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(Degree)

博士 (保健学)

(Date of Degree)

2022-03-25

(Date of Publication)

2023-03-01

(Resource Type)

doctoral thesis

(Report Number)

甲第8336号

(URL)

<https://hdl.handle.net/20.500.14094/D1008336>

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博士論文

Clinical impact of functional independent measure (FIM) on 180-day readmission and mortality in elderly patients hospitalized with acute decompensated heart failure

(急性非代償性心不全患者の 180 日再入院・死亡に対する機能的自立度評価法 (FIM)
の臨床的影響)

令和 4 年 1 月 11 日

神戸大学大学院保健学研究科保健学専攻

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Clinical impact of functional independent measure (FIM) on 180-day readmission and mortality in elderly patients hospitalized with acute decompensated heart failure

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ABSTRACT

Activities of daily living (ADL) are important prognostic factors for heart failure. The functional independent measure (FIM) has emerged as a comprehensive valid measure of ADL from both physical and cognitive perspectives. This study aimed to investigate the prognostic impact of the FIM score on clinical outcomes in hospitalized patients with acute decompensated heart failure (ADHF). We retrospectively analyzed 473 ADHF patients, with available pre-discharge FIM scores, admitted to our institution between May 2018 and May 2020. Primary outcome measures, defined as a composite of 180-day all-cause deaths and readmissions, were compared among 3 tertiles. The median FIM score was 102 (interquartile range: 85–115). Tertile 1 corresponded to an FIM score >111 (n=154), Tertile 2 to that of 90–111 (n=167), and Tertile 3 to that of <90 (n=152). During follow-up, 28 deaths and 114 readmissions occurred. Patients with lower FIM scores were associated with a graded increase in the risk of primary outcome measure ($p=0.001$). Even after multivariable adjustment, the results remained significant (Tertile 1 vs. 3; adjusted hazard ratio: 3.28 [95% confidence interval: 1.72–6.56], $p<0.001$; Tertile 2 vs. 3; 2.32 [1.27–4.47], $p=0.006$). FIM scores were significantly associated with readmission or death within 180 days of discharge in hospitalized ADHF patients.

Keywords: activities of daily living, heart failure, frailty, elderly

INTRODUCTION

Heart failure is increasing rapidly with the aging of the population. Currently, the number of patients with heart failure is estimated to be approximately 1 million; however, the number of hospitalized patients with heart failure is clearly increasing by 10,000 every year, and it is expected to increase further by 2035 [1]. Therefore, it is also called a "heart failure pandemic" in a super-aging society [2]. Heart disease, including myocardial infarction and angina, is the second leading cause of death in Japan, and exacerbated symptoms are found in 17% of heart failure patients within 6 months of discharge from the acute care hospital, and the patients are repeatedly re-admitted [2-4]. It has been reported that this is prevalent. Therefore, treatment and rehabilitation of heart failure has become an urgent issue.

Activities of daily living (ADL) refer to basic daily self-care activities and are used to measure people's functional status. Limitation in ADL for elderly people allows prediction of increased morbidity, mortality, and nursing home admission after hospital discharge [5-8]. A systematic review identified physical and cognitive functions as risk factors associated with adverse outcomes in elderly patients after hospital discharge [9]. Thus, assessment of physical and cognitive functions, such as ADL, is important in determining appropriate supportive care required subsequently. Motor and cognitive functions in patients with heart failure are independent prognostic factors, and they are included among ADL elements. One of the goals of rehabilitation for patients with ADHF is the recovery of ADL [10-12]. Functional independent measure (FIM), an evaluation index of ADL, comprehensively evaluates motor and cognitive functions [13-15]. However, few studies have demonstrated a relationship between FIM and post-discharge readmission or death. ADL has not been established as a predictive criterion for adverse events in elderly patients with ADHF. Therefore, in order to assess the association, it is hypothesized that limitations in ADL, such as disabilities in physical and cognitive functions, lead to poor prognostic events after hospitalization for ADHF.

This study aimed to investigate whether ADL is an independent predictive factor for death or readmission within 6 months after discharge for elderly patients hospitalized for ADHF.

METHODS

Study design and participants

This retrospective, single-center cohort study included 529 consecutive patients who were admitted to our institution due to ADHF between May 2018 and May 2020. Among them, we analyzed 473 patients in whom pre-discharge FIM scores were available.

This study was approved by the Ethics Committee of Kobe City Medical Center General Hospital (approval no. ZN201206) and was conducted in accordance with the principles of the Declaration of Helsinki regarding investigations in humans. Patients were not required to provide informed consent to participate in the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent. We also applied the opt-out method to obtain consent for this study.

Outcomes and data collection

The primary outcome measure was defined as a composite of all-cause death and readmission within 180 days after discharge. Data on adverse events were collected by means of indexed hospital medical records up to 180 days after the initial discharge and by telephone survey. Scheduled hospitalizations after discharge were excluded from all-cause readmission so as not to count. Data were retrospectively collected by reviewing computerized medical records, including age, sex, medication (angiotensin converting enzyme inhibitor, angiotensin receptor blocker, β -blocker), left ventricular ejection fraction, laboratory values on admission (albumin, blood urea nitrogen [BUN], C-reactive protein, estimated glomerular filtration rate], hemoglobin, glycated hemoglobin A1c, sodium, N-terminal pro brain natriuretic peptide, and

creatinine), FIM score at discharge, and 180-day adverse events [16].

Activities of daily living

The FIM is a measurement tool that assesses 18 items (13 motor tasks and 5 cognitive tasks) using a 7-point rating scale, with 1-point equating to total assistance and 7-points indicating complete independence in evaluating ADL. The FIM motor tasks include eating, grooming, bathing, upper body dressing, lower body dressing, toileting, bladder management, bowel management, transfers to bed/chair/wheelchair, transfers to toilet, transfers to tub/shower, walk/wheelchair, and stairs. The FIM cognitive tasks include comprehension, expression, social interaction, problem solving, and memory. FIM scores of 6 and 7 were defined as “independence with no helper,” while FIM scores below 6 as “requiring helpers for supervision or assistance.” By adding the points for each item, the possible FIM scores ranged from 18 to 126 points. The FIM score for each patient was assessed by a physical therapist at discharge. The total FIM score was trichotomized into three groups (>111, 90–111, and <90). The FIM, whose original purpose was to evaluate disability levels of people who had strokes, has proven reliable for other diseases in quantitative reviews and in people from a multilevel continuing care retirement community [17].

Statistical analysis

Quantitative variables were expressed as median (interquartile range [IQR]), and qualitative variables were expressed as numbers (percentages). Participants were divided into three groups according to their FIM score tertiles. Among the three groups, patient characteristics and clinical parameters were compared using one-way analysis of variance and χ^2 tests. The rate of 180-day adverse events was analyzed using the Kaplan–Meier analysis and a log-rank test between the three groups. The relationship between the rate of 180-day adverse events and

ADL was assessed using the Cox proportion hazard model. Model 1 included age, sex, and FIM at discharge. Model 2 included LVEF, Hb, Na, Cre, Nt-proBNP, ACEI or ARB, and β B in addition to Model 1.

All statistical analyses were performed using EZR (Saitama Medical Center, Jichii Medical University, Saitama, Japan), a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria) [18]. EZR is a modified version of R commander designed to add statistical functions that are frequently used in biostatistics. A p-value <0.05 was considered statistically significant.

RESULTS

Patient characteristics

A flowchart describing the inclusion of patients in this study is shown in **Figure 1**. A total of 529 patients were initially considered eligible for this study; however, 27 patients were later excluded because they died during hospitalization. Of the remaining 502 patients, 29 were excluded because their FIM at discharge was incomplete during the initial hospitalization, preventing correct interpretation. A final cohort of 473 patients was included in this study.

The mean age of the cohort was 76.7 ± 11.7 years, 273 (57.8%) patients were men, and the median FIM score was 102 (interquartile range: 85–115). Participants were divided into three groups according to the tertiles of their FIM scores. Tertile 1 corresponded to an FIM score >111 (n=154), Tertile 2 to that of 90–111 (n=167), and Tertile 3 to that of <90 (n=152). The demographic data are shown in **Table 1**. Lower FIM scores were associated with older, women, higher BUN and C-reactive protein levels, less beta-blocker prescription, anemia, and lower albumin levels.

Outcomes

During the follow-up after discharge from the index hospitalization, 26 patients died and 103

were readmitted, leading 116 patients experienced the primary outcome measure. The lower FIM scores showed a graded increase in the risk of adverse events ($p<0.001$, **Figure 2**). In addition, lower FIM scores were associated with higher event rates as compared to the other groups (Tertile 1 vs 3, hazard ratio [HR]: 2.58, 95% confidence interval [CI]: 1.58–4.22, $p<0.001$; Tertile 1 vs 2, HR: 1.91, 95% CI: 1.18-3.10, $p=0.009$, **Table 2**). After adjustment by age and sex, the results remained significant (Model 1, Tertile 1 vs 3, adjusted HR: 2.43, 95% CI: 1.42-4.16, $p=0.001$; Tertile 1 vs 2, adjusted HR: 1.86, 95% CI: 1.12-3.06, $p=0.016$). The results remained significant after multivariable adjustment as well (Model 2, Tertile 1 vs 3, adjusted HR: 3.35, 95% CI: 1.72-6.52, $p<0.001$; Tertile 1 vs 2, adjusted HR: 2.37, 95% CI: 1.27-4.43, $p=0.006$)

DISCUSSION

This study investigated the association between functional disability and prognostic factors in patients with ADHF. We found that functional disability was significantly associated with all-cause readmission and death in elderly patients after hospitalization for ADHF.

Elderly patients with heart failure have often multiple comorbidities, and extra-cardiac factors such as physical and cognitive functions were reported to be associated with poor prognosis [19-22]. Impaired physical and cognitive functions leading to decreased ADL, has been known to be a strong predictor of readmission in patients with stroke [23-26]. Recently, Testa et al. has reported that comprehensive evaluation of frailty was a better predictor of outcomes than physical frailty alone [27]. As FIM is a comprehensive measurement that includes motor and cognitive functions for the assessment of ADL, and thus reflecting a patient's physical activity, FIM is considered an independent prognostic factor for all readmissions or deaths within 180 days of discharge [28,29]. However, the clinical impact of FIM in patients with heart failure has not been evaluated. In the current study, we showed that

impaired ADL assessed by FIM was significantly associated with post-hospital mortality and readmission in elderly patients with ADHF. Since interventions for increasing the amount of physical activity has been reported to be able to prevent re-hospitalization for heart failure after discharge, it may be important to evaluate FIM for patients with heart failure during their hospitalization and to plan post-discharge rehabilitation programs based on the FIM scores. Further study is required to investigate whether the post-discharge physiotherapy intervention strategy based on the FIM scores can prevent post-discharge mortality or readmission in elderly patients hospitalized due to ADHF.

In this study, 21.8% of the 473 enrolled patients were readmitted and 5.4% died within 180 days after discharge from the index hospitalization. It has been reported that the one-year mortality rate of hospitalized patients with ADHF is 7.3%, and the readmission rate due to exacerbation of heart failure is 27% 6-month after discharge. In these studies, the average age was 70 years or older in all reports [30-33]. Recent study showed that the precipitating factors which lead to decompensation may be different between younger and older patients [34]. In the study, infection was identified as one of the most powerful factors for decompensation in older patients [34]. Decrease in ADL was known to be associated with an increased risk of pneumonia [17]. In the current study, we found that a decrease in ADL at discharge was associated with post-hospital mortality and readmission within 180 days. These results can be generalizable because the baseline characteristics of patients in the current study were in close agreement with those of previous studies [30-33].

Limitations

The present study had some limitations. First, there was a risk of sampling bias and problems with generalizability because this retrospective study was conducted at a single institution with a small sample size. Second, a survey on socio-demographic factors was not conducted. In

addition, frailty was not included in the analyses. Comprehensive frailty assessment including physical frail and ADL might be a better predictor of outcome in older HF patients [27]. Third, it was not possible to determine whether motor or cognitive function had a stronger effect. Finally, additional factors, such as comorbidity and swallowing function, were difficult to investigate using a retrospective study design.

CONCLUSION

Functional disability assessed by FIM scores was associated with higher adverse event rates in patients with ADHF. Further studies are warranted to examine effective physiotherapy interventions based on FIM scores to prevent post-discharge death and readmission in elderly patients with ADHF

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Table 1. Clinical characteristics of participants

	All patients (n=473)	Tertile 1 (n=154)	Tertile 2 (n=167)	Tertile 3 (n=152)	p
Age, years	76.7±11.7	71.0±11.8	78.1±10.4	83.0±7.6	<0.001
Male	273 (57.8)	102 (66.2)	92 (55.1)	79 (52.0)	0.029
Medications					
ACEI or ARB	173 (36.6)	62 (40.3)	60 (35.9)	48 (31.6)	0.29
ACEI	141 (29.8)	51 (33.1)	51 (30.5)	39 (25.7)	0.35
ARB	29 (6.1)	11 (7.1)	9 (5.4)	9 (5.9)	0.8
β-blocker	285 (60.2)	107 (69.5)	108 (64.7)	70 (46.1)	<0.001
LVEF, %	44.7±16.1	43.3±16.3	45.6±15.6	46.0±15.7	0.35
LVEF <50 %	226 (47.8)	83 (53.9)	76 (45.5)	67 (44.1)	0.24
FIM, points	96±24	120±5	101±6	67±20	<0.001
Laboratory data					
NT-pro BNP, pg/mL	1886 [883, 4604]	1335 [610, 2757]	2421 [1038, 4141]	2320 [1191, 5691]	0.041
Albumin, g/dL	3.3±0.5	3.5±0.4	3.2±0.4	3.1±0.5	<0.001
BUN, mg/dL	25.3 [17.9, 37.2]	21.9 [16.4, 32.2]	24.3 [18.4, 39.7]	29.5 [19.3, 40.2]	0.001
Creatinine, mg/dL	1.13 [0.87, 1.77]	1.08 [0.85, 1.60]	1.16 [0.88, 1.77]	1.14 [0.90, 1.79]	0.45
eGFR, ml/min/1.73 m ²	43.0 [27.0, 59.0]	31.0 [48.0, 62.0]	41.0 [25.5, 54.0]	39.0 [26.0, 54.3]	0.022
C-reactive protein, mg/dL	0.46 [0.17, 1.38]	0.29 [0.14, 0.86]	0.49 [0.18, 1.45]	0.55 [0.21, 1.96]	0.004
Hemoglobin, g/dL	11.4±2.1	12.1±2.3	11.2±1.9	10.9±1.7	<0.001

HbA1c, %	6.2±0.9	6.3±1.1	6.3±0.9	6.1±0.8	0.023
Na, mEq/L	138.6±3.4	138.9±3.0	138.3±3.5	138.7±3.8	0.21

Data are shown in n (%), mean ±SD or median [interquartile range].

ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin II receptor blocker; LVEF, left ventricle ejection fraction; FIM, functional independence measure; NT-pro BNP, N-terminal B type natriuretic peptide; BUN, blood urea nitrogen; eGFR, estimated glomerular filtration ratio.

Table 2. Results of Cox regression analyses of the factors associated with 180-day events

	Hazard ratio	95% CI	p
Unadjusted			
Tertile 1	1.00	reference	
Tertile 2	1.91	1.18–3.10	0.009
Tertile 3	2.58	1.58–4.22	<0.001
Model 1*			
Tertile 1	1.00	reference	
Tertile 2	1.86	1.12–3.06	0.016
Tertile 3	2.43	1.42–4.16	0.001
Model 2**			
Tertile 1	1.00	reference	
Tertile 2	2.37	1.27–4.43	0.006
Tertile 3	3.35	1.72–6.52	<0.001
*model 1 was adjusted by age and sex **model 2 was adjusted by age, sex, LVEF, hemoglobin, Na, creatinine, NT-pro BNP, ACEI or ARB, and β-blocker. CI, confidence interval; FIM, functional independence measure.			

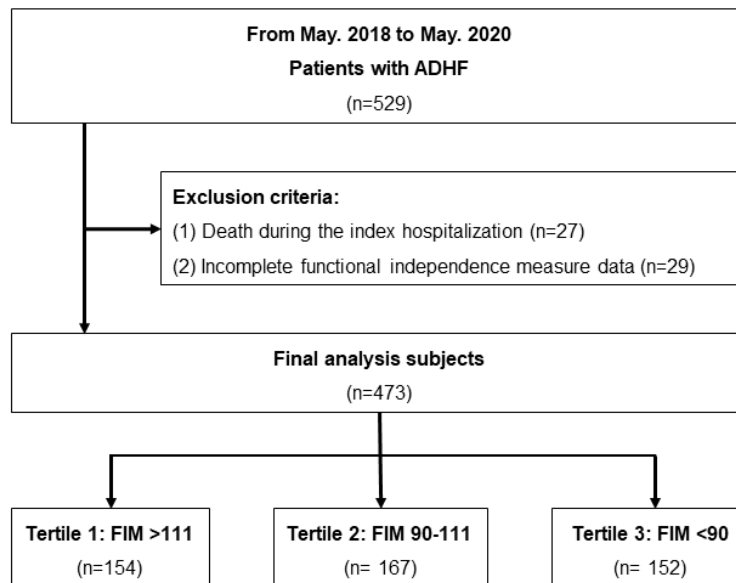


Figure 1. Flowchart of included patients.

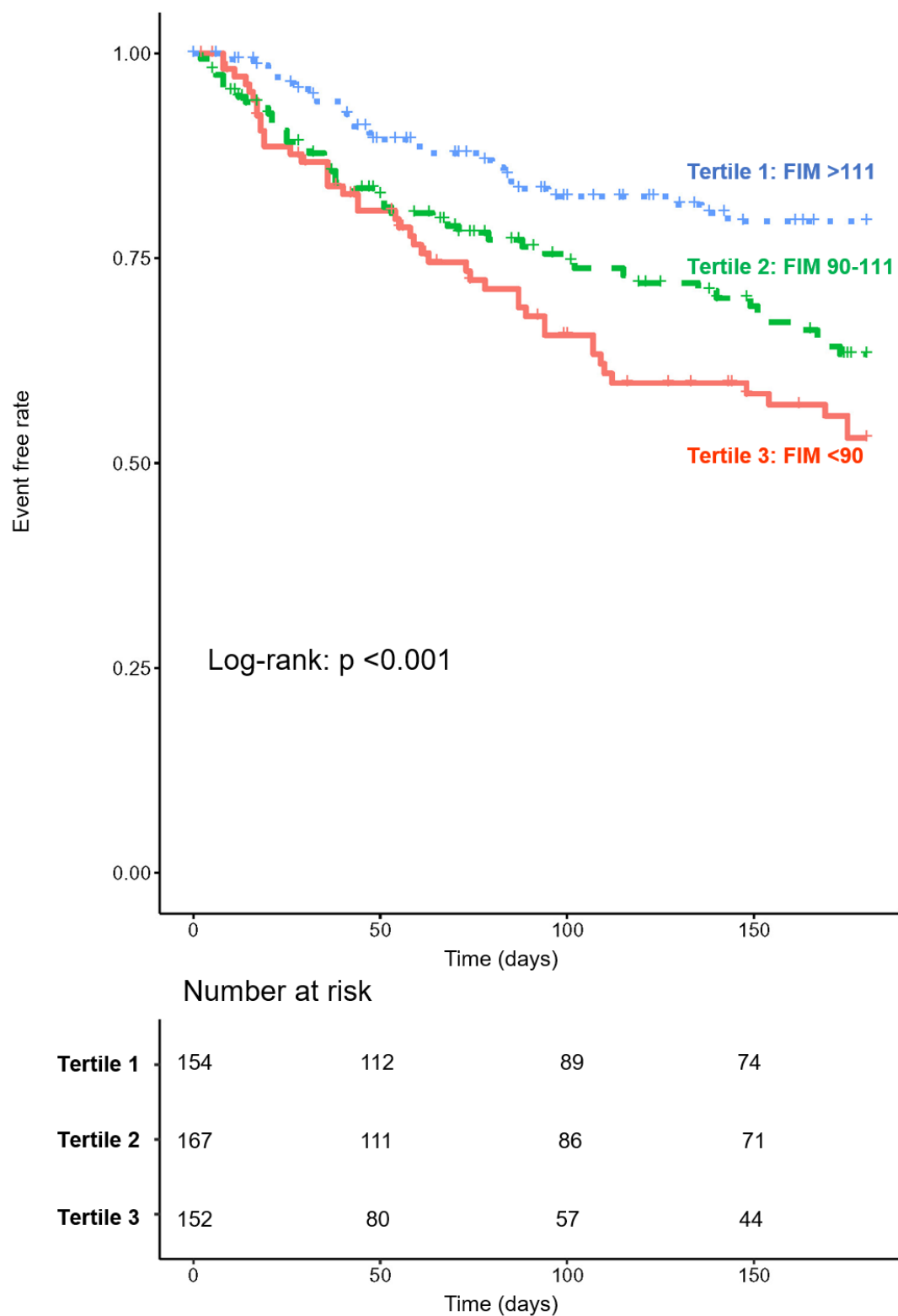


Figure 2. Kaplan–Meier analysis plot for readmission or death stratified by the FIM.