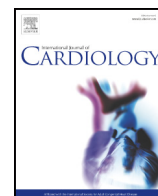




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## Contemporary practice and outcomes of an elderly cohort of Japanese patients with non-ST-elevation acute coronary syndrome in the era of routine early invasive strategy<sup>☆</sup>

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## ABSTRACT

**Background:** An early invasive strategy for patients with non-ST-segment elevation acute coronary syndrome (NSTEMI-ACS) has been recommended. However, patients at greater risk including the elderly are more often managed conservatively. We aimed to elucidate contemporary practice and outcomes of patients with NSTEMI-ACS who were referred to our hospital located in Kitakyushu City, one of the most aging metropolises in Japan.

**Methods:** A total of 270 consecutive NSTEMI-ACS patients hospitalized between January 2012 and December 2014 were retrospectively studied.

**Results:** Median [interquartile range] age was 73 [64, 80] years. Coronary angiography was performed in 264 (98%) patients. Importantly, 75% and 89% underwent angiography within 24 h and 72 h after admission, respectively. Revascularization was done in 124 (79%). The all-cause, in-hospital mortality was 3.7% and was higher in patients aged  $\geq 80$  years (8.5% vs. 2.0% in those aged  $< 80$  years,  $p < 0.0001$ ). No patient developed major bleeding or stroke during hospitalization. Killip class IV at presentation (odds ratio [OR] 8.77, 95% confidence intervals [CI] 1.64–47.6) and left main trunk disease (OR 7.58, 95% CI 1.28–45.5) were independently associated with in-hospital death. These two variables and a high ( $\geq 140$ ) GRACE score were associated with a higher 1-year mortality by Kaplan-Meier survival analysis ( $p < 0.0001$ ).

**Conclusions:** An early invasive strategy was safely done in an elderly cohort of Japanese patients with NSTEMI-ACS. In addition to early invasive approach, a further therapeutic strategy, most probably targeting a shock status, is needed to improve both short- and long-term survival.

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### 1. Introduction

Non-ST-segment-elevation acute coronary syndrome (NSTEMI-ACS) remains a clinical challenge in diagnosis and treatment, even in the era of primary percutaneous coronary intervention [1–3]. The clinical spectrum of NSTEMI-ACS ranges widely among patients, and the mortality in a certain group of NSTEMI-ACS patients is comparable with or even higher than that of ST-elevation myocardial infarction [4]. An early invasive strategy is recommended for patients with NSTEMI-ACS, especially for those at high risk [5–12], and an increasing age is known to be among important predictors of worse outcome. [1–3,11,13] However, coronary angiography is more likely to be done in lower-risk patients and is often withheld in aged subjects [13–16].

Japan is one the most aging countries in the world [17]. Our hospital is located in Kitakyushu City, which is one of the most aging metropolises in Japan and has a population of approximately 972,000, with those aged  $\geq 65$  years comprising 28.5% of the total resident population and those aged  $\geq 75$  years 14.0% [18]. In the present study, we aimed to elucidate clinical backgrounds, contemporary practice and outcomes of patients with NSTEMI-ACS referred to our hospital where an early invasive management was a routine practice for NSTEMI-ACS patients.

### 2. Methods

#### 2.1. Patients

A total of 270 consecutive patients with NSTEMI-ACS presenting to our hospital between January 2012 and December 2014 were retrospectively studied. The diagnosis of NSTEMI-ACS was based on the guidelines on NSTEMI-ACS of American Heart Association/American College Cardiology and European Society of Cardiology [3,19]. Briefly, patients were eligible for inclusion if they presented with unstable angina or myocardial infarction without ST-segment elevation. They must have symptoms consistent with acute myocardial ischemia occurring at rest or lasting for  $> 20$  min and either electrocardiographic changes (new

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or presumed new ST-segment depression or T-wave inversion) or positive myocardial biomarkers (troponin-T).

An early invasive strategy with radial artery catheterization using a 6-French system was our routine practice for patients with acute coronary syndrome. Recommended medication included oral aspirin (162 mg to 325 mg) at emergency room if patients had not been on antiplatelet therapy. Peri-procedural anticoagulation was achieved with an intravenous heparin (a bolus of 3000 U followed by 5000 U when angioplasty was needed), and post-procedural anticoagulation was at the discretion of operators and physicians-in-charge. Clopidogrel or prasugrel was used as antiplatelet agent for those undergoing percutaneous coronary intervention. Glycoprotein IIb/IIIa inhibitors were not available in Japan and were not given to any patient. Coronary artery bypass grafting was considered for patients who had left main trunk disease and/or three-vessel disease; however, multiple factors such as age, coronary anatomy, renal function, hemodynamic status, left ventricular function and patient's preference were taken into consideration for selection of revascularization procedure. Coronary artery bypass grafting was performed by an on-site surgical team.

In-hospital bleeding complications were prospectively registered in all patients using a dedicated formula and was classified according to modified Thrombolysis in Myocardial Infarction trial definitions; a bleeding event was defined as major if it was intracranial or if red blood cell transfusion was clinically indicated in association with a significant drop of hemoglobin [5].

GRACE score was calculated using an updated GRACE 2.0 ACS Risk Calculator [14]. Briefly, age (years), heart rate (beats per minute), systolic blood pressure (mmHg), Killip class, creatinine level (mg/dL), and the presence or absence of cardiac arrest at admission, electrocardiographic ST-segment deviation, or elevated troponin were used for calculation. Patients with a score of  $\geq 140$  were defined as high-risk [19].

## 2.2. Statistical analysis

Data are shown as median [interquartile range (IQR)] for continuous variables, and number (percentage) for categorical data. Student's *t*-test, Mann-Whitney U test, Fischer's exact test, and chi-square test were used, as appropriate. Factors associated with in-hospital mortality were analyzed by multiple logistic regression. Covariates with  $p < 0.20$  on univariate analysis were used. A forward stepwise procedure was subsequently done to identify factors independently associated with mortality. Survival within 1 year was evaluated with Kaplan-Meier analysis and log-rank test. A  $p$ -value  $< 0.05$  was considered statistically significant. Statistical analysis was performed with GraphPad Prism 7 (GraphPad Software, San Diego, US) and IBM SPSS Statistics Version 21 (IBM Japan, Tokyo, Japan).

## 3. Results

### 3.1. Patient characteristics, managements and in-hospital outcomes

Median [IQR] age of the studied 270 patients was 73 [64, 80], indicating that a quarter of the patients were aged 80 years or older (Table 1).

**Table 1**  
Patient clinical characteristics.

	All <i>n</i> = 270	Age < 80 years <i>n</i> = 199	Age $\geq$ 80 years <i>n</i> = 71	<i>p</i> value
Age, years	73 [64, 80]	69 [61, 75]	85 [82, 88]	<0.0001
Male	178 (66%)	143 (72%)	35 (49%)	0.0006
Killip class				0.044
I	217 (80%)	167 (84%)	50 (70%)	
II/III	27 (10%)	17 (9%)	10 (14%)	
IV	26 (10%)	15 (8%)	11 (16%)	
Cardiac arrest	5 (2%)	3 (2%)	2 (3%)	0.6093
Height, cm	160 [153, 166]	162 [156, 168]	153 [146, 159]	<0.0001
Weight, kg	59.0 [51.0, 66.9]	61 [54, 69]	53 [45, 57]	<0.0001
BMI	23.3 [21.2, 25.4]	23.6 [21.3, 25.9]	22.6 [20.6, 24.3]	0.015
SBP, mmHg	137 [121, 158]	139 [122, 160]	133 [117, 156]	0.1233
HR, beats/min	75 [66, 88]	74 [66, 90]	77 [66, 90]	0.2408
SCr, mg/dL	0.92 [0.77, 1.32]	0.90 [0.75, 1.32]	1.03 [0.82, 1.33]	0.1719
DM	131 (49%)	102 (51%)	29 (41%)	0.1665
HT	224 (83%)	163 (82%)	61 (86%)	0.5813
DL	219 (81%)	166 (83%)	53 (75%)	0.1141
Active cancer	7 (3%)	4 (2%)	3 (4%)	0.3841
Prior MI	59 (22%)	40 (20%)	19 (27%)	0.2462
Prior PCI	83 (31%)	57 (29%)	26 (37%)	0.2321
Prior CABG	27 (10%)	18 (9%)	9 (13%)	0.3663
ST deviation	133 (49%)	93 (47%)	40 (56%)	0.1702
Troponin	117 (43%)	82 (41%)	35 (49%)	0.2655

Data are shown as median [interquartile range] or number (percentage) of patients. Abbreviations: BMI, body mass index; CABG, coronary artery bypass grafting; DL, dyslipidemia; DM, diabetes mellitus; HR, heart rate; HT, hypertension; MI, myocardial infarction; PCI, percutaneous coronary intervention; SBP, systolic blood pressure; SCr, serum creatinine.

Twenty-seven (10%) patients had a heart failure (Killip class II or III) and 26 (10%) were in shock at presentation (Killip class IV). ST-segment deviation was present in 49% and cardiac troponin was positive in 43%.

Coronary angiography was performed in 264 (98%) patients. The reasons for unperformed angiography included brain death ( $n = 2$ ), refusal ( $n = 2$ ), concomitant sepsis ( $n = 1$ ). One patient had undergone angiography before admission and was transferred to us for coronary artery bypass surgery. Importantly, 75% and 89% underwent angiography within 24 h and 72 h after admission, respectively (Table 2). Three-vessel disease, left main trunk disease, or both were seen in 36%. Thirty-two patients (12%) were found to have non-obstructive (<50% diameter stenosis) epicardial coronary artery disease, and 29 patients (91%) of these patients underwent spasm provocation testing during the past or index hospitalization, with a positive result in 28 patients (97% of spasm provocation). Revascularization was achieved in 79% of the studied patients either by percutaneous coronary intervention (66%) or surgical bypass grafting (14%). The most common reason for unperformed revascularization ( $n = 56$ ) was non-obstructive coronary artery disease ( $n = 32$ ) followed by small target vessels that were inappropriate for intervention ( $n = 14$ ).

In-hospital complications occurred in 16 (5.9%) patients, and all of them were non-critical bleeding. No patient developed major bleeding or stroke. Ten patients died during hospitalization (in-hospital mortality 3.7%). Direct causes of death were ischemic encephalopathy (brain damage) in 2 patients and pump failure in 8 patients. Out of the latter 8 patients, 5 patients had a prior history of myocardial infarction and had a decreased left ventricular ejection fraction already before admission (0.23 to 0.45), 2 patients had a concomitant severe valvular heart disease (aortic stenosis and mitral regurgitation), and one patient had an intractable heart failure most likely due to an extensive three-vessel disease. Mean peak concentrations of creatine kinase in the 7 non-survivors (except for 3 patients having cardiac arrest at presentation) were 545 IU/L, which was not significantly different from that of 260 survivors (442 IU/L).

Clinical characteristics, managements and outcomes of patients aged  $\geq 80$  years and  $< 80$  years are shown in Tables 1 and 2. Octogenarians were more likely women and had worse Killip class. The overall rate of coronary angiography was 99% and 94% in patients aged  $< 80$  years and aged  $\geq 80$  years, respectively ( $p = 0.023$ ), and non-obstructive coronary artery disease was more common in younger patients (15% vs. 4%,  $p = 0.019$ ). In-hospital mortality was higher in very elderly patients (8.5% vs. 2.0%,  $p < 0.0001$ ).

### 3.2. Hospital survivors vs. non-survivors

Table 3 summarizes clinical variables between hospital survivors and non-survivors. Non-survivors were more elderly and had higher prevalence of Killip class IV (shock), cardiac arrest, positive troponin and left main trunk disease, lower body mass index, lower systolic blood pressure, higher heart rate, higher GRACE score and higher rate of unperformed coronary angiography. Serum creatinine concentrations were marginally ( $p = 0.13$ ) higher in non-survivors. These variables except GRACE score were used for multivariate analysis; GRACE score had significant correlations to variables such as age ( $p < 0.0001$ ) and Killip class ( $p < 0.0001$ ) and was not included in the analysis. On multivariate analysis Killip class IV (odds ratio [OR] 8.77, 95% confidence intervals [CI] 1.64–47.6) and left main trunk disease (OR 7.58, 95% CI 1.28–45.5) remained to be independently associated with in-hospital death.

### 3.3. Discharge medications

Aspirin, angiotensin converting enzyme inhibitors or angiotensin receptor blockers, beta-blockers and statin were prescribed in 93%, 68%, 59% and 89% of hospital survivors, respectively. Kaplan-Meier survival

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