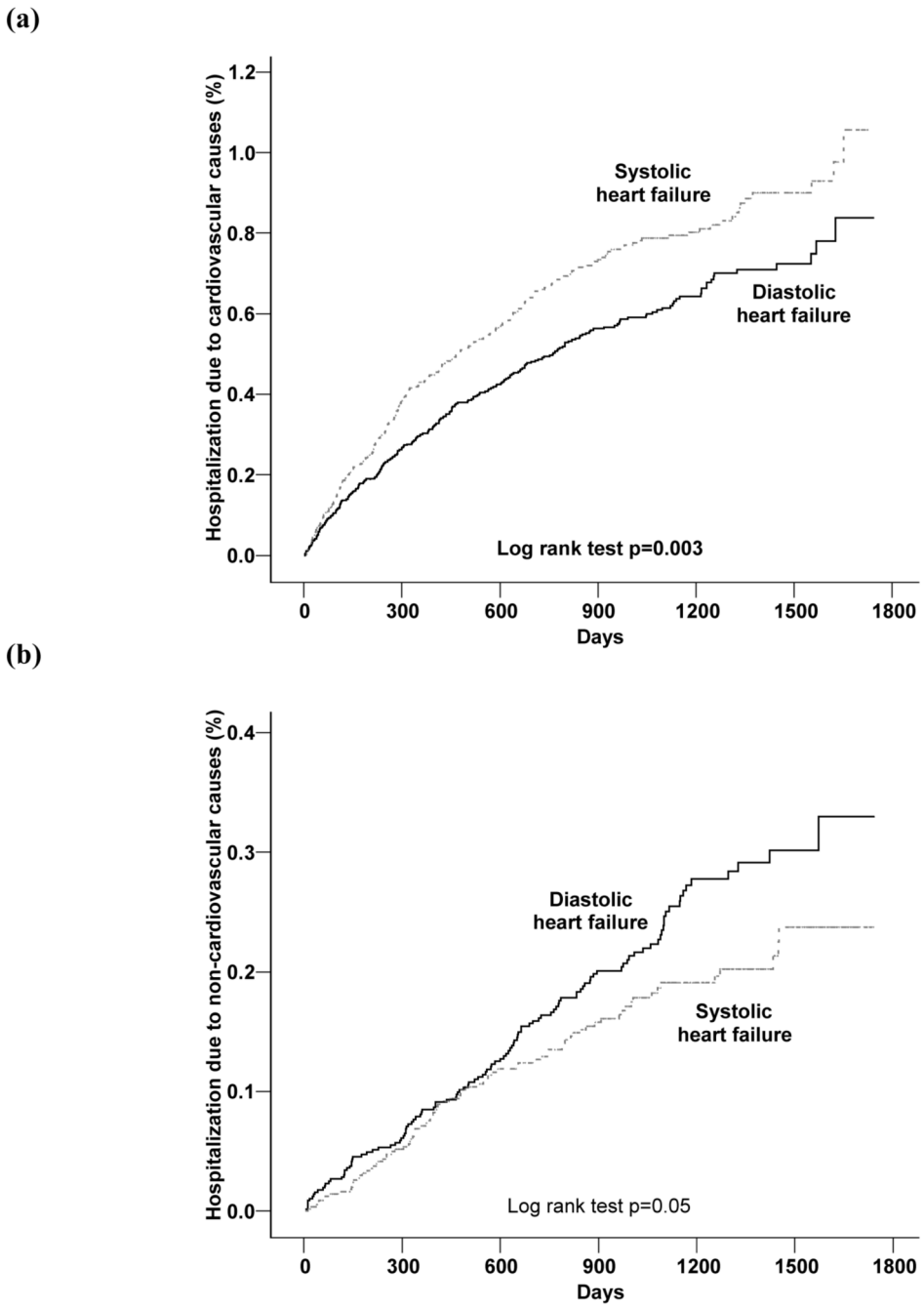

Figure 3.
Kaplan-Meier plots demonstrating hospitalization due to (a) cardiovascular and (b) non-cardiovascular causes among chronic heart failure patients by left ventricular systolic function

Table 1

Baseline patient characteristics by left ventricular systolic function after age-sex-race matching

	Systolic heart failure N = 571	Diastolic heart failure N = 571	P value
Age (years), mean (±SD)	72.6 (±5.6)	72.6 (±5.6)	>0.999
Female	244 (42.7%)	244 (42.7%)	>0.999
Non-white	64 (11.2%)	64 (11.2%)	>0.999
Duration of heart failure (months), mean (±SD)	28.0 (±32.9)	25.1 (±29.3)	0.116
Primary cause of heart failure			
Ischemic	412 (72.2%)	345 (60.4%)	
Hypertensive	62 (10.9%)	158 (27.7%)	<0.001
Idiopathic	63 (11.0%)	50 (8.8%)	
Others	34 (6%)	18 (3.2%)	
Comorbid conditions			
Prior myocardial infarction	380 (66.5%)	292 (51.1%)	<0.001
Current angina	151 (26.4%)	181 (31.7%)	0.051
Hypertension	288 (50.4%)	357 (62.5%)	<0.001
Diabetes	167 (29.2%)	160 (28.1%)	0.660
Chronic kidney disease	360 (63.0%)	327 (57.3%)	0.046
Medications			
Pre-trial digoxin use	245 (42.9%)	193 (33.8%)	0.002
Digoxin use	288 (50.4%)	283 (49.6%)	0.767
ACE inhibitors	538 (94.2%)	492 (86.2%)	<0.001
Non-potassium sparing diuretics	461 (80.7%)	440 (77.1%)	0.128
Potassium sparing diuretics	43 (8.9%)	50 (8.8%)	0.449
Potassium supplement	157 (27.5%)	157 (27.5%)	>0.999
Symptoms and signs of heart failure (current)			
Dyspnea at rest	396 (69.4%)	389 (68.1%)	0.655
Dyspnea on exertion	544 (95.3%)	550 (96.3%)	0.376
Activity limitation	533 (93.3%)	521 (91.2%)	0.183
Jugular venous distension	315 (55.2%)	265 (46.4%)	0.003
Third heart sound	269 (47.1%)	166 (29.1%)	<0.001
Pulmonary râles	439 (76.9%)	421 (73.7%)	0.217
Lower extremity edema	300 (52.5%)	335 (58.7%)	0.037
NYHA functional class			
I	58 (10.2%)	102 (17.9%)	
II	299 (52.4%)	321 (56.2%)	<0.001
III	197 (34.5%)	138 (24.2%)	
IV	17 (3.0%)	10 (1.8%)	
Heart rate (/minute), mean (±SD)	78.4 (±12.5)	75.2 (±11.6)	<0.001
Blood pressure (mm Hg), mean (±SD)			
Systolic	128.5 (±20.1)	139.9 (±20.7)	<0.001
Diastolic	74.0 (±11.6)	76.5 (±11.0)	<0.001
Chest radiograph findings			
Pulmonary congestion	401 (70.2%)	353 (618%)	<0.001
Laboratory data, mean (±SD)			
Serum creatinine (mg/dL),	1.34 (±0.40)	1.28 (±0.39)	0.010
Serum potassium (mEq/L)	4.37 (±0.47)	4.35 (±0.41)	0.339
Left ventricular ejection fraction (%), mean (±SD)	29.3 (±9.0)	55.7 (±8.1)	<0.001

Table 2

Crude and adjusted hazard ratios (95% confidence intervals) for various outcomes for older adults with systolic vs. diastolic heart failure

	Events (systolic / diastolic (p value))	Unadjusted	Adjusted*
Mortality due to all causes	41.0% / 26.6% (< 0.001)	0.59 (0.48 - 0.72)	0.73 (0.58 - 0.91)
Mortality due to heart failure	14.2% / 7.0% (< 0.001)	0.45 (0.31 - 0.65)	0.54 (0.36 - 0.82)
Hospitalization due to all causes	66.9% / 67.8% (0.752)	0.91 (0.79 - 1.05)	0.97 (0.83 - 1.14)
Hospitalization due to heart failure	31.3% / 20.0% (< 0.001)	0.55 (0.44 - 0.70)	0.68 (0.52 - 0.88)
Hospitalization due to cardiovascular causes	52.0% / 46.6% (< 0.067)	0.78 (0.66 -0.91)	0.83 (0.69 -0.99)
Hospitalization due to non-cardiovascular causes	14.7% / 21.0% (0.005)	1.32 (1.00 - 1.78)	1.38 (1.02 - 1.88)
Hospitalization due to heart failure or all-cause mortality	55.0% / 38.0% (< 0.001)	0.59 (0.50 - 0.71)	0.72 (0.60 - 0.88)

* Adjusted for duration and etiology of heart failure, history of myocardial infarction, angina, hypertension, diabetes mellitus, and chronic kidney disease, use of digoxin, non-potassium sparing diuretics, and angiotensin-converting enzyme inhibitors, New York Heart Association functional class, heart rate, systolic and diastolic blood pressure, jugular venous distention, third heart sound, pulmonary râles, lower extremity edema, and pulmonary congestion by chest x-ray.