

The Impact of Nutritional Status on the Outcome of Transcatheter Aortic Valve Implantation

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ABSTRACT

Background: The present study aims to evaluate how nutritional status may affect transcatheter aortic valve implantation (TAVI) outcomes.

Materials and Methods: This is a retrospective study of 383 TAVI patients. In-hospital, 1-month, and 12-month survival was evaluated. Since most patients undergoing TAVI are over 75 years old, the NRI definition for a geriatric population (GNRI) was used. Preoperative baseline clinical and laboratory data were collected and then the corresponding nutritional status was calculated, including Geriatric Nutritional Risk Index (GNRI), Prognostic Nutritional Index (PNI), and Controlling Nutritional Status Score (CONUT). Survival analysis and receiver operating characteristic curve (ROC) analysis were used to evaluate the correlation between these parameters and TAVI outcome.

Results: By CONUT and GNRI scores, 168 (58.9%) and 40 (14.0%) patients were considered to have mild malnutrition, respectively. By using PNI, CONUT, and GNRI scores, 16 (5.7%), 29 (10.3%), and 39 (13.7%) patients were moderately or severely malnourished.

Survival analysis showed that patients with worse nutritional status had a worse prognosis regardless of the nutritional score used. Subgroup analysis showed that these differences remained significant in subgroups of patients over age 75. COX multivariate analysis showed that GNRI, PNI, and CONUT were independently associated with all-cause mortality during the follow-up.

Conclusion: Patients with worse nutritional status had a worse prognosis regardless of the nutritional score used. Subgroup analysis showed that these differences remained significant in subgroups of patients over age 75. GNRI, PNI, and CONUT were independent predictors of all-cause mortality after TAVI.

INTRODUCTION

Malnutrition is frequent in elderly patients and has been shown to affect survival in several cardiovascular diseases, such as chronic heart failure or coronary artery disease [Sargento 2017; Kunimura 2017]. Transcatheter aortic valve implantation (TAVI) is mainly performed in high-risk patients, many of whom are geriatric patients with some degree of malnutrition [Kim 2011]. In such patients, nutritional status could be a useful prognostic factor to be considered before any planned TAVI. NRI (nutritional risk index), PNI (prognostic nutritional index), and CONUT score (Control Nutritional Status score) are not only easy tools to assess nutritional status, but they do not require any complex or additional test to those performed routinely on admission [Lu 2012; Koifman 2015]. The geriatric nutritional risk index (GNRI) is a version of the NRI adapted for elderly patients; thus, it could be particularly useful for the population undergoing TAVI [Bouillanne 2005]. The present study sought to evaluate the impact of nutritional status, measured using both GNRI and other conventional parameters, on clinical outcomes and particularly short-term survival after TAVI. According to the prognostic nutritional index (PNI), patients were classified into three groups, normal ($PNI \geq 38$), moderate malnutrition ($35 \leq PNI < 38$), and severe malnutrition ($PNI < 35$) [Kang 2012]. Control Nutritional Status score (CONUT): serum albumin levels and total lymphocyte count and total cholesterol are assigned different values, depending on their size. The CONUT score is the sum of the three assignments. A CONUT score of 0-1 is normal, 2-4 is mildly malnourished, 5-8 is moderate malnutrition, and 9-12 is classified as severe malnutrition [Ignacio 2005].

MATERIALS AND METHODS

Study population: From April 2012 to September 2018, a total of 383 patients underwent TAVI in West China Hospital. Among them, 85 patients had no records of preprocedural laboratory test results, 3 patients aged less than 75 years, 3 patients had preprocedural aortic regurgitation, 4 patients had a prior surgical aortic valve replacement, and "valve-in-valve" TAVI was performed. Four patients underwent thoracotomy, and three patients underwent emergency TAVI. So,

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these patients were excluded, and 285 patients were included in the final analysis.

The primary endpoints of the study include 30 days and one-year all-cause mortality, 30 days and one year of cardiogenic mortality. Secondary endpoints include permanent pacemaker implantation, hemorrhagic complications, vascular complications, and stroke. Endpoints of the study were defined according to the VARC-2 standard [Kappetein 2012].

Cardiogenic mortality: mortality primarily due to cardiac causes (including myocardial infarction, cardiac tamponade, worsened heart failure, pulmonary embolism, aortic rupture, aortic aneurysm rupture, and other vascular diseases). All-cause mortality included operation-related mortalities (including those resulting from surgical complications and those resulting from surgical complications), all valvular-related mortalities (including structural or unstructured valvular insufficiency), sudden mortality, and mortality from unknown causes.

Nutrition score calculation method and grouping criteria:

GNRI: Since most patients undergoing TAVI are older than 60, the NRI definition adapted to an old population was used, as described by Bouillanne et al. [Silaschi 2015]

GNRI was calculated as follows: $GNRI = 1.489 \times \text{albumin (g/L)} + 41.7 \times \text{weight (kg)} / \text{ideal body weight (kg)}$. Ideal weight = height² (m²) \times 22 (kg/m²) [Shibata 2018].

Based on this definition, patients were divided into four grades of nutrition-related risk, as suggested in the literature [Silaschi 2015].

Classification criteria are:

$GNRI \geq 98$ is normal; $92 \leq GNRI < 98$ is mildly malnourished; $82 \leq GNRI < 92$ is moderate malnutrition; and $GNRI < 82$ were classified as severe malnutrition [Bouillanne 2005; Shibata 2018].

Prognostic nutritional index (PNI) was calculated as follows: $PNI = 10 \times \text{albumin (g/dL)} + 0.005 \times \text{total lymphocyte number (pieces /mL)}$. According to PNI, the patients were classified into three groups. These were normal ($PNI \geq 38$), moderate ($35 \leq PNI < 38$), and severe malnutrition ($PNI < 35$) [Kang 2012].

Control Nutritional Status score (CONUT): serum albumin levels and total lymphocyte count and total cholesterol are assigned different values, depending on their size. The CONUT score is the sum of the three assignments. Albumin ≥ 3.5 mg/dL, total lymphocyte number ≥ 1600 /mL and total cholesterol ≥ 180 mg/dl is normal (score 0). The total CONUT score is between 0 and 12. Specific scoring principles as shown in Table 2. (Table 2) A CONUT score of 0-1 is normal, 2-4 is mildly malnourished, 5-8 is moderate malnutrition, and 9-12 is classified as severe malnutrition [Ignacio 2005].

Statistical analysis: We described the continuous variables that meet the characteristics of normal distribution by mean \pm standard deviation (SD). In addition, categorical variables were expressed as the number of patients and the percentage of the total cohort [n (%)].

Kaplan-Meier curve analysis was used for survival analysis and the log-rank test was used to compare the survival time

Table 1. Patient baseline characteristics

	Overall (N = 370)
Age (year)	79 \pm 5.2
Male	200 (54.1%)
BMI (kg/m ²)	22.3 \pm 3.6
Serum creatinine (mg/dl)	1.1 \pm 0.7
NYHA heart function level III-IV	333 (90%)
STS score (%)	7.8 \pm 4.6
Complication	
Chronic obstructive pulmonary disease	227 (61.4%)
Peripheral angiopathy	188 (50.8%)
Hypertension	162 (43.8%)
Coronary heart disease	154 (41.6%)
Diabetes	67 (18.1%)
Cerebral vascular disease	66 (17.8%)
Atrial fibrillation	56 (15.1%)
Chronic kidney disease	40 (10.8%)
PCI surgery history	28 (7.6%)
Implant valve type	
Venus A	230 (62.2%)
Core valve	39 (10.5%)
Lotus	32 (8.6%)
Vita Flow	24 (6.5%)
Taurus One	24 (6.5%)
Sapien XT	21 (5.7%)
Surgical approach	
Femoral artery	366 (98.9%)
Through the subclavian artery	2 (0.6%)
Ascending aorta	1 (0.3%)
The carotid artery	1 (0.3%)

Table 2. Principles of CONUT grading

Index	Score			
Albumin, g/dL	≥ 3.5	3.0 - 3.49	2.50 - 2.99	< 2.50
Albumin score	0	2	4	6
Total cholesterol, mg/dL	≥ 180	140 - 179	100 - 139	< 100
Cholesterol score	0	1	2	3
Total number of lymphocytes, per/mL	≥ 1600	1200 - 1599	800 - 1199	< 800
Lymphocyte score	0	1	2	3

of different groups of patients. Univariate COX proportional hazard regression model and multivariate COX proportional

Table 3. Incidence of malnutrition in TAVI patients

	Normal	Mild malnutrition	Moderate malnutrition	Severe malnutrition
PNI	269 (94.4%)	0	9 (3.2%)	7 (2.5%)
CONUT	88 (31.2%)	168 (58.9%)	27 (9.5%)	2 (0.7%)
GNRI	206 (72.3%)	40 (14.0%)	34 (11.9%)	5 (1.8%)

Table 4. Clinical Outcome in TAVI patients

	Vs.	r value	P-value	Undernourished score	Normal score
GNRI	PNI	0.47			
CONUT	GNRI	0.32	<0.001	12 (4.2%)	71 (24.9%)
CONUT	PNI	0.63			

Table 5. Clinical outcome

	Total number (N = 285)
30 days all-cause mortality rate	12/285 (4.2%)
30 days cardiogenic mortality	11/285 (3.9%)
1 year all-cause mortality rate	13/180 (7.2%)
1 year cardiogenic mortality	9/180 (5.0%)
Permanent pacemaker implantation	62/285 (21.8%)
Hemorrhagic complications	27/285 (9.5%)
Vascular complications	26/285 (9.1%)
Stroke	7/285 (2.5%)

hazard regression model were used to determine the independent risk factors associated with TAVI prognosis. Variables with $P < 0.1$ in univariate analysis were included in multivariate logistic regression analysis. We used univariate and multivariate logistic regression analysis to explore the risk factors for postoperative complications of TAVI. The receiver operating characteristic curve (ROC curve) was used to assess the ability of each anthropometric index to identify postoperative complications, and the area under the curve (AUC) and its 95% confidence interval (CI) were calculated.

SPSS 22.0 statistical software was used for all statistical analyses. Two-tailed $P < 0.05$ was considered statistically significant.

RESULTS

Baseline characteristics of the overall cohort: The overall study cohort included 153 males (53.7%) and 132 females (46.3%). The average age was 79.2 ± 5.0 years, and the age range was 75–92 years. The most common commodities were

chronic obstructive pulmonary disease (60.7%), peripheral vascular disease (54.7%), coronary heart disease (43.2%), and hypertension (42.8%). A total of 282 patients (98.9%) received trans-femoral TAVI. The subclavian artery (0.4%), ascending aorta (0.4%), and carotid artery (0.4%) were used in the rest of the patients shown in Table 1.

Follow-up time and clinical results of the overall cohort: The median follow-up time was 12 months (inter-quartile interval: 6–18 months). A total of 35 patients died during follow-up. The 30-day all-cause mortality rate in the overall cohort was 4.2%, and the 1-year all-cause mortality rate was 7.2%.

Control nutritional status score (CONUT): The patient's serum albumin level, total lymphocyte count, and total cholesterol were assigned different values based on their size. The CONUT score is the sum of these three assignments. Albumin ≥ 3.5 mg/dL, total lymphocyte number ≥ 1600 /mL, and total cholesterol ≥ 180 mg/dL were normal (score 0). The CONUT total score is between 0 and 12. See Table 2 for specific scoring principles. A CONUT score of 0–1 is normal, 2–4 is mildly malnourished, 5–8 is moderately malnourished, and 9–12 is severely malnourished [Ignacio 2005].

Overall distribution characteristics of each nutrition score: The frequency distribution histogram of the three nutrition scores is shown in Figure 1.

Although there was a correlation between the three nutrition scores (CONUT vs. GNRI: $r = 0.32$; CONUT vs. PNI: $r = 0.63$; CONUT vs. PNI: $r = 0.63$; GNRI vs. PNI: $r = 0.47$; all P values < 0.001), however, only 12 (4.2%) patients were classified as undernourished at all scores, and 71 (24.9%) patients were classified as normal at all scores shown in Table 4.

By CONUT and GNRI scores, 168 (58.9%) and 40 (14.0%) patients were considered to have mild malnutrition, respectively. By using PNI, CONUT, and GNRI scores, 16 (5.7%), 29 (10.3%), and 39 (13.7%) patients were considered moderately or severely malnourished, as shown in Table 3.

The correlation between GNRI and TAVI prognosis: From baseline characteristics between the three groups, a higher proportion of men with poor nutritional status, a lower BMI, and a higher STS score was observed. The proportion of hypertension and diabetes in the normal group was higher than that in the poor nutritional status group, while the rate of atrial fibrillation was lower than that in the malnutrition group.

During follow-up with a median of 12 months, 10 (4.9%) patients died in the normal group, 3 (7.5%) in the mild malnutrition group, and 8 (20.5%) in the moderate to severe malnutrition group ($P = 0.004$). Survival analysis showed that the lower the GNRI score, the worse the prognosis (log-rank $P = 0.001$) shown in Table 5. (Table 5)

GNRI was significantly correlated with all-cause mortality after TAVI in univariate analysis. After adjustment for age, STS score, hypertension, and diabetes, GNRI was independently associated with all-cause mortality during follow-up (HR 0.950; 95% CI 0.911-0.990; $P = 0.016$).

Subgroup analysis revealed significant differences in survival between groups among patients aged >75 years, and the poorer the nutritional status, the worse the prognosis (log-rank $P = 0.015$). There was no significant difference in survival among subgroups <75 years of age (log-rank $P = 0.069$), shown in Figure 2.

Correlation of GNRI with other peri-procedural clinical outcomes: The 30-day all-cause mortality rate (10.3%) and 1-year all-cause mortality rate (17.2%) of patients with moderate and severe malnutrition were higher than those of the other two groups, but the results were not statistically significant. Other clinical outcomes showed no significant difference between the groups.

Prognostic correlation between PNI and TAVI: The baseline characteristics of the two groups: The STS score of the moderate to severe malnutrition group was higher than that of the normal group and more patients had atrial fibrillation.

During follow-up with a median of 12 months, 16 (5.9%) patients in the normal group died, while 5 (31.25%) patients in the moderate to severe malnutrition group died ($P = 0.001$). Survival analysis showed that the mortality rate of the moderate and severe malnutrition group was significantly higher than that of the normal group (log-rank $P = 0.001$).

The univariate analysis showed that PNI score was significantly correlated with all-cause mortality after TAVI, after adjustment for age, STS score, hypertension, and diabetes. PNI remained independently associated with all-cause mortality (HR 0.915; 95% CI 0.849-0.987; $P = 0.021$).

Further subgroup analysis revealed significant differences in survival time between groups in patients ≥ 75 years of age, and the poorer the nutritional status of the group, the worse the prognosis (log-rank $P = 0.001$). In the subgroup analysis with age <75 years, there was no significant difference in survival between groups (log-rank $P = 0.215$), shown in Figure 3. (Figure 3)

Correlation between PNI and other perioperative clinical outcomes: Thirty-day all-cause mortality rate (18.8% vs. 3.3%; $P = 0.019$), 30-day cardiogenic mortality (18.8% vs. 3.0%; $P = 0.012$), one-year all-cause mortality rate (33.3% vs. 5.3%; $P = 0.006$), and 1-year cardiogenic mortality (33.3% vs. 3.0%; $P = 0.001$) were significantly higher than those in the normal group. The incidence of other clinical outcomes was not significantly different between the two groups.

Correlation between CONUT score and TAVI prognosis: Baseline characteristics of the two groups are the malnutrition group had higher age, male proportion, and STS score than the normal group, and more patients had chronic obstructive pulmonary disease, chronic kidney disease and atrial fibrillation.

During the median 12-month follow up, 2 patients (2.3%) from the normal group died, 11 (6.5%) from the mild malnutrition group died, 7 (25.9%) from the moderate malnutrition

group died, and 1 (50.0%) from the severe malnutrition group died ($P < 0.001$).

Survival analysis showed that the group with poorer nutritional status had higher all-cause mortality (log-rank $P < 0.001$).

In the univariate analysis, the CONUT score was significantly associated with all-cause mortality after TAVI. After adjustment for age, STS score, hypertension, and diabetes, CONUT was independently associated with all-cause mortality (HR 1.497; 95% CI 1.203-1.862; $P = 0.001$).

Subgroup analysis revealed a significant difference in survival time between groups among patients aged >75 years, and the poorer the nutritional status, the worse the prognosis (log-rank $P = 0.000$). There was no significant difference in survival among the subgroups <75 years of age (log-rank $P = 0.105$), shown in Figure 4.

Correlation of CONUT with other perioperative clinical outcomes: One-year all-cause mortality rate (10.0% vs. 0.0%) in the malnourished group (CONUT ≥ 2 ; $P = 0.045$) was significantly higher than that of the normal group. Other clinical outcomes showed no significant difference in incidence between the two groups.

DISCUSSION

The results of the current study showed that patients with worse nutritional status, evaluated using GNRI, PNI and the CONUT score, had higher rate of all-cause mortality after TAVI. However, this does not apply in patients younger than 75 years.

GNRI showed a higher discrimination in prediction of short-term mortality than its individual parameters, as shown by ROC-curves. In this study GNRI, the 30-day all-cause mortality (10.3%) and 1-year all-cause mortality (17.2%) of patients with moderate and severe malnutrition were both higher than those of the other two groups but did not reach statistical significance. Other clinical outcomes did not differ significantly between groups.

Overall outcomes in the current TAVI population are in line with those previously described in the literature, with short-term mortality and in-hospital complications, according to VARC-2 criteria being similar to those reported for all new generation valves [Kappetein 2012; Genereux 2012; Magri 2013].

Malnutrition and the malabsorption of nutrition are serious health problems in the elderly and can have a negative influence on function and quality of life [Marshall 2014]. Recent research has already shown the prognostic relevance of malnutrition in other populations, such as acute heart failure, due to left ventricular systolic dysfunction [Sze 2017]. When recognized early on, malnutrition can be reversible [Posner 1993]. Obesity has become an increasingly common chronic condition that is associated with significant morbidity and mortality [Effect of BMI]. A recent investigation identified the paradoxical survival benefits of obesity in patients after TAVI [Masanori 2021]. A simple marker, the Geriatric Nutritional Risk Index (GNRI), was recently proposed and

investigated in predicting the risk of nutrition-related complications and increased risk of mortality in the elderly population [Shibata 2018].

According to the screening of the three nutrition score systems, malnutrition is prevalent in TAVI patients and is associated with a poor TAVI prognosis. Previous studies suggested a correlation between BMI and nutritional status, and postoperative complications. GNRI showed higher discrimination in the prediction of short-term mortality than its individual parameters or BMI, as shown by ROC-curves. A preliminary GNRI cut-off value of 109.8 is suggested; further studies in larger populations are warranted to confirm its clinical value. The trend to a less common NYHA improvement in patients with some degree of nutritional risk is consistent with the overall impact of poor nutrition on clinical outcomes. In previous studies, GNRI was demonstrated to be a nutrition-related risk index that makes it possible to classify patients, according to a risk of morbidity and mortality in relation to pathology in elderly patients that are often associated with malnutrition [Bouillanne 2005; Magri 2013; Cereda 2009]. However, the incidence of malnutrition is closely related to the nutritional scoring system used. For the same study population, malnutrition was assessed by different scoring systems ranging from 5.7% (PNI) to 68.8% (CONUT). In this study, there was poor consistency among the scoring criteria in determining nutritional status, suggesting that these scoring systems could not be substituted for each other. In univariate analysis, PNI score was negatively associated with postoperative all-cause mortality after TAVI. After adjustment for age, STS score, hypertension, and diabetes, PNI remained independently associated with all-cause mortality (HR 0.915; 95%CI 0.849-0.987; $P = 0.021$). Thirty-day all-cause mortality rate (18.8% vs. 3.3%; $P = 0.019$), 30-day cardiogenic mortality (18.8% vs. 3.0%; $P = 0.012$), one-year all-cause mortality rate (33.3% vs. 5.3%; $P = 0.006$), and 1-year cardiogenic mortality (33.3% vs. 3.0%; $P = 0.001$) were significantly higher than those in the normal group.

The CONUT score was calculated based on blood protein content, lipid metabolism, and immune function status. PNI has a similar metabolic profile to CONUT but does not contain cholesterol. Compared with PNI and GNRI, more patients were judged to be malnourished by CONUT score, which may be related to patients taking lipid-lowering drugs. Since the classification of PNI does not include mild malnutrition but only moderate and severe malnutrition, the incidence of malnutrition in the general population may be underestimated when using PNI.

In this study, 30-day all-cause mortality in the moderate-severe malnutrition group (18.8% vs. 3.3%; $P = 0.019$), 30-day cardiogenic mortality (18.8% vs. 3.0%; $P = 0.012$), 1-year all-cause mortality (33.3% vs. 5.3%; $P = 0.006$), and 1-year cardiogenic mortality (33.3% vs. 3.0%; $P = 0.001$) were significantly higher than those in normal group. The incidence of other clinical outcomes was not significantly different between the two groups.

It was found that the three scoring groups of nutritional status were all associated with TAVI prognosis in the general population. However, the results of subgroup analysis by age

showed that nutrition grouping was significantly correlated with prognosis in patients ≥ 75 years old, but not significantly correlated with prognosis in patients < 75 years old, indicating that nutrition score was the most valuable for prognosis assessment in patients ≥ 75 years old [Sargento 2017].

Malnutrition can progress gradually and in severe cases even cardiac cachexia, which then consumes all components of the human body, including skeletal muscle, fat, and bone. The use of appropriate malnutrition screening tools can detect patients who may progress to cardiac cachexia earlier and prevent and treat them earlier [Marshall 2014; Sze 2017]. Further studies are needed to clarify whether early nutritional intervention can improve the prognosis of TAVI patients.

Limitations: First, this study is a single-center retrospective study and there may be some selection bias. In addition, due to the small sample size of this study, patients with moderate and severe malnutrition had to be combined into one group for survival analysis in the subgroup analysis. In addition, these nutritional evaluation criteria are not derived from the Chinese population, which is the limitation of the application of these scoring systems to the Chinese population. Finally, the present study was unable to compare the existing nutritional scoring system with other commonly used nutritional assessment tools, such as the Subjective Global Assessment (SGA) and the Mini-Nutritional Assessment (MNA), because relevant nutritional information, such as diet and body weight changes, has not been collected.

CONCLUSION

The proportion of patients with malnutrition in TAVI patients is high. Patients with worse nutritional status had worse prognosis regardless of the nutritional score used. Subgroup analysis showed that these differences remained significant in subgroups of patients over 75 years old. GNRI, PNI and CONUT were independent predictors of all-cause mortality after TAVI.

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