Circulation Reports
Circ Rep 2023; 5: 442–449
doi:10.1253/circrep.CR-23-0055

ORIGINAL ARTICLE
Nutrition

Preprocedural Controlling Nutritional Status Score as a Predictor of Mortality in Patients Undergoing Transcatheter Mitral Valve Repair

— A Single Center Experience in Japan —

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Background: A high score for controlling nutritional status (CONUT) due to poor nutritional status has been associated with adverse outcomes in patients with chronic heart failure. However, because little is known about the effect of CONUT score on mortality rates after transcatheter mitral valve repair, we evaluated nutrition screening tools for prognosis prediction in patients undergoing transcatheter mitral valve repair using the MitraClip™ system.

Methods and Results: We retrospectively analyzed 148 patients with severe mitral regurgitation (MR) who underwent MitraClip™ implantation between April 2018 and April 2021. The preprocedural CONUT scores were assessed at the time of hospitalization, the primary outcome was all-cause death, and the analysis was of the mortality and incidence rates of cardiac events 1 year post-operation. Functional MR was of ischemic origin in the majority of patients (69.6%), with a mean left ventricular ejection fraction of 48.9±15.8%. Kaplan-Meier curves indicated that all-cause death was significantly worse in the high-CONUT score group than in the low-CONUT score group. Cox hazard analysis showed a significant association between all-cause death and CONUT score, as well as MitraScore.

Conclusions: Preprocedural CONUT score, as well as MitraScore, in patients undergoing transcatheter edge-to-edge mitral valve repair may predict an increased risk of all-cause death. This knowledge should allow the heart team to accurately assess the clinical implications and prognostic benefits of the procedure in individual patients.

Key Words: Controlling nutritional status (CONUT); Death; Transcatheter mitral valve repair

Transcatheter edge-to-edge mitral valve repair (TEER) with the MitraClip™ (Abbott Vascular, Santa Clara, CA, USA) System (Abbott Vascular) has become the first-line interventional treatment for patients with severe functional mitral regurgitation (MR) after optimal medical therapy,[1–6] and MitraScore,[7–9] as a prediction tool for death in patients undergoing TEER, was recently reported as opposed to the EuroSCORE II and Society of Thoracic Surgeons score. Despite recent developments in medical and surgical therapy for patients with heart failure (HF), mortality rates remain high, and could be related to altered intestinal function caused by malnutrition in HF patients,[10,11] which is considered a source of inflammation.[12–14] The controlling nutritional status (CONUT) score is a risk evaluation tool for assessing nutritional status,[15–18] and a high CONUT score is associated with adverse outcomes in patients with chronic HF.[18,19] However, for patients in whom the MitraClip yields mechanical improvement of MR, little is known about the association between nutritional status and death.

Received May 28, 2023; revised manuscript received October 7, 2023; accepted October 12, 2023; J-STAGE Advance Publication released online November 2, 2023 Time for primary review: 40 days

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ISSN-2434-0790

Table 1. Baseline Patient Characteristics

Characteristic	Overall (n=148)	CONUT <4 (n=97)	CONUT ≥5 (n=51)	P value
Age, years	78.0±8.6	76.5±8.7	80.8±8.2	<0.01
Male	93 (62.8)	56 (57.7)	37 (72.6)	0.07
BMI, kg/m^2	21.7±4.0	22.2±4.4	20.9±3.0	0.04
Congestive HF within 1 year	96 (65)	54 (56)	42 (82)	<0.01
NYHA class III/IV	117 (79)	73 (75)	44 (86)	0.14
Diabetes	50 (33.8)	29 (29.9)	21 (41.2)	0.18
Systolic blood pressure	157.9±10.7	157.3±11.4	159.1±9.2	0.35
Hypertension	110 (74.3)	72 (74.2)	38 (74.5)	0.97
Dyslipidemia	78 (52.7)	51 (52.6)	27 (52.9)	0.97
Liver cirrhosis	2 (1.4)	1 (1.0)	1 (2.0)	0.68
COPD	16 (10.8)	12 (12.4)	4 (7.8)	0.40
Prior stroke	13 (8.9)	8 (8.4)	5 (9.8)	0.78
CKD	113 (77.4)	70 (72.9)	43 (86)	0.05
CAD	39 (26.7)	26 (27.1)	13 (26)	0.89
Cardiac valve replacement	3 (2.0)	3 (3.1)	0 (0)	0.08
Other chest surgery	8 (5.4)	6 (6.2)	2 (3.9)	0.57
β-blocker	118 (79.7)	79 (81.4)	39 (76.5)	0.48
ACEi or ARB	99 (66.9)	65 (67.0)	34 (66.7)	0.96
Loop diuretic	117 (79.1)	74 (76.3)	43 (84.3)	0.26
Tolvaptan diuretic	54 (36.5)	26 (26.8)	28 (54.9)	<0.01
Antiplatelet	70 (47.3)	48 (49.5)	22 (43.1)	0.47
Anticoagulant	95 (64.2)	63 (64.9)	32 (62.7)	0.79
Prior CABG	14 (9.5)	12 (12.4)	2 (3.9)	0.05
Prior PCI	40 (27.0)	25 (25.8)	15 (29.4)	0.63
Cardiac rhythm device implantation	29 (19.6)	19 (19.6)	10 (19.6)	0.99
LVDd	56.4±10.9	56.3±11.8	56.3±9.01	0.98
LVDs	43.5±13.9	43.2±15.1	43.9±11.5	0.76
LVEDV	140.3±66.5	139.3±72.4	142.1±54.1	0.79
LVESV	78.0±58.4	77.1±64.7	79.9±45.0	0.76
LAVI	78.3±37.7	74.2±32.0	85.9±46.0	0.07
Af	97 (65.5)	59 (60.8)	38 (74.5)	0.09
Functional MR	103 (69.6)	68 (70.1)	35 (68.6)	0.85
TP	6.7±0.8	6.9±0.6	6.2±0.9	<0.01
Hemoglobin, g/dL	11.7±1.8	12.4±1.6	10.4±1.4	<0.01
WBC, ×1,000/μg	5.6±1.9	5.5±1.5	5.7±2.4	0.56
Serum Na, mEq/L	138.6±3.7	138.9±3.1	138.1±4.6	0.32
Creatinine, mg/dL	1.7±1.6	1.5±1.3	2.0±2.0	0.10
eGFR, mL/min/1.73 m^2	41.8±21.0	43.0±18.2	39.6±25.7	0.40
Median NT-proBNP (IQR), pg/mL	2,123 (1,017–4,674)	1,570 (733–3,709)	4,024 (2,057–6,476)	0.20
CRP, mg/dL	0.82±2.3	0.32±0.59	1.76±3.6	<0.01
HbA1c, %	6.1±0.8	6.0±0.7	6.2±1.0	0.36
LVEF, %	48.9±15.8	50.0±16.3	46.9±14.8	0.27
GNRI	95.2±12.3	100.5±10.3	85.0±8.7	<0.01
MitraScore	3.5±1.4	3.2±1.4	4.1±1.3	<0.01
MR jet area	29.9±14.1	27.9±13.5	33.7±14.5	0.07
MR vena contracta	5.9±4.6	5.6±4.6	6.6±4.6	0.35
MR ERO PISA	0.3±0.2	0.3±0.2	0.3±0.2	0.47
MR RV (PISA)	45.1±23.0	45.0±23.1	45.2±23.1	0.96
MR RV (volumetric)	26.7±26.8	24.9±29.9	30.0±20.2	0.34
MR RF (volumetric)	42.0±19.1	39.2±21.6	46.4±13.5	0.08

Values are mean±SD [median] or n (%) interquartile range (IQR). ACEi, angiotensin-converting enzyme inhibitor; Af, atrial fibrillation; ARB, angiotensin-receptor blocker; BMI, body mass index; BNP, B-type natriuretic peptide; CABG, coronary artery bypass graft; CAD, coronary artery disease; CKD, chronic kidney disease; CONUT, controlling nutritional status; COPD, chronic obstructive pulmonary disease; CRP, C-reactive protein; eGFR, estimated glomerular filtration rate; ERO, effective regurgitant orifice; GNRI, Geriatric Nutritional Risk Index; HF, heart failure; LAVI, left atrial volume index; LVDd, left ventricular end-diastolic diameter; LVDs, left ventricular end-systolic diameter; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; LVESV, left ventricular end-systolic volume; MR, mitral regurgitation; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PISA, proximal isovelocity surface area; RF, regurgitant fraction; RV, regurgitant volume; TP, total protein; WBC, white blood cell.

Table 2. Events After MitraClip Implantation

Event	Overall (n=148)	CONUT <4 (n=97)	CONUT ≥5 (n=51)	P value
Death	26 (18)	6 (6)	20 (39)	<0.01
Cardiovascular death	14 (9)	3 (3)	11 (22)	<0.01
Myocardial infarction	0	0	0	
Intersititial pneumonia	2 (1)	0	2 (4)	0.16
Stroke	4 (3)	2 (2)	2 (4)	0.55
Hospitalization for HF after procedure	19 (13)	8 (8)	11 (22)	0.04

CONUT, controlling nutritional status; HF, heart failure.

Therefore, in this study we aimed to identify nutritional screening tools that can predict death in patients undergoing TEER with the MitraClip system.

Methods

Patient Population

This retrospective cohort study of 148 consecutive patients who underwent MitraClip was conducted between April 2018 and April 2021 implantation. Indication for TEER using the MitraClip included presence of moderate-to-severe (3+) or severe (4+) MR in symptomatic patents, with a high risk for surgery. All patients were evaluated by a multidisciplinary heart team comprising an interventional cardiologist, echocardiographer, cardiac surgeon, HF specialist, and anesthesiologist. Patients with adverse clinical comorbidities such as endstage cancer that limited their lifespan to <6 months were excluded. Patients were also excluded if the morphology of the mitral valve for MitraClip implantation was unfeasible or impossible according to the EVEREST criteria (i.e., short or calcified posterior leaflet reducing the possibility of successful grasping by the clip or the beginnings of mitral stenosis).[20–23]

All patients provided informed consent prior to the procedure and the study protocol was approved by the Institutional Review Board of St. Marianna University School of Medicine (approval no. 5959).

Transthoracic and Transesophageal Echocardiographic Measurements

We performed transthoracic and transesophageal echocardiography (TTE) to quantify the MR parameters, as well as to assess morphologic suitability for MitraClip™ implantation. According to the American Society of Echocardiography guidelines,[24,25] MR severity was defined as none or trace (0/4+), mild (1+/4+), moderate (2+/4+), moderate-to-severe (3+/4+), and severe (4+/4+).

MitraClip Implantation Procedure

All clips were implanted via the femoral vein under general anesthesia, using fluoroscopy and TTE. Hemostasis of the femoral vein was achieved by Z-suture and compression of the vein for 8 h.

Predictors of All-Cause Death

The CONUT score was calculated from serum albumin (Alb) level, total lymphocyte count, and total cholesterol level, as described previously.[10,26,27] Additionally, we determined the geriatric nutritional risk index (GNRI; see **Supplementary Table 1**). The preprocedural CONUT score was calculated at the time of hospitalization: a low CONUT score was defined as 0–4 and high CONUT score as 5–12. The patients were divided into 4 groups based on their preprocedural CONUT score: 0–1 normal, 2–4 mildly high, 5–8 moderately high, and 9–12 markedly high with the highest Youden's J value of 0.55 in receiver-operating characteristic (ROC) analysis, according to previous reports.[10,26,27] The MitraScore[7] has 8 independent predictors: age ≥75 years, anemia, estimated glomerular filtration rate <60 mL/min/1.73 m^2, left ventricular ejection fraction (LVEF) <40%, peripheral artery disease, chronic obstructive pulmonary disease, high diuretic dose (≥80 mg of furosemide/day or use of ≥2 diuretic agents excluding antialdosteronic drugs), and no therapy with renin-angiotensin system inhibitors. The MitraScore is derived by assigning 1 point to each independent predictor, as shown in the Central Illustration. The sum of the weighted integers (range 0–8 points) estimates the risk of follow-up death.

Clinical Follow-up

Patients were evaluated at baseline, during the procedure, and at discharge, as well as at 30 days and 1 year after the procedure. Cardiovascular events included hospitalization for HF and death due to cardiovascular complications. HF was defined as the appearance of signs such as dyspnea and orthopnea with New York Heart Association (NYHA) functional class II–IV, requiring hospitalization. We evaluated clinical follow-up data using medical records.

Statistical Analysis

Categorical variables are presented as percentages and counts and were compared between groups using the chi-square test or Fisher's exact test. Continuous variables are presented as mean±standard deviation. The incidences of death and cardiovascular events were compared between groups using Fisher's exact test. To determine the independent predictors of death, a logistic regression model was constructed on a patient-level basis. Additionally, a multivariate logistic regression model was used to predict death by incorporating the preprocedural CONUT score and MitraScore. Statistical significance was set at $P<0.05$ for all tests. All statistical tests were performed using IBM SPSS Statistics for Windows (Version 22.0; IBM Corp., Armonk, NY, USA).

Results

Baseline Characteristics

In total, 148 patients (mean aged, 78±9 years; males, 62.8%; NYHA class III/IV, 79%) with severe MR were included. Functional MR was of ischemic origin in 69.6% of the patients, and the mean LVEF was 48.9±15.8%.

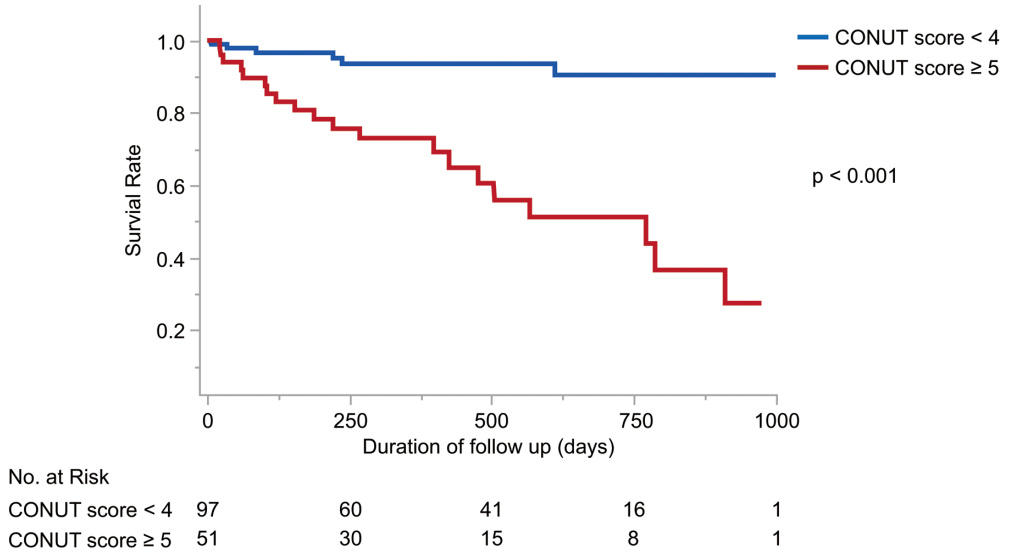

Figure 1. Kaplan-Meier curves for all-cause death in the high- and low-CONUT score groups show significantly worse outcomes in the ≥5 score group (P<0.001).

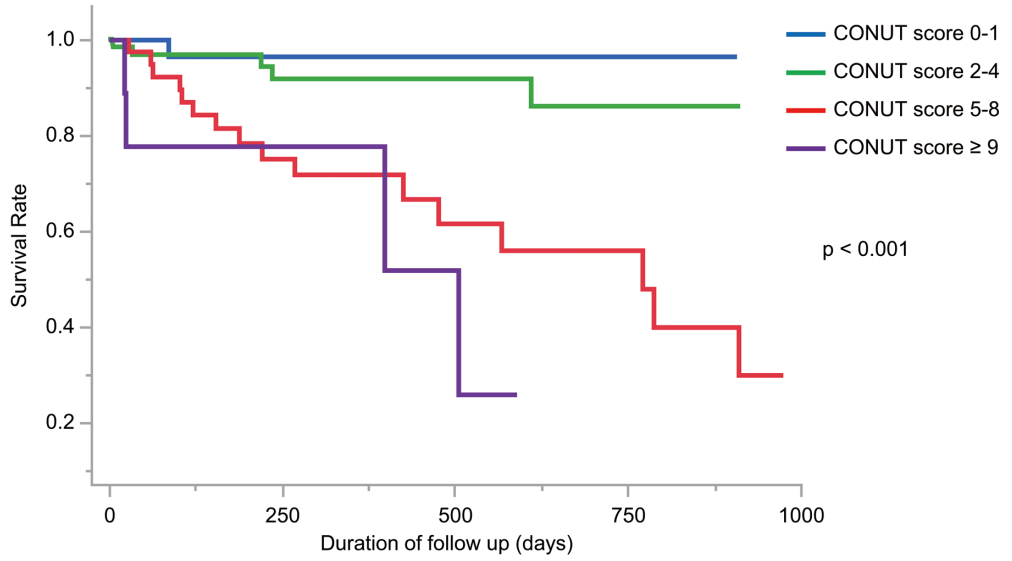

Figure 2. Kaplan-Meier curves for the groups subdivided by preprocedural CONUT score show that increasing score was associated with an incrementally higher risk of all-cause death.

Baseline demographics and comorbidities according to the CONUT score classification are summarized in **Table 1**. Patients in the high-CONUT score group were older (80.8±8.3 vs. 76.5±8.7 years, P<0.01), mostly male, with lower BMI (20.9±3.0 vs. 22.2±4.4, P<0.04), hemoglobin (10.4±1.4 vs. 12.4±1.6 g/dL, P<0.01), and total protein (6.2±0.9 vs. 6.9±0.6, P<0.01) levels. The group also had higher proportions of patients with congestive HF within 1 year (82% vs. 56%, P<0.01) and renal dysfunction (86% vs. 73%, P=0.05), higher C-reactive protein (CRP) levels (1.76±3.6 vs. 0.32±0.6 mg/dL, P<0.01); and had lower GNRI, compared with the low-CONUT score group (**Table 1**). Patients in the low-CONUT score group had lower MR jet area and less MR regurgitant fraction than the high-CONUT score group.

Clinical Outcomes in High- vs. Low-CONUT Score Groups

The mean follow-up period was 389±291 days; 26 patients died (1 died before hospital discharge; 2 died within 30 days of undergoing the MitraClip procedure). At 30 days

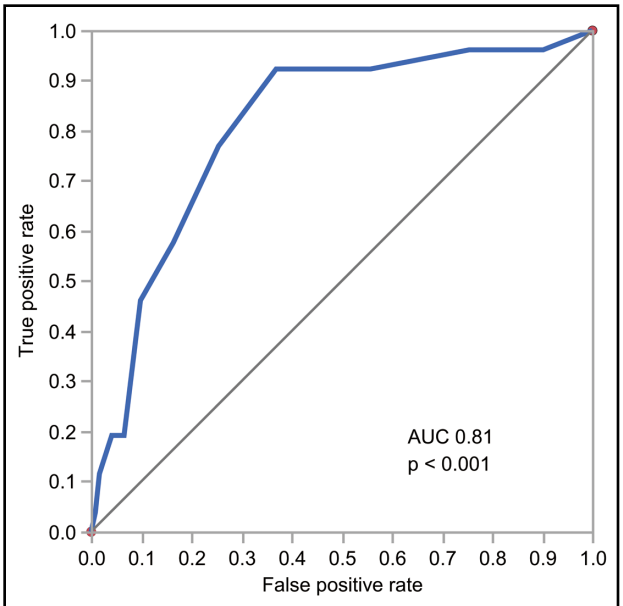

Figure 3. Receiver-operating characteristic curve for all-cause death by CONUT score. The area under the curve (AUC) is 0.81 (95% confidence interval [CI] 0.70–0.88) for the CONUT score.

after MitraClip implantation, 2 patients required mitral valve surgery or a repeat MitraClip procedure, but no cases of MitraClip embolization or mitral valve stenosis were detected. The high-CONUT score (≥5) group had significantly higher incidences of death, cardiovascular death, and hospitalization for HF after the procedure, compared with the low-CONUT (<4) group (**Table 2**). Kaplan-Meier curves indicated that all-cause death was significantly worse in the high-CONUT score group than in the low-CONUT score group (P<0.001; **Figure 1**). When the patients were divided according to preprocedural CONUT score, increasing CONUT score was associated with an incrementally higher risk of all-cause death (**Figure 2**). ROC analysis showed an area under the curve for all-cause death of 0.81 (95% confidence interval [CI] 0.70–0.88) for CONUT score (**Figure 3**). Cox hazard analysis showed that the CONUT score, as well as MitraScore, was significantly associated with all-cause death (hazard ratio [HR]: 1.31, 95% CI: 1.12–1.52, P<0.01) (**Table 3**).

Discussion

In the present study we assessed the preprocedural nutritional status using the CONUT score in patients undergoing TEER, and our main findings were that (1) all-cause death was significantly worse in the high-CONUT score (≥5) group than in the low-CONUT score (<4) group (P<0.001), and (2) the preprocedural CONUT score, as well as the MitraScore, was significantly associated with all-cause death in patients undergoing TEER.

Malnutrition is very common among patients undergoing TEER. In this study, according to the CONUT score, most patients had some degree of risk for malnutrition at the time of their TEER procedure. There are reports on the association between each CONUT score component and clinical outcomes.[10,26,27] In particular, a reduction in the lymphocyte count, which may be associated with physical stress, malnutrition, and chronic inflammation, predicted adverse outcomes in patients undergoing TEER using the MitraClip procedure. This information should allow the heart team to more accurately assess the clinical implications and prognostic benefits of the TEER procedure on a patient-by-patient basis. Hypoalbuminemia is also a well-known prognostic predictor for patients with HF, although Alb levels are influenced by reduced renal function and show a shortened half-life due to severe conditions. In fact, the bivariate Cox analysis of Alb and CONUT score with death as the outcome showed that the CONUT score remained a significant predictor of prognosis (Alb HR: 0.67 P=0.53, CONUT score: HR=1.51, P=0.002). Because the CONUT score incorporates total cholesterol, we conducted an additional analysis to explore its association with statin use. That analysis revealed that statin use was not associated with the CONUT score (P=0.930) (**Supplementary Figure**). We consider that these underlying mechanisms were closely linked to not only nutrition status but also acute exacerbation of HF due to severe MR; it has been hypothesized that the preprocedural CONUT score, and a complex of immune conditions, metabolism, and protein profile are associated with adverse outcomes for patients undergoing TEER using with the MitraClip.[28] In this study, 4 patients were excluded because of the morphology of their mitral valve made MitraClip implantation unfeasible or impossible according to the EVEREST criteria. In such high-risk cases, death may occur from complications associated with the procedure, even if the patient is in good general condition and well nourished. In fact, our Cox hazard analysis showed that the CONUT score was significantly associated with all-cause death in patients including the 4 who were excluded by the Everest criteria (HR: 1.30, 95% CI: 1.10–1.59, P<0.01). When considering the preprocedural score, the STS risk score is a known valuable screening tool for predicting death after cardiac surgery. However, our Cox hazard analysis revealed a significant association between all-cause death and the CONUT score as compared with the STS score as well as MitraScore (**Supplementary Table 2**). Of note, all-cause death were not associated with transfusion administration, elevated CRP level, use of assisted circulation, postoperative acute kidney injury and preoperative CONUT score (**Supplementary Table 3**).

The CONUT score was originally designed to predict "acute worsening" in surgical patients and subsequently adapted for chronic HF, which may affect its applicability in patients undergoing TEER using the MitraClip procedure.[28] In other studies,[11,26] the association between the CONUT score at the time of hospitalization and adverse outcomes was reported in patients with acute decompensated HF, and the CONUT score on admission expressed a malignant cycle in patients with HF, whereby HF caused malnutrition through fluid retention and malnutrition, leading to inflammation and neurohormonal activation. Recently, Kalbacher et al reported that being underweight (body mass index <20 kg/m^2) was associated with procedural failure, bleeding, and transfusion in hospital deaths after MitraClip implantation.[29] As one of the purposes of the MitraClip procedure is to slow down the progression of HF, a multidisciplinary approach to assessing risk is crucial.[30] To complicate matters further, 10–15% of HF patients develop cardiac cachexia, characterized by loss of body weight due to deterioration of muscle and adipose

Table 3. Predictors of All-Cause Death in Univariate and Multivariate Cox Regression Analyses

	Univariate analysis			Multivariate analysis		
	HR	95% CI	P value	Adjusted HR	95% CI	P value
Age, years	1.04	0.99–1.10	0.09			
Male	1.62	0.68–4.48	0.28			
BMI	0.92	0.81–1.04	0.19			
Congestive HF within 1 year	3.96	1.45–14.1	<0.01			
NYHA III/IV	0.76	0.30–2.30	0.6			
GNRI	0.93	0.90–0.97	<0.01			
Diabetes	1.80	0.82–3.94	0.14			
Hypertension	1.15	0.46–3.45	0.78			
Dyslipidemia	0.74	0.34–1.62	0.45			
Liver cirrhosis	2.92	0.16–14.0	0.37			
COPD	2.46	0.90–5.80	0.08			
Prior stroke	1.66	0.48–4.36	0.38			
CKD	4.65	1.37–29.0	<0.01			
CAD	0.50	0.18–1.21	0.13			
Other chest surgery	0.65	0.04–3.10	0.66			
β-blocker	1.38	0.52–4.74	0.54			
ACEi or ARB	0.45	0.21–0.98	0.045			
Loop diuretic	2.98	0.89–18.6	0.083			
Tolvaptan diuretic	2.80	1.29–6.29	<0.01			
Antiplatelet	0.43	0.18–0.97	0.04			
Anticoagulant	1.20	0.55–2.82	0.66			
Prior CABG	0.88	0.14–2.96	0.85			
Prior PCI	0.55	0.18–1.35	0.2			
Cardiac rhythm device implantation	1.49	0.58–3.41	0.38			
LVDd	1.02	0.98–1.06	0.38			
LVDs	1.02	0.99–1.04	0.26			
LVEDV	1.00	0.99–1.01	0.3			
LVESV	1.00	0.99–1.01	0.32			
LAVI	1.01	0.99–1.02	0.073			
Af	0.75	0.35–1.69	0.48			
Functional MR	1.52	0.65–4.16	0.35			
TP	0.60	0.38–0.94	0.027			
Albumin	0.28	0.14–0.53	<0.01			
Hemoglobin	0.70	0.55–0.88	<0.01			
WBC	1.08	0.88–1.28	0.43			
Na	0.94	0.84–1.05	0.28			
Cr	1.10	0.94–1.24	0.22			
eGFR	0.97	0.95–0.99	<0.01			
NT-proBNP	1.00	0.99–1.00	0.23			
CRP	1.13	1.05–1.20	<0.01			
HbA1c	1.18	0.72–1.77	0.48			
LVEF	0.99	0.96–1.01	0.3			
MR jet area	1.00	0.97–1.04	0.8			
MR Vena contracta	0.96	0.76–1.09	0.68			
MR ERO PISA	0.55	0.03–5.23	0.64			
MR RV (PISA)	0.99	0.97–1.01	0.22			
MR RV (volumetric)	1.01	0.99–1.02	0.56			
MR RF (volumetric)	1.02	0.99–1.05	0.31			
Residual MR grade	0.69	0.23–1.95	0.49			
MNA-SF (every 1-point decrease)	1.09	0.98–1.19	0.10			
MitraScore (every 1-point increase)	1.82	1.37–2.45	<0.01	1.47	1.10–2.00	<0.01
CONUT score (every 1-point increase)	1.40	1.23–1.61	<0.01	1.31	1.12–1.52	<0.01

CI, confidence interval; HR, hazard ratio. Other abbreviations as in Table 1.

tissue.[10,27] Implantation of the MitraClip in the early stages of HF may help improve patients' functional capacity.

Using the CONUT score to assess the fitness of patients before the TEER procedure, we can implement an appropriate nutritional intervention to improve the likelihood of better outcomes for elderly patients with MR.[31]

Study Limitations

First, the sample size was very small, and the study was conducted at a single center in Japan. Second, nutritional status was assessed only on admission. Additional clinical data obtained using the CONUT score may be useful. The Mini Nutritional Assessment was not included as a nutritional tool in the evaluation conducted in this study. Third, the 95% CIs of the odds ratios for the CONUT score were wide, probably due to the small sample size. Further studies should be conducted in a large population to determine the applicable nutritional assessment score.

Conclusions

Malnutrition may be related to all-cause death in patients undergoing MitraClip procedure, so preprocedural assessment of nutritional status may provide additional prognostic information, allowing the heart team to more accurately assess both the clinical implications and prognosis before deciding on the best course of action.

Acknowledgments

We thank Editage (www.editage.com) for English language editing.

Disclosures

S.K. and M.I. are consultants at Abbott Medical in Japan. Y.J.A. is a member of *Circulation Reports*' Editorial Team. The other authors have no conflicts of interest to declare.

Funding

None.

IRB Information

The Ethics Committee of St. Marianna University School of Medicine (No. 5959).

Data Availability

6th May 2023.

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Supplementary Files

Please find supplementary file(s);
https://doi.org/10.1253/circrep.CR-23-0055