

Impact of Severe Sarcopenia on Rehospitalization and Survival One Year After a TAVR Procedure in Patients Aged 75 and Older

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Background: Transcatheter aortic-valve replacement (TAVR) reduces mortality and improves quality of life in patients with severe aortic valve stenosis. One third of patients have no benefit one year after TAVR. Sarcopenia, an age-related loss of skeletal muscle mass, is associated with increased physical disability and mortality. The main purpose was to evaluate the impact of severe sarcopenia on rehospitalization one year after TAVR in older patients.

Methods: All patients aged ≥ 75 referred for a TAVR in 2018 were included. Severe sarcopenia was defined by a loss of skeletal muscle mass defined on CT-scan measurement associated with a gait speed ≤ 0.8 m/s. The main outcome was rehospitalization one year after TAVR.

Results: Median age of the 182 included patients was 84, and 35% had an unplanned hospitalization at one year. Severe sarcopenia was diagnosed in 9 patients (4.9%). Univariable analysis showed that gait speed was a factor associated with readmission [HR=0.32, 95% CI (0.10–0.97), $p=0.04$] but not severe sarcopenia. In multivariable analysis, only diabetes was significantly associated with rehospitalization [HR=2.06, 95% CI (1.11–3.84), $p=0.02$]. Prevalence of severe sarcopenia varied according to different thresholds of skeletal muscle mass on CT-scan.

Conclusion: Even though severe sarcopenia was not correlated with rehospitalization and mortality at one year after TAVR, our results emphasize the changes in the prevalence according to cutoff used. It highlights the need to define standardized methods and international threshold for sarcopenia diagnosis by CT-scan measurements, in general population and for patients with valvular heart disease.

Keywords: sarcopenia, older, aortic stenosis, transcatheter aortic valve replacement, hospitalization

Introduction

Aortic stenosis is the most common valve disease in patients aged 75 years and older.¹ Severity and prognosis depend on echocardiographic criteria and the symptomatology presented by the patient. For older patients, curative treatment indication is based on two criteria: aortic stenosis considered severe on echocardiographic assessment with symptoms (exertional dyspnea, exertional syncope and angina).² The curative treatment is valve replacement, by conventional surgery or transcatheter aortic valve replacement (TAVR). This minimally invasive aortic valve replacement under angiographic control reduces mortality at 2 years and improves quality of life by reducing dyspnea.^{3,4}

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However, one year after TAVR, 15 to 30% of patients have no benefit of the intervention with no improvement in quality of life, severe complications or death.^{4,5} Geriatric syndromes are associated with the occurrence of these events.^{6,7} Sarcopenia is an interesting and understudied syndrome in this context. The term “sarcopenia” was proposed in 1989 by Rosenberg.⁸ Sarcopenia is defined as the loss of muscle strength secondary to a progressive and generalized loss of skeletal muscle mass with aging.⁹ The evaluation of sarcopenia is based on the measurements of muscle strength and muscle mass. Severe sarcopenia is defined by low muscle mass and loss of muscle strength with altered physical performances.⁹ The impact of sarcopenia on older people is significant in terms of morbidity, disability, quality of life, high costs of health care, and mortality.^{10–12} Thus, an increased risk of death, rehospitalization or complications can be expected after TAVR in sarcopenic patients. In the literature, some studies highlighted the impact of sarcopenia on the increase in mortality, rehospitalization or high resource utilization after TAVR, while others found diverging results.^{13–21} But none of these studies included a complete geriatric assessment with physical performance and complete nutritional assessment. The main purpose of our study was to evaluate the impact of severe sarcopenia on rehospitalization and survival one year after a TAVR procedure in patients aged 75 years and older.

Methods

Study Population

Between January 2018 and January 2019, all patients aged 75 and older hospitalized for TAVR procedure in the Cardiology Department of the Nantes University Hospital (France) were all screened for inclusion in our retrospective monocentric observational study. The decisions on aortic valve stenosis treatment (surgical procedure, TAVR or medical treatment) and the details of procedures (eg, valve type, valve size, access route, and type of anesthesia) were finalized through discussions by a multidisciplinary heart team after the same standardized preoperative general evaluation including a comprehensive geriatric assessment.

The inclusion criteria were 1) 75 years old and older, 2) severe symptomatic aortic valve stenosis or bioprosthesis aortic valve degeneration treated by TAVR, 3) comprehensive pre-operative geriatric assessment including physical performance and nutritional assessment, 4)

with CT-scan of the chest, abdomen and pelvis. The following patients were excluded: patients under legal protection, patients for whom TAVR was done as an emergency procedure or salvage intervention. All patients received TAVR procedure, by transfemoral, carotid or apical approach, at the Nantes University Hospital Cardiology Centre.

The study was conducted in accordance with the ethical standards set forth in Declaration of Helsinki (1983). This study was approved by the local ethics committee, Groupe Nantais d’Ethique dans le domaine de la Santé (GNEDS), which waived the need for informed consent in keeping with legislation on retrospective analyses of anonymized data.

Baseline Data

As part of the TAVR preprocedural assessment done in the 2 months before intervention, a comprehensive geriatric assessment was performed by a geriatrician for all patients to assess comorbidities, physical performances, functional status, cognition, depression, and nutritional status. The complete definition of the comprehensive geriatric assessment (CGA) variables is detailed in [supplementary data](#). In our study, physical performances were assessed by gait speed with the 4-meter gait speed test.

During the same time, all patients underwent a preprocedural CT evaluation which included chest, abdomen, and pelvis acquisition. The images were recorded on the Millennium PACS software. Skeletal muscle area was measured at the inferior margin of L3 vertebra on the abdominal scan of pre-TAVR CT (axial CT images at L3 level with both transverse processes fully visible). The level of the section was determined from the MPR application of the Millennium PACS software by adjusting the axial and sagittal sections centered on L3. A single cross-sectional CT image of L3 was selected and used to measure skeletal muscle area which was performed in a semi-automated fashion with manual “polygone” tracing tool and setting the density threshold between –29 and 150 Hounsfield units (HU). The skeletal muscle area included abdominal skeletal muscles, para-vertebral muscles and psoas (cm²). The L3 skeletal muscle mass index (SMI) was calculated as skeletal muscle area divided by height squared (cm²/m²). For psoas mass index (cm²/m²), measurements of the left and right psoas muscles were summed (cm²), then indexed to the square of the patient’s height (m²).

CT images of 50 randomly selected patients were independently analyzed by a second observer to obtain inter-observer reproducibility.

Severe sarcopenia criteria were defined according to European Working Group on Sarcopenia in Older People including:⁹

- Loss of skeletal muscle mass index (SMI) measured on CT-scan
- Gait speed measurement $\leq 0.8\text{m/s}$

Because no international consensus exists on total SMI threshold, cut-off values for loss of skeletal muscle mass were defined according to previously published studies: total skeletal muscle index (total SMI) $< 55.4\text{ cm}^2/\text{m}^2$ in men and $< 38.9\text{ cm}^2/\text{m}^2$ in women.^{16,18–20}

To discuss the results, prevalence of severe sarcopenia was assessed using the other previous total skeletal muscle index thresholds.^{13–21}

Study End Points

The main outcome was rehospitalization one year after aortic valve replacement by the TAVR procedure. The secondary outcome was death at one year after aortic valve replacement by the TAVR procedure.

For all patients, the general practitioner (GP) was contacted by phone to collect data concerning rehospitalization (numbers, post-TAVR delay, reason) and/or the occurrence of a death (post-TAVR delay, reason). If either GP or cardiologist had not had contact with the patient at one year, the patient was considered alive and without readmission during the first year after TAVR.

Statistical Analysis

For the participants' baseline characteristics, quantitative variables were described as mean \pm SD if normally distributed and as median and Interquartile Range (IQR) otherwise and were compared using Student's *t*-test or Mann–Whitney *U* test respectively. Qualitative variables were described as number (%) and were compared using Chi-squared test or Fisher's exact test depending on size (>5). Univariable Cox regression was used to identify factors associated with rehospitalization or death. All baseline variables with a *p*-value < 0.20 in univariable analysis and all the variables already known to be confounding factors were included in multivariable Cox regression model. The hazard ratio (HR) and the confidence intervals (CI) were presented in the charts.

Reproducibility of the measurement methods was assessed by Spearman's correlation coefficients and Interclass correlation coefficient.

All *p*-values were two-sided and *p*-value less than 0.05 was considered statistically significant.

All statistics were performed using the R statistical package, version 3.6.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Between January 2018 and February 2019, 362 patients ≥ 75 years had a pre-operative geriatric assessment in Nantes University Hospital for severe aortic stenosis and 215 were referred for a TAVR procedure. CT-scan could not be analyzed for five patients (performed in other hospital), geriatric assessment including gait speed was not evaluated for 28 patients. Finally, 182 patients were included in the study (Figure 1).

Patients' Characteristics

The median age of the study population was 84 years (IQR=81–86), and 50% were men. Table 1 shows the detailed baseline characteristics of the whole population and of rehospitalized patients. The mean of total SMI was $52.5\text{ cm}^2/\text{m}^2$. The mean gait speed was 0.90 m/s (± 0.23). Severe sarcopenia (loss of skeletal muscle mass and gait speed $< 0.8\text{m/sec}$) was present in 9 patients (4.9%).

Reproducibility

For total SMI, Spearman's correlation coefficient was 0.91 (*p*-value < 0.001) and the ICC was at 0.93 (*p*-value < 0.001).

Primary Outcome

Five general practitioners could not be join to collect information concerning post-TAVR condition, these patients were considered alive and without rehospitalization at one year. During 12-month follow-up, 64 patients underwent unplanned hospitalization (35%) of whom 54.7% were men. Most of the rehospitalizations were related to a cardiological complication such as heart failure, heart attack, atrial fibrillation or third-degree atrioventricular block (21 patients). The other reasons for rehospitalization were geriatric complication (16 patients for falls, delirium, malnutrition ...) or other reasons such as infections (4 patients) or gastro-intestinal bleeding (8 patients)

Univariable statistical analysis showed that gait speed was a factor associated with readmission [HR=0.32, 95%

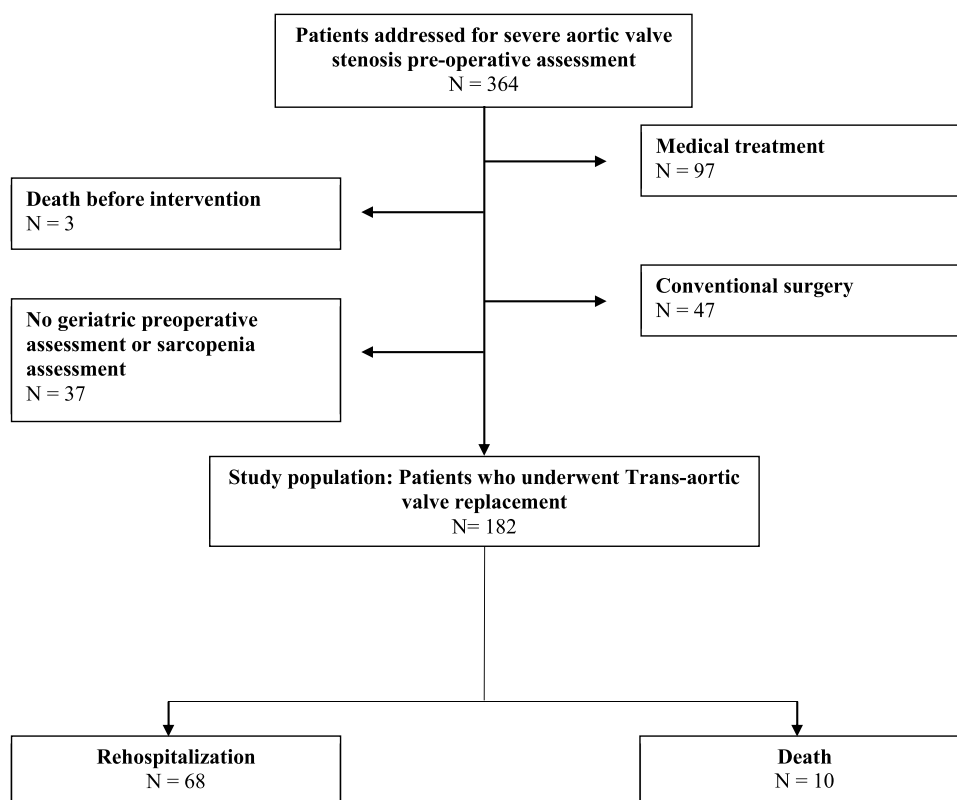


Figure 1 Patients flow diagram.

Abbreviations: TAVR, transcatheter aortic valve replacement; GP, general practitioner.

CI (0.10–0.97), $p=0.04$] in contrast to severe sarcopenia [HR=0.98, 95% CI (0.14–2.38), $p=0.45$] or total SMI [HR=1.00, 95% CI (0.97–1.03), $p=0.78$] (Table 1S in supplementary data). Other peroperative factors significantly associated with rehospitalization were: EuroSCORE I [HR=1.03, 95% CI (1.00–1.06), $p=0.008$] and diabetes [HR=2.01, 95% CI (1.22–3.62), $p=0.007$] (Table 1S in supplementary data).

In multivariable analysis, only diabetes was significantly associated with rehospitalization one year after the procedure by TAVR [HR=2.06, 95% CI (1.11–3.84), $p=0.02$] (Table 2).

Secondary Outcome

During 12-month follow-up, 10 patients died (5.1%) of whom 60% were men, all of them had previously been hospitalized at least once. Only one of them had pre-operative severe sarcopenia.

Univariable statistical analysis showed that neither severe sarcopenia, gait speed nor total SMI were associated with the occurrence of death [HR=2.04, 95% CI (0.25–16.39), $p=0.49$], [HR=0.56, 95% CI (0.03–8.46),

$p=0.67$], [HR=0.96, 95% CI (0.89–1.04), $p=0.37$] (Table 2S in supplementary data). The pre-operative factors significantly associated with death in univariable analysis were EuroSCORE I [HR=1.05, 95% CI (1.00–1.11), $p=0.04$], pulmonary hypertension [HR=4.96, 95% CI (1.39–17.58), $p=0.01$], and atrial fibrillation [HR=4.46, 95% CI (1.15–17.28), $p=0.03$] (Table 2S in supplementary data). No preprocedural factors were associated with mortality in multivariable Cox regression analysis (Table 3S in supplementary data).

Prevalence of Loss of Muscle Mass on CT-Scan and Prevalence of Severe Sarcopenia

Depending of the SMI threshold, prevalence of loss of muscle mass on CT-scan was heterogeneous and varied between 14.3% and 64.3% (Table 3).

Discussion

In this study, no association was found between severe sarcopenia (loss of muscle mass and altered gait speed) and rehospitalization one year after TAVR intervention. Altered physical performance defined by a gait speed ≤ 0.8 m/s was associated

Table I Baseline Characteristics of Patients (N=182) and With or Without Rehospitalization

Characteristics	All Participants	Rehospitalization		
	182	Yes=64	No=118	p-value
Age ^a	84 (81–86)	84 (82–86)	84 (80–85)	0.19
Male ^b	91 (50)	35 (54.7)	54 (45.7)	0.50
Baseline Characteristics				
CIRS-G score ^a	9.0 (7.0–11.0)	9 (8–11)	9 (7–11)	0.16
Euroscore I ^a	9.4 (7.0–13.9)	10.6 (7.2–18.6)	8.8 (6.7–13)	0.02
Euroscore II	2.9 (1.8–4.6)	3.4 (1.9–5.1)	2.8 (1.8–4.2)	0.14
Cockcroft Renal clearance ^a	55.9 (44.4–70.0)	53 (42–70)	59 (45–70)	0.28
NYHA ≥ 3, n (%)	46 (25.2)	17 (26.5)	29 (24.6)	1
LVEF ^a	60 (54–65)	60 (55–65)	61 (55–65)	0.20
Reduced LVEF ^b	24 (13.2)	10 (15.6)	13 (11.0)	0.59
Pulmonary hypertension ^b	42 (23.1)	18 (28.1)	24 (20.3)	0.41
Atrial fibrillation ^b	63 (34.6)	24 (37.5)	36 (30.5)	0.58
Peripheral artery disease ^b	17 (9.3)	7 (10.9)	8 (6.7)	0.55
Diabetes ^b	30 (16.5)	16 (25.0)	14 (11.8)	0.02
Coronary artery disease ^b	96 (52.7)	35 (54.7)	58 (49.1)	0.83
Body mass index ^a	26.4 (23.8–29.6)	26.6 (24.1–29.9)	26.3 (24.1–30.3)	0.56
Mini Nutritional Assessment ^a	25 (24–26)	25 (24–26)	25 (24–26)	0.38
Malnutrition* ^b	9 (4.9)	2 (3.1)	6 (5.1)	0.71
Mini Mental Status score ^a	25 (24–28)	26 (24–27)	26 (24–28)	0.78
ADL ^a	6 (6–6)	6 (6–6)	6 (6–6)	0.55
IADL ^a	4 (3–4)	4 (3–4)	4 (3–4)	0.59
Sarcopenia data				
Gait speed ^a	0.90 ± 0.23	0.85 ± 0.25	0.92 ± 0.22	0.10
Total SMI**, cm ² /m ² ^a	52.5 ± 8.3	53.1 ± 8.1	52.6 ± 8.5	0.64
Total SMRA**, UH ^a	25.1 ± 14.5	24.7 ± 13.8	25.3 ± 12.1	0.79
Severe Sarcopenia ^b	9 (4.9)	3 (4.7)	6 (5.0)	0.58
TAVR procedure				
Femoral approach ^b	167 (91.7)	58 (90.6)	104 (88.1)	0.81
Length of stay ^a	6 (5–8)	7 (5–8)	5 (4–7)	0.04
Rehabilitation	37 (20)	15 (23)	22 (18)	0.56

Notes: Significant p-value (ie, $p < 0.05$) indicated in bold. *Malnutrition, BMI ≤ 21 kg/m² or MNA < 17 ; **total: psoas, paraspinal and abdominal wall muscles; ^amedian (Interquartile Range), or mean \pm SD depending on normality; ^bn(%).

Abbreviations: CIRS-G, Cumulative Illness Rating Scale-Geriatric (range 0 to 56); NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; ADL, activity of daily living. IADL, instrumental activities of daily living; SMI, skeletal muscle index; SMRA, skeletal muscle mean attenuation.

with an increased risk of rehospitalization in univariable analysis. In multivariable analysis, only diabetes was significantly associated with rehospitalization.

Regarding rehospitalization, some studies reported that low muscle mass was a predictive factor of increased morbidity, early complications, and rehospitalization at 30 days in TAVR patients.^{22,23} In the same way, Soud et al showed in a meta-analysis of 8 studies with 1881 patients, that a high muscle surface area was associated with lower long-term all-cause mortality after a TAVR.²⁴ Several studies highlighted an association between low

muscle surface area and the increased risk of mortality after a TAVR procedure, whether muscle surface area was total skeletal muscle surface area or psoas area.^{13–17} However, some studies did not find this association, probably due to confounding factors.^{18,25,26} Michel et al, for example, showed that patients with lower psoas area were older, had more comorbidities, and had higher surgical risk but without a significant association between psoas area and mortality.²⁶ This variability in results could be explained by the lack of validated methodology for the CT-scan measurement of skeletal muscle surface area. The

Table 2 Association of Preprocedural Factors with Rehospitalization One Year After Transcatheter Aortic Valve Implantation, in Multivariable Cox Regression

Preprocedural Factors	Rehospitalization	
	HR (95% CI)	p-value
Age	1.04 (0.96–1.12)	0.29
Male	1.05 (0.61–1.83)	0.85
EuroSCORE I	1.03 (0.99–1.06)	0.06
Left Ventricular Ejection Fraction	0.99 (0.96–1.02)	0.41
Diabetes	2.06 (1.11–3.84)	0.02
Severe Sarcopenia	0.98 (0.71–2.13)	0.34

Note: p-value and hazard ratio (HR) significant (ie, $p < 0.05$): indicated in bold.

vertebral level where muscle area measurements should be performed is not defined. Some authors used the level of the 3rd or 4th lumbar vertebra, sometimes the 12th thoracic vertebra.^{9,27} The muscle measurements were adjusted, or not, for height squared or body mass index. Moreover, the EWGSOP specifies that no value defining loss of muscle mass by CT-scan measurements has yet been validated even though the evaluation of muscle mass loss for sarcopenia by CT-scan can be considered as the gold standard.⁹ In our study, muscle measurements were performed at L3 level. The muscle surface area measured at this level is correlated to the whole body muscles and it is used in other medical specialties to evaluate prognostics and risk of mortality.^{9,28,29} The prevalence of sarcopenia in

our population widely varied according to total SMI thresholds used, in the same way as in a recently published review.¹⁴

Physical performances assessed by gait speed are more often evaluated as prognostic factor. In our study, low gait speed was associated with an increased risk of rehospitalization. Our result is consistent with previous studies that showed an association between low gait speed and increased risk of mortality after a TAVR procedure.^{6,30} Alfredsson et al found that each decrease in gait speed of 0.2 m/s corresponds to an 11% increase in mortality at 30 days.⁶ Gait speed was also associated with an increased risk of rehospitalization at 3 years.³¹ However, gait speed is a multidimensional concept that not only involves muscles but also central and peripheral nervous function.⁹ Therefore, it seemed interesting to add information on muscle quality to confirm sarcopenia diagnosis and to understand the underlying mechanism of this poor prognostic factor.

In this study, diabetes was a preprocedural factor associated with rehospitalization one year after TAVR procedure. Diabetes was already being identified as a marker of poor prognosis after cardiac surgery.^{32,33} However, studies showed that diabetes does not affect rates of complications following TAVR.^{32–34} In a meta-analysis including 28,440 patients, Ando et al showed that the risk of perioperative complications was similar between diabetic and non-diabetic cohorts.³⁴ To explain this result, Conrotto et al

Table 3 Prevalence of Loss of Skeletal Muscle Mass on CT-Scan and Severe Sarcopenia According to Previously Published Threshold

Study (Year)	CT-Scan Cut-Off for Loss of Skeletal Muscle Mass for Men and Women	Prevalence	
		Loss of Skeletal Muscle Mass on CT-Scan	Severe Sarcopenia (Loss of Skeletal Muscle Mass on CT-Scan + Gait Speed < 0.8m/sec)
Dahya (2016) ¹⁵ Damluji (2021) ²¹	Total SMI < 55.0 cm ² /m ² in men < 39.0 cm ² /m ² in women	55 (30.2%)	9 (4.9%)
Mok (2016) ¹⁹ Nemec (2017) ¹⁸ Heidari (2019) ¹⁶ Tokuda(2020) ²⁰	Total SMI < 55.4 cm ² /m ² in men < 38.9 cm ² /m ² in women	56 (30.7%)	9 (4.9%)
Krishnan (2019) ¹⁷	Total SMI < 50.0 cm ² /m ² in men < 35.0 cm ² /m ² in women	26 (14.3%)	4 (2.2%)
Mamane (2019) ¹³	Psoas SMA < 20.3 cm ² in men < 11.8 cm ² in women	117 (64.3%)	36 (19.7%)

explained that old patients had many comorbidities connected to each other, reducing the independent impact of diabetes on periprocedural complications.³²

In our study, post-TAVR hospitalization was longer in patients who were readmitted in the following year. Length of hospital stay following TAVR was already known to be associated with 30-day rehospitalization.^{35,36} Its association with mid-term rehospitalization suggests that frailty, multiple comorbidities, and in-hospital complications may play an important role in increased rehospitalization rates in older patients rather than post-procedure complications.

This study has some important limitations. First, the mortality rate was low (5.1% at 1 year). In the Cardiology Department of the Nantes University Hospital, patients were selected after a strict pre-operative assessment including a preoperative geriatric assessment. As shown in Table 1, few patients had malnutrition (<5%), mean gait speed was fairly high, and patients had few comorbidities. This careful patient selection may explain the low mortality rate. However, the primary purpose of our study was to examine the relationship between SMI and rehospitalization, which was still high (35%). Second, the CT-scan measurements and the values defining loss of muscle on muscle surface area measurements were taken in studies but no cutoffs are widely recommended. Third, 20% of the population had geriatric personalized care plan with prehabilitation and/or rehabilitation after geriatric assessment. This care plan could include physical exercises which are recommended in case of low gait speed. Even though few patients had this individualized care plan, this might have participated in the absence of significant results.

In conclusion, even though our study failed to show association between severe sarcopenia and rehospitalization one year after TAVR, it has research implications. It highlights the need to define precisely the loss of muscle mass on CT-scan and to establish international threshold values for sarcopenia diagnosis by CT-scan measurements, in the general population and for patients with valvular heart disease.

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