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Original article

Impact of the preprocedural nutrition status on the clinical outcomes of patients after pacemaker implantation for bradycardia

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ABSTRACT

Background: Malnutrition is associated with a poor prognosis in heart failure, angina pectoris, and peripheral artery disease. However, the clinical importance of the preprocedural nutrition status of patients requiring pacemaker implantation (PMI) for bradycardia is unclear.

Methods: We retrospectively enrolled 521 patients (median 79 years) who underwent their first PMI between January 1, 2012 and June 30, 2017. The nutrition status before implantation was assessed by the geriatric nutritional risk index (GNRI). The association between the preprocedural GNRI-based nutritional status and all-cause mortality was investigated.

Results: GNRI-based high (GNRI <82) and moderate (GNRI 82 to <92) malnutrition status were found in 9.2% and 34.0%, respectively. During a median follow-up of 1178 days, 71 patients died. The mortality rate, which was analyzed using survival curves, was significantly stratified by the GNRI-based malnutrition status [high: 52.0% (25/48), moderate: 16.9% (30/177), low: 5.4% (16/296), $p < 0.001$). On a multivariate Cox-proportional hazard analysis, GNRI-based high malnutrition status independently predicted all-cause death (hazard ratio: 4.49, 95% confidence interval: 2.59–7.80, $p < 0.001$). A sensitivity analysis based on the controlling nutritional status score showed consistent results. On a receiver operating characteristic curve analysis, GNRI had a high predictive value for all-cause mortality (area under the curve, 0.78, 95% confidence interval: 0.72–0.84, $p < 0.001$).

Conclusions: Preprocedural malnutrition was significantly associated with poor outcomes of patients who underwent PMI. Assessing the nutritional status in advance is important for risk stratification, and improving the nutritional status may be an option for managing these patients.

Introduction

Malnutrition is reported to be associated with a poor prognosis in various cardiovascular diseases, such as heart failure [1,2], angina pectoris [3], and peripheral artery disease [4]. The geriatric nutritional risk index (GNRI) is a simple and established method for evaluating the objective nutritional status and is easily calculated from the serum albumin and body weight [5]. GNRI-based malnutrition is shown to be associated with a poor prognosis for patients on hemodialysis [6] and those with acute and chronic heart failure [7–9], angina pectoris [3], and peripheral artery disease [4].

Recently, the number of patients who require pacemaker implantation (PMI) for bradycardia has been increasing, mainly because of the aging of society [10]. In addition, recipients have become older and complicated with many comorbidities [11,12]. Malnutrition is reported to be found more frequently in elderly people than in younger ones [5]. However, the clinical importance of the preprocedural nutrition status of the patients requiring PMI is poorly understood.

The present study aimed to assess the association between the preprocedural GNRI-based nutritional status and all-cause mortality in patients requiring their first PMI.

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Materials and methods

Study population

We retrospectively enrolled 521 patients (median 79 years, 50.1% male) who underwent their first PMI for bradycardia intravenously between January 1, 2012 and June 30, 2017. Patients who underwent cardiac resynchronization therapy were not included in this study. We first identified 532 consecutive patients who received PMI for bradycardia during this period for chronic pacing according to the guidelines of the Japanese Circulation Society [13]. We excluded patients for whom we could not calculate the nutrition score ($n = 8$) and who did not attend even the first follow-up outpatient appointment and were lost to follow-up ($n = 3$; two patients transferred to another city and one was followed up by another hospital). After exclusion, we ultimately enrolled 521 eligible patients (Fig. 1).

We divided these patients into three groups according to the GNRI-based malnutrition status as described in a previous report [5]: high for a GNRI <82, moderate for a GNRI 82 to <92, low for a GNRI ≥92. Baseline characteristics and clinical outcomes were compared among these three groups.

Data collection

The following demographic and clinical data were obtained from medical records: age, gender, height, weight, laboratory data on admission, concomitant diseases such as hypertension, diabetes mellitus, history of myocardial infarction, chronic kidney disease (CKD), active malignancy, and the indication for PMI (atrio-ventricular conduction disturbance, sick sinus syndrome, and atrial fibrillation with bradycardia). As previously demonstrated, the preprocedural GNRI was calculated using the following formula: GNRI = 14.89 × serum albumin (g/dL) + 41.7 × body mass index (BMI)/22 [5,8]. The estimated glomerular filtration rate (eGFR) was calculated using the following formula: eGFR = 194 × Cr − 1.094 × age − 0.287 (×0.739 in women) [14]. CKD was defined as an eGFR <60 ml/min/1.73 m^2.

The pacing mode was determined as follows in our facility: (1) DDD pacing for atrio-ventricular conduction disturbance or sick sinus syndrome, (2) VVI pacing for persistent atrial fibrillation, and (3) VVI or VDD pacing for patients with specific reasons, such as implantation in elderly patients to shorten the procedure time. Primary position of the leads was right ventricular apex in our facility. After the procedures, patients were followed up in the outpatient clinic 1 week after implantation to check the wounds, 3 months for a second visit, and then every 12 months to evaluate the functional status of the device.

Acute procedural complications were defined as the composite of local device-related infection, device-related hematoma, lead displacement, and device-related pneumothorax within 30 days after the procedure.

Cause of death was classified as cardiac, malignancy, infection, and others. Cardiac death was defined as death from heart failure, myocardial infarction, or ventricular arrhythmia. Any death that did not have a clear cardiac cause or that was due to cancer or infection was defined as non-cardiac death. Acute procedural complications and the cause and time of death were obtained from hospital records or a telephone interview with the family of the deceased. Patients who were lost to follow-up after the first follow-up outpatient visit were censored at the date of last contact/follow-up. Patients who were alive on August 31, 2018, were censored for the overall survival analysis.

Ethical considerations

This research plan was designed by the authors and approved by the Institutional Review Board of the Japanese Red Cross Musashino Hospital (approval number: 30037). The requirement for informed consent was waived because the data were anonymized. The information disclosure document of this study has been published on the hospital website. Our study complies with the Declaration of Helsinki and Japanese Ethical Guideline for Medical and Health Research involving Human Subjects.

Statistical analyses

Data are expressed as the mean and standard deviation for normally distributed variables, and as the median with the interquartile range (IQR) for non-normally distributed data. Continuous variables were compared by an analysis of variance or the Kruskal–Wallis test as appropriate. Categorical data are expressed as numbers and percentages and were compared by Fisher's exact test. The mortality rate was analyzed by the Kaplan–

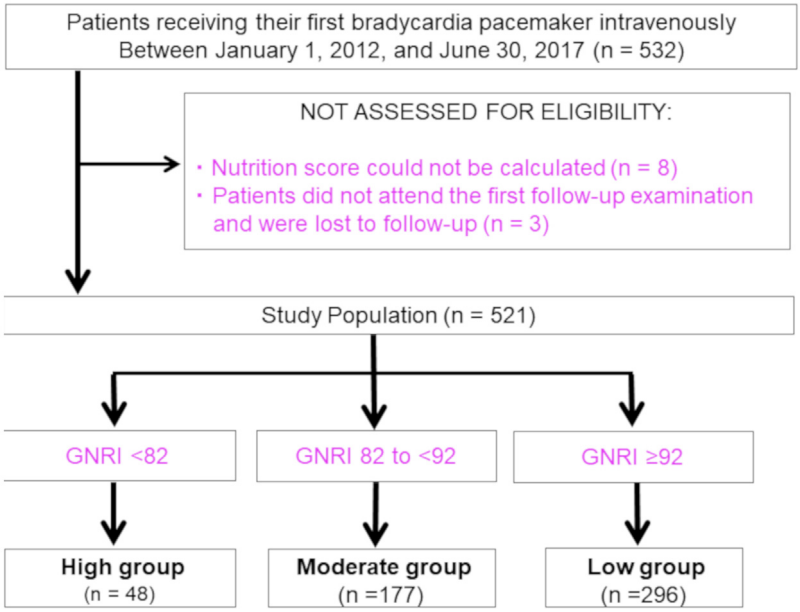

Fig. 1. Study flow chart. GNRI, geriatric nutritional risk index.

Table 1
Baseline characteristics of this study.

Variables	GNRI-based malnutrition			*p*-Value
	High risk	Moderate risk	Low risk	
Number	48	177	296	
Age (years)	84.0 [78.8, 88.3]	82.0 [73.0, 86.0]	77.0 [69.0, 82.0]	<0.001
Male (%)	25 (52.1)	81 (45.8)	159 (53.7)	0.24
Height (cm)	154.0 [147.5, 160.9]	155.6 [149.5, 162.7]	157.7 [151.4, 165.0]	0.060
Body weight (kg)	44.3 [36.8, 48.3]	48.5 [43.2, 54.9]	59.0 [51.0, 65.9]	<0.001
Body mass index (kg/m^2)	17.9 [15.6, 20.0]	20.1 [18.7, 22.0]	23.6 [21.7, 26.1]	<0.001
Comorbidities				
Hypertension (%)	18 (37.5)	66 (37.3)	71 (24.0)	0.004
Diabetes mellitus (%)	7 (14.6)	27 (15.3)	43 (14.5)	0.98
Myocardial infarction (%)	4 (8.3)	3 (1.7)	3 (1.0)	0.003
Chronic kidney disease (%)	36 (75.0)	114 (64.4)	150 (50.7)	0.001
Malignancy (%)	10 (20.8)	6 (3.4)	16 (5.4)	<0.001
Indication and procedure				
Af with bradycardia (%)	11 (22.9)	39 (22.0)	74 (25.0)	0.76
Sick sinus syndrome (%)	12 (25.0)	60 (33.9)	110 (37.2)	0.092
Atrio-ventricular block (%)	25 (52.1)	78 (44.1)	112 (37.8)	0.12
VVI pacing (%)	14 (29.2)	42 (23.7)	80 (27.0)	0.64
Laboratory data				
Serum albumin (g/dl)	2.9 [2.7, 3.3]	3.5 [3.4, 3.8]	4.1 [3.9, 4.4]	<0.001
eGFR (ml/min/1.73 m^2)	42.1 [26.4, 57.2]	54.5 [39.0, 65.6]	59.8 [44.9, 72.9]	<0.001
Brain natriuretic peptide (pg/ml)	219.7 [130.6, 525.5]	182.1 [61.8, 454.7]	89.6 [33.5, 215.9]	<0.001
Hemoglobin (g/dl)	10.6 [9.5, 11.5]	11.9 [10.9, 13.0]	13.4 [12.3, 14.3]	<0.001
Total cholesterol (g/dl)	169.0 [142.0, 189.0]	171.0 [150.0, 194.0]	185.0 [165.0, 206.3]	<0.001
Total protein (g/dl)	6.2 [5.5, 6.5]	6.6 [6.1, 7.0]	7.0 [6.8, 7.4]	<0.001
White blood cell count ($10^3\ \mu l^{-1}$)	59.5 [46.3, 74.5]	58.0 [48.0, 74.0]	59.0 [49.0, 74.3]	0.55
Lymphocyte count (μl^{-1})	945.5 [240.0, 2484.0]	1152.0 [312.0, 4278.0]	1297.9 [234.0, 5941.4]	<0.001
C reactive protein (mg/dl)	1.1 [0.5, 3.3]	0.2 [0.06, 0.8]	0.1 [0.04, 0.4]	<0.001
Nutrition score				
GNRI	79.9 [73.4, 81.8]	92.3 [88.8, 95.3]	105.1 [101.2, 109.9]	<0.001
CONUT score	6 [5, 7]	3 [2, 4]	2 [1, 3]	<0.001

Categorical variables are expressed as numbers (%), and continuous variables are expressed as the mean ± standard deviations or median and interquartile range [IQR].
Af, atrial fibrillation; eGFR, estimated glomerular filtration rate; GNRI, geriatric nutritional risk index; CONUT, controlling nutritional status.

Meier method, and the differences in the survival curves were evaluated with a log-rank test. A Cox proportional hazard model analysis was performed to calculate hazard ratios (HRs) and 95% confidence intervals (CIs) for the association between the GNRI-based malnutrition status and all-cause mortality, adjusted for the age, gender, history of myocardial infarction and diabetes mellitus, eGFR, brain natriuretic peptide (BNP), pacing mode, and malignancy. The selection of variables for the multivariate analysis was based on previous reports [11,12,15–18] and clinical importance. Spearman's rank correlation test was performed to investigate the multi-collinearity of the selected variables. For the sensitivity analysis, we analyzed the association between the malnutrition status and mortality by the controlling nutritional status (CONUT) score [4,19], which reflects the protein reserve depletion, caloric depletion, and impaired immune defenses, to confirm the consistency of the results. A receiver operating characteristic (ROC) curve analysis was performed to evaluate and compare the sensitivity and specificity of the GNRI and CONUT score for all-cause mortality. In addition, we performed an ROC curve analysis comparing the simple BMI and GNRI. Moreover, we calculated the net reclassification index (NRI) and integrated discrimination index (IDI) to compare the quality of improvement for correct reclassification. All statistical analyses were performed using the R software program, version 3.2.4 (R Foundation for Statistical Computing, Vienna, Austria; ISBN 3-900051-07-0, http://www.R-project.org). A two-sided *p*-value <0.05 was considered statistically significant.

Results

Patients' characteristics

As shown in Table 1, 48 (9.2%), 177 (34.0%), and 296 patients had a high, moderate, and low risk of GNR-based malnutrition, respectively. The median age, prevalence of CKD, prevalence of malignancy, BNP, and C-reactive protein levels were significantly higher in the high group than in the other groups. There were no significant differences in the indication for PMI or the proportion of single-chamber lead among these groups.

Acute procedural complications

There were no procedure-related in-hospital deaths in this study. Although acute procedural complications occurred in 10.4% of the patients in the high group, there were no significant differences in the incidence or types of acute complications among the three groups (Table 2). In contrast, the length of hospitalization was significantly longer in the high group.

Long-term clinical outcomes

During a median follow-up of 1178 days, 71 patients (13.6%) died; 45 of these deaths were attributed to non-cardiac causes (63.4%) (Table 2). There were no marked differences in the cause of death among the three groups. All-cause mortality assessed by the survival curve was significantly stratified by the GNRI-based malnutrition status [high: 52.0% (25/48), moderate: 16.9% (30/177), low: 5.4% (16/296), log-rank $p < 0.001$) (Fig. 2). Table 3 shows the results of the multivariate Cox-proportional hazard analysis. No significant correlations were found between the GNRI and malignancy or the CONUT score and malignancy (correlation coefficient <0.10 in both groups). A GNRI-based high malnutrition status was significantly associated with a higher mortality even after adjusting for covariates (HR: 4.49, 95% CI: 2.59–7.80, $p < 0.001$). The GNRI-based malnutrition grade showed an approximately 2.7-fold increase in all-cause mortality per 1-grade increase (HR: 2.69, 95% CI: 1.89–3.81, $p < 0.001$). An older age,

Table 2
Clinical outcomes of each group.

	High risk N = 48	Moderate risk N = 177	Low risk N = 296	p-Value
Acute outcomes				
Procedure-related in-hospital deaths	0 (0.0)	0 (0.0)	0 (0.0)	1.0
Acute procedural complications	5 (10.4)	9 (5.1)	13 (4.4)	0.22
Types of device-related complications				
Infection	2 (4.2)	1 (0.6)	2 (0.7)	0.057
Hematoma	2 (4.2)	5 (2.8)	5 (1.7)	0.48
Lead displacement	0 (0.0)	1 (0.6)	2 (0.7)	0.85
Pneumothorax	1 (2.1)	2 (1.1)	4 (1.4)	0.88
Length of hospitalization (days)	8 [5, 14]	6 [4, 9]	5 [4, 6]	<0.001
Long-term outcomes				
All-cause death	25 (52.0)	30 (16.9)	16 (5.4)	<0.001
Cause of death	N = 25	N = 30	N = 16	
Cardiac	8 (32.0)	11 (36.7)	7 (43.8)	0.76
Malignancy	6 (24.0)	6 (20.0)	3 (18.8)	0.91
Infection	7 (28.0)	7 (23.3)	3 (18.8)	0.80
Others	4 (16.0)	6 (20.0)	3 (18.8)	0.93

Categorical variables are expressed as numbers (%), and continuous variables are expressed as median and interquartile range.
Cardiac death was defined as death from heart failure, myocardial infarction, or ventricular arrhythmia.
Others included any death that did not have a clear cardiac cause, that due to cancer, and that due to infection.

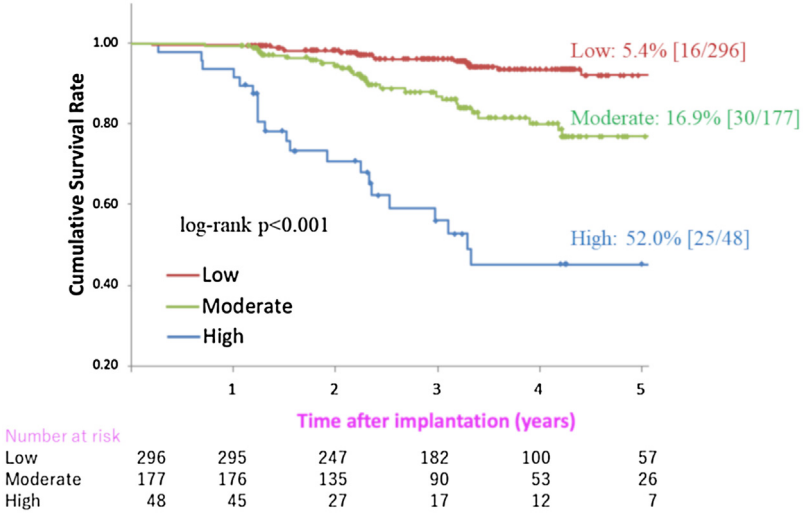

Fig. 2. The all-cause mortality of three groups stratified by GNRI-based malnutrition. The survival curve was significantly stratified by the GNRI-based malnutrition status. GNRI-based malnutrition status was defined as (high: GNRI <82, moderate: GNRI 82 to <92, low: GNRI ≥92). GNRI, geriatric nutritional risk index.

Table 3
Univariate and multivariate logistic regression analyses for all-cause death.

Variables	Univariate		Multivariate	
	Hazard ratio (95% CI)	p-Value	Hazard ratio (95% CI)	p-Value
Age	1.09 (1.06–1.12)	<0.001	1.07 (1.04–1.10)	<0.001
Male sex	1.09 (0.68–1.74)	0.72	1.25 (0.76–2.03)	0.38
Myocardial infarction	1.75 (0.43–7.17)	0.44	1.09 (0.26–4.62)	0.91
eGFR	0.97 (0.96–0.98)	<0.001	0.99 (0.97–0.99)	0.046
BNP (increase by 10)	1.01 (1.00–1.01)	<0.001	1.01 (1.00–1.01)	<0.001
Single chamber atrio-ventricular dyssynchronous pacing	0.84 (0.49–1.45)	0.53	0.90 (0.50–1.60)	0.71
Malignancy	3.55 (1.75–7.20)	<0.001	3.22 (1.53–6.78)	0.002
GNRI-based high malnutrition status	7.06 (4.33–11.51)	<0.001	4.49 (2.59–7.80)	<0.001

CI, confidence interval; BNP, brain natriuretic peptide; GNRI, geriatric nutritional risk index; eGFR, estimated glomerular filtration rate.
A GNRI-based high malnutrition status was defined as GNRI <82.

increased BNP, lower eGFR, and malignancy were statistically significant as independent predictors of all-cause death. A sensitivity analysis based on the CONUT score showed consistent results (every 1-point increase in the CONUT score: HR, 1.44; 95% CI, 1.28–1.63, $p < 0.001$) (Table 4). On an ROC curve analysis, both the GNRI and CONUT score had a high predictive value for all-cause mortality [GNRI: area under the curve (AUC), 0.78, 95% CI, 0.72–0.84, $p < 0.001$, with the optimal cut-off value of 91.3, the sensitivity and specificity were 0.65 and 0.83, respectively; CONUT score: AUC, 0.75, 95% CI, 0.68–0.82, $p < 0.001$, with the optimal cut-off of 4, the sensitivity and specificity were 0.69 and 0.78, respectively] (Fig. 3A). There were no marked differences in the predictive value between the GNRI and CONUT score ($p = 0.41$). Additionally, there were no differences in NRI and IDI of the GNRI

Table 4
Univariate and multivariate logistic regression analyses for all-cause death.

Variables	Univariate		Multivariate	
	Hazard ratio (95% CI)	*p*-Value	Hazard ratio (95% CI)	*p*-Value
Age	1.09 (1.06–1.12)	<0.001	1.08 (1.05–1.11)	<0.001
Male sex	1.09 (0.68–1.74)	0.72	1.45 (0.88–2.39)	0.14
Myocardial infarction	1.75 (0.43–7.17)	0.44	0.85 (0.20–3.65)	0.83
eGFR	0.97 (0.96–0.98)	<0.001	0.99 (0.98–1.00)	0.077
BNP (increase by 10)	1.01 (1.00–1.01)	<0.001	1.004 (1.001–1.006)	0.002
Single chamber atrio-ventricular dyssynchronous pacing	0.84 (0.49–1.45)	0.53	0.85 (0.48–1.51)	0.58
Malignancy	3.55 (1.75–7.20)	<0.001	3.11 (1.45–6.67)	0.004
CONUT score	1.50 (1.36–1.65)	<0.001	1.44 (1.28–1.63)	<0.001

CI, confidence interval; BNP, brain natriuretic peptide; CONUT, controlling nutritional status; eGFR, estimated glomerular filtration rate.

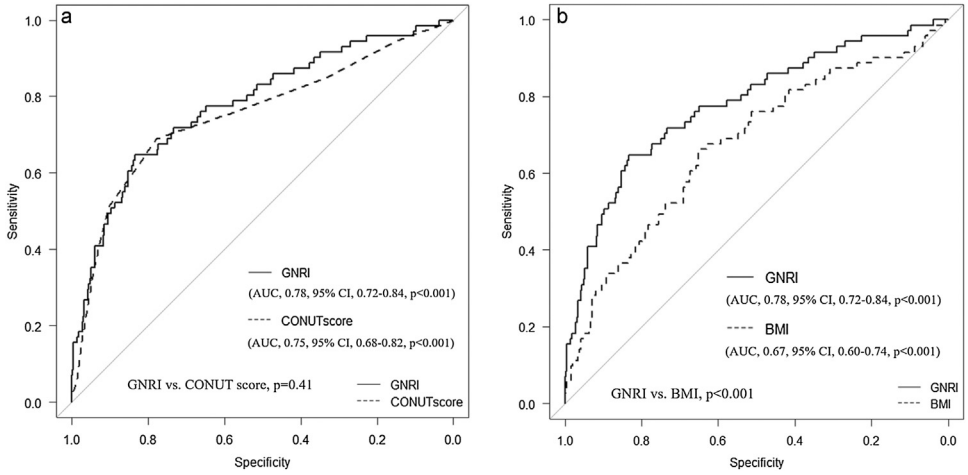

Fig. 3. (A) A receiver operating characteristic curve analysis comparing the GNRI and CONUT score. Both the GNRI and CONUT score had a high predictive value for all-cause mortality. There were no marked differences in the predictive value between the GNRI and CONUT score ($p = 0.41$). (B) A receiver operating characteristic curve analysis comparing the GNRI and BMI. Both the GNRI and BMI had a high predictive value for all-cause mortality. However, the predictive value was significantly higher for the GNRI than the BMI ($p < 0.001$). GNRI, geriatric nutritional risk index; CONUT, controlling nutritional status; AUC, area under the curve; CI, confidence interval; BMI, body mass index.

compared with CONUT score (NRI, 0.13, 95% CI, −0.12 to 0.38, $p = 0.31$; IDI, 0.031, 95% CI, −0.007 to 0.069, $p = 0.11$). Although the BMI can predict all-cause mortality (AUC: 0.67, 95% CI: 0.60–0.74, $p < 0.001$, with the optimal cut-off of 21.0, the sensitivity and specificity were 0.66 and 0.65, respectively), the predictive value was significantly higher for the GNRI than the BMI (AUC 0.78 vs. 0.67, $p < 0.001$; NRI, 0.82, 95% CI, 0.59–1.06, $p < 0.001$; IDI, 0.12, 95% CI, 0.085–0.16, $p < 0.001$) (Fig. 3B).

Discussion

To our knowledge, this is the first study to assess the relationship between the preprocedural nutritional status and the outcomes of patients who have undergone PMI. The main finding was that preprocedural malnutrition was significantly associated with poor mortality, even after adjusting for covariates.

Previous studies have shown that classical cardiac risk factors, such as age, renal dysfunction, male gender, a history of coronary artery disease, heart failure, and diabetes, are predictors for mortality after PMI [11,12,15–18]. However, the incidence of cardiac death in previous studies was not very high (35.4% [16] and 33% [18]). The incidence of cardiac death was similarly small in our study (36.6%). These results suggest that patients who undergo PMI mainly die of non-cardiac causes, which reflects the large number of comorbidities common in elderly patients and the difficulty in improving the mortality rates associated with intervention for the heart. This may also explain why atrio-ventricular dyssynchronous pacing and the left ventricular function were not associated with the all-cause mortality of patients receiving PMI [20,21]. Indeed, VVI pacing was not an independent predictor for all-cause mortality in our study. Moreover, although not statistically significant, the incidence of cardiac death was smaller and that of non-cardiac death (infection and malignancy) was higher in the malnutrition group (Table 2). Therefore, another approach is necessary in order to improve the outcomes of these patients.

Previous studies have shown that, in addition to classic cardiac risk factors, a low BMI at implantation was a strong predictor for the all-cause mortality of patients receiving PMI [15,19]. A low BMI in elderly patients usually suggests malnutrition and is directly related to a low GNRI. Similarly, in this study, the BMI was able to predict the all-cause mortality. However, the predictive value for the all-cause mortality was significantly higher for the GNRI than for the BMI, even though the GNRI is calculated by the simple addition of the serum albumin level and the BMI. Although the acute procedural complication rates did not differ to a statistically significant extent among three groups, the survival curve was significantly stratified by the GNRI-based malnutrition status, and the predictive value of the GNRI was relatively high (AUC 0.78). For these reasons, the preprocedural assessment of the nutritious status by the GNRI is useful and effective for stratifying the mortality risk.

Oral nutritional supplementation has been shown to improve not only the nutritional status, length of stay, episode cost, and the rate of 30-day readmission [22], but also to reduce mortality [23,24] and complications [23] in undernourished elderly patients. However, several studies [25,26] failed to show a statistically significant improvement in mortality. Further studies are needed to ascertain the impact of improving the nutritional status on mortality.

Malignancy was another important predictor for all-cause death in the present study. The latest (2017) demographic statistics published by the Japanese Ministry of Health, Labor and Welfare showed that the primary cause of death in Japan was malignancy (27.9%) followed by cardiac diseases (15.3%) [27]. However, few studies have assessed the clinical importance of concomitant malignancy on the mortality of patients receiving PMI. In addition, malnutrition is closely related to advanced cancer and was reported to be a strong predictor for a poor prognosis in patients with various cancers [19,28–30]. In fact, the prevalence of active malignancy in the patients with high GNRI-based malnutrition status was high (20.8%) in this study. Therefore, we may also have to assess the possibility of coexisting cancer before performing the procedure, especially for elderly patients with malnutrition (i.e. GNRI <82).

Study limitations

This study has several limitations to be considered. First, the retrospective, single-center, observational nature of the study may have affected the results because of confounding factors. Selection bias could not be avoided because patients who were severely fragile could not undergo PMI in the real-world setting. However, because the nutritional status and prognosis of these severely fragile patients are likely to be poor, the result of this study is thought to be consistent. Second, we lacked data concerning medications, the pacing rate, other comorbidities (e.g. connective tissue diseases), the concise status of cancer treatment, trends in the nutritional status after implantation, and frailty status which may have affected the outcome. Third, the follow-up period [median follow-up of 1178 days (39 months)] was relatively short. Finally, the small sample size (n = 521) of this study may be another possible limitation. The prevalence of acute procedural complications might differ in a larger-scale analysis.

Conclusions

Preprocedural malnutrition was significantly associated with poor outcomes of patients who underwent PMI. Assessing the nutritional status before the procedure is important for risk stratification and improving the nutritional status may be another option for managing these patients.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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