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Research Article

Katz Frailty Syndrom has no Predictive Value in Low-Risk Patients Undergoing Transcatheter Aortic Valve Implantation

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Abstract:

Background: Aortic stenosis is a disease of the elderly people, with multiple comorbidities and often with the frailty syndrome. Therefore, we decided that frailty as a clinical factor requires precise characterization as it is a valuable supplement to the risk stratification in transcatheter aortic

Valve implantation (TAVI).

Objective: The aim of our study was to evaluate the prognostic value of the Katz frailty scale in patients undergoing TAVI in relation to the risk of mortality assessed with the STS scale.

Material and methods: The study included 105 patients with severe aortic stenosis (AS) treated with TAVI at the Department of Invasive Cardiology, Central Clinical Hospital of the Ministry of Interior. In our group, the Katz frailty syndrome confirmed in all patients, and 48% in the advanced stage.

Results: Statistical analysis showed a significant difference between survival and Katz frailty score before TAVI. Analysis using Cox's model confirmed a significant prognostic value for the Katz frailty syndrome before TAVI. Patients with moderate to severe frailty on the Katz score (values ≤ 4) had a 13,68 times higher risk of death per year compared to the group with Katz frailty syndrome ≥ 5. Multivariate regression analysis indicated that Katz frailty score and STS score were prognostically significant factors of cardiovascular death in patients undergoing TAVI.

Conclusion: The Katz frailty score had a significant prognostic value in the high- and intermediate risk patients. Katz frailty score and STS risk score significantly correlated with the risk of death from cardiovascular causes in frailty patients undergoing TAVI.

Key words: severe aortic stenosis; frailty syndrome; TAVI

Introduction

Aortic stenosis (AS) is the most commonly diagnosed valve disease in the world [1,2]. Pharmacotherapy is associated with a poor prognosis [3] and a mortality rate of 30-50% within 2 years of the onset of clinical symptoms [4-6]. AS is a disease of the elderly, with multiple comorbidities and often the frailty syndrome. Approximately 30% of patients are disqualified from cardiac surgery [7,8].

Classic risk scores have been developed to predict mortality and periprocedural complications in patients undergoing cardiac surgery [9-12]. However, they do not include factors such as cognitive decline and difficulties in independent daily activity, and have limitations in predicting mortality in the population of patients undergoing transcatheter aortic valve implantation (TAVI). Several studies have shown that frailty is associated with higher morbidity and all-causes mortality in patients undergoing cardiac surgery or TAVI [13-17]. In our group, the frailty syndrome concerned all patients, and 48% in the advanced stage. Therefore, we decided that frailty as a clinical factor requires precise characterization as it may be a valuable supplement to the risk stratification of TAVI. So far, it has not been possible to establish one universally accepted scale of frailty syndrome that would be the reference for better prognosis in patients undergoing TAVI.

Objective

The aim of our study was to evaluate the prognostic value of the Katz frailty scale in patients undergoing TAVI in relation to the risk of mortality assessed with the STS scale.

Material and methods

Study population

The study included 105 patients with severe aortic stenosis (mean age 82,36±4,5; 46% men) and the Katz frailty syndrome treated with TAVI in the Department of Invasive Cardiology, Central Clinical Hospital of the Ministry of Interior and Administration. Inclusion criterion was severe high gradient aortic stenosis treated with TAVI. Severe AS was diagnosed on the transthoracic echocardiography and determined by the following parameters: AVA <1 cm2 or AVA Id <0,6 cm2 / m2 and mean gradient > 40 mmHg. The decision on qualifying patients for TAVI, vascular access and the type of valve was made by an interdisciplinary heart team. All patients underwent laboratory tests, ECG, echocardiography and was assessed based on the STS scale and the Katz frailty scale (Table I) (11).

Activities	Independence (1 point)	Dependence (0 points)
Bathing	Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity	Need help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing.
Dressing	Get clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	Needs help with dressing self or needs to be completely dressed
Toileting	Goes to toilet, gets on and off, arranges clothes, cleans genital area without help	Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
Transferring	Moves in and out on bed or chair unassisted. Mechanical transfer aids are acceptable	Needs help in moving from bad to chair or requires a complete transfer.
Continence	Exercises complete self-control over urination and defecation	Is partially or totally incontinent of bowel or bladder
Feeding	Gets food from plate into mouth without help.	Needs partial or total help with feeding or requires parental foods
Scoring: 6 – patient independent 4 – moderate frailty syndrome 2 – severe frailty syndrome		

Table I: *Katz frailty scale*

We were used five types of bioprothesis - Medtronic CoreValve 43,8% (n=46), Medtronic Evolut R 31,4% (n=33), Edwards Sapien 7,6% (n=8), Symetis Accurate 13,3% (n=14), and St. Jude Medical Portico 3,8% (n=4). The following access were used: transfemoral in 88,6% (n = 93) patients, trans-apical in 6,7% (n = 7), trans-aortic in 1,9% (n = 2) and trans-clavicular in 2,9% (n = 3). Follow-up observations were carried out at 1 month and 1 year.

Statistical analysis

In order to assess the normality of a change in the application of the Shapiro-Wilk test. In the absence of normal use, the Mann-Whitney test. In the study mode of the Kaplan-Meier method of survival, and the survival functions were compared using the log-rank test. The Cox hazards model was used as a multi-feature condition that is important to indicate which variables are significant factors influencing survival. To assess the influence of the investigated explanatory possibilities on the dichotomous variable, one-dimensional and multi-dimensional logistic regression were used. The critical significance level (α) for all tests was 0.05 (α = 0,05). Statistical analysis was performed with the use of Statistica v.12.5 (StatSoft).

Results

General characteristics of the studied population

The mean STS score was 7,03 ± 4,24% (STS ≥ 8% – 23,6% of patients, STS 4-8% - 40%, STS ≤ 4% - 36,4%). The Katz frailty syndrome, grade ≤ 4, was found in 44,8% of patients. The clinical characteristics of patients qualified for the TAVI procedure are presented in Table II.

Basic clinical characteristic	Before TAVI
	n=105 (%)
Male, n (%)	48 (46)
Age (years)	82,36±4,5
BSA (m2)	1,77±0,1
BP (mmHg)	138/87
NYHA class, n (%)	
NYHA I	8 (7,6)
NYHA II	60 (57,1)
NYHA III	37 (35,2)

EuroScore II (%)	7,39±4,97
STS (%)	7,03±4,24
Hypertention, n (%)	84 (80)
Diabetes, n (%)	41 (39)
Dyslipidemia, n (%)	36 (34,2)
Atrial fibrillation, n (%)	33 (31,4)
Ischemic heart disease, n (%)	66 (62,9)
Past myocardial infarction, n (%)	31 (29,5)
Past CABG, n (%)	10 (9,5)
Bleeding, n (%)	23 (21,9)
Comorbidities, not included in the risk scales (thyroid diseases, oncological treatment), n (%)	52 (49)
RBBB, n (%)	5 (4,8)
LBBB, n (%)	10 (9,5)
Stimulator before TAVI, n (%)	14 (13,3)
Creatynine (mg/dl)	1,23±0,32
eGFR (ml/min.)	53,87±13,2
Hb (g/dl)	12,52±1,3
NT-proBNP (pg/ml)	2858,33±2077,5
6MWT	235,53±64,8
Katz frailty score ≤ 4, n (%)	47 (44)
Pharmacotherapy	
ACE-I/ARB, n (%)	72 (68)
β-blockers n (%)	61 (58)
α-blockers, n (%)	15 (14,2)
Calcium channel blockers, n (%)	43 (41)
Statins, n (%)	71 (67,6)
Clopidogrel, n (%)	34 (32,3)
ASA, n (%)	72 (68)
OAC and NOAC, n (%)	32 (30,5)
LVEF (%)	54,51 ± 6,44
AVA (cm^2)	0,65 ± 0,14
AVAI (cm/m^2)	0,38 ± 0,08
Ao V maks. (m/s)	4,57 ± 0,47
Ao grad. Śr. (mmHg)	51,69 ± 10,66
DVI	0,21 ± 0,15

Table II: *Basic clinical characteristic patients undergoing TAVI*

Katz frailty syndrome

Mild or moderate and severe frailty in the Katz scale was observed in patients in 55,2% or 44,8%, respectively (Table III). The greatest reduction in the number of patients with Katz frailty score ≤ 4 was observed in the high-risk patients ($p \leq 0,05$) after 1-month follow-up and in the intermediate- and high-risk patients after 1-year follow-up ($p \leq 0,05$, $p \leq 0,05$ respectively). These relations were not observed in low-risk patients ($p > 0,05$) (Table III).

Comparison Katz frailty score in patients undergoing TAVI											
BEFORE TAVI (n=105)				**1-MONTH FOLLOW-UP (n=99)**				**1 YEAR FOLLOW-UP (n=81)**			
Baseline characteristic	**Katz frailty score ≤ 4, n (%)**	**Katz frailty score ≥ 5, n (%)**	**P (**ANOVA Kruskal-Wallis)	**Baseline characteristic**	**Katz frailty score ≤ 4, n (%)**	**Katz frailty score ≥ 5, n (%)**	**P (**ANOVA Kruskal-Wallis)	**Katz frailty score ≤ 4, n (%)**	**Katz frailty score ≥ 5, n (%)**	**P (**ANOVA Kruskal-Wallis)	
	47 (44,8)	**58 (55,2)**			**41 (41,4)**	**58 (58,6)**		**29 (35,8)**	**52 (64,2)**		
Male, n (%)	27 (57)	21 (36)	> 0,05	**All-causes mortality**	6 (14)	0 (0)	**≤ 0,05**	18 (62)	1 (2)	**≤ 0,05**	
Female, n (%)	36 (76)	21 (36)	**≤ 0,05**	**Cardiovascular mortality**	3 (7)	0 (0)	**≤ 0,05**	8 (28)	1 (2)	**≤ 0,05**	
EuroScore II (%)	8,75±5,06	5,35 ±2,13	> 0,05	**All-causes mortality of high risk patients (STS >8%)**	2 (5)*	0 (0)	**≤ 0,05**	6 (21)*	0 (0)	**≤ 0,05**	*** p ≤ 0,05**
STS (%)	8,38±4,76	5,1±2,24	> 0,05	**All-causes mortality of intermediate risk patients (STS 4-8%)**	3 (7)*	0 (0)	**≤ 0,05**	11 (38)*	1 (2)	**≤ 0,05**	*** p ≤ 0,05**
				All-causes mortality of low risk patients (STS <4%)	1 (2)#	0 (0)	> 0,05	1 (3)#	0 (0)	> 0,05	#p >0,05
				Stimulator implantation after TAVI	19 (46)	25 (43)	> 0,05	17 (58)	15 (29)	> 0,05	
NYHA I class	6 (12,7)	2 (3)	> 0,05	**NYHA I class**	23 (56)	27 (46)	> 0,05	19 (65)	23 (44)	> 0,05	
NYHA II class	31 (66)	29 (50)	> 0,05	**NYHA II class**	4 (10)	1 (2)	> 0,05	6 (20)	1 (2)	**≤ 0,05**	
NYHA III class	26 (55)	11 (19)	**≤ 0,05**								
AVA (cm2)	0,59 ± 0,17+`	0,67 ± 0,11+`	> 0,05	**AVA (cm2)**	1,69±0,24 +	1,65±0,22 +	> 0,05	1,6 5± 0,22`	1,62 ± 0,21`	> 0,05	**` p ≤ 0,05 + p ≤ 0,05**
LVEF (%)	52,5 9± 12,9	56,88 ± 13,9	> 0,05	**LVEF (%)**	52,34±12, 5	55,13±12, 9	> 0,05	51,22 ± 12,3	55,66 ± 13,3	> 0,05	
Mean aortic gradient (mmHg)	52,15 ± 10,8^	50,67 ± 10,2^	>0,05	**Mean aortic gradient (mmHg)**	7,89±1,02 ^	8,97±1,03 ^	> 0,05	7,76 ± 0,98^	8,95 ± 1,02^	> 0,05	**^ p ≤ 0,05**
High-risk patients (STS ≥ 8%), n(%)	19 (40)*	6 (10)	**≤ 0,05**	**High-risk patients (STS ≥ 8%), n(%)**	10 (24)*	12 (20)	**>0,05**	8 (28)*	11 (21)	>0,05	*** p ≤ 0,05**
Intermediate-risk patients (STS 4-8%), n(%)	22 (47)*	20 (34)	> 0,05	**Intermediate-risk patients (STS 4-8%), n(%)**	26 (63)	24 (41)	> 0,05	16 (55)*	16 (31)	>0,05	*** p ≤** 0,05
Low-risk patients (STS ≤ 4%), n (%)	6 (12)#	32 (55)	**≤ 0,05**	**Low-risk patients (STS ≤ 4%), n (%)**	5 (12)#	22 (38)	**≤ 0,05**	5 (17)#	25 (48)	**≤ 0,05**	#p >0,05

In the study population, a significant reduction in the symptoms of the Katz frailty syndrome was observed in 1-month ($p \leq 0,05$) and 1-year follow-up after TAVI ($p \leq 0,05$) compared to the output. There were no significant changes ($p > 0,05$) between 1-month and 1-year follow-up (Figure 1).

Table III: *Clinical characteristics depending on the stage of the Katz frailty score.*

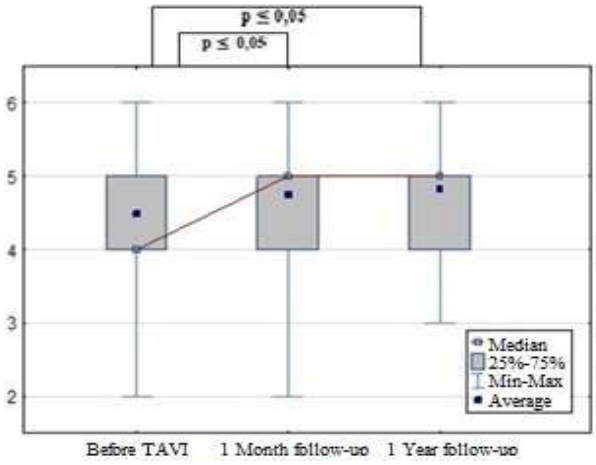

Figure 1: *Change in the stage of Katz frailty score over time.*

a) Katz frailty syndrome and the risk of all-causes mortality after TAVI

There was a statistically significant difference between survival and the Katz frailty syndrome assessed before TAVI (log-rank test, p = 0,0008) (Figure 2). The median survival time was 817 days (Q1, Q3: 408 days, 1,229 days) in patients with Katz scores ≤ 4 and 867 days (Q1, Q3: 389 days, 1,249 days) in patients with Katz scores ≥ 5. 1-year mortality of patients with moderate and severe Katz frailty syndrome was 30%, and with mild Katz frailty syndrome was 3% (p ≤ 0,001).

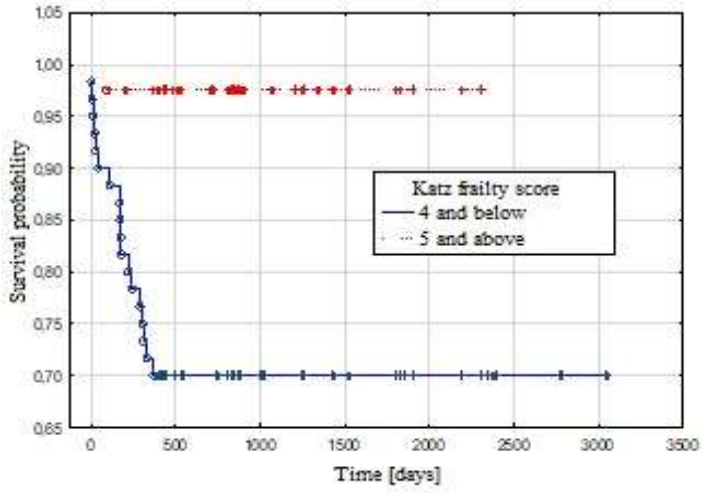

Figure 2: *Kaplan-Meier survival probability due to Katz frailty score.*

One-month and 1-year all-causes mortality after TAVI in high- and intermediate-risk patients was a significantly dependent on Katz frailty score (p ≤ 0,05, p ≤ 0,05 respectively). There was no significant change (p > 0,05) in the low-risk patients (Table III).

The Cox proportional hazard model confirmed a significant prognostic value for the Katz frailty syndrome prior to TAVI (p ≤ 0.05). Patients with moderate to severe frailty (values ≤ 4) had a 13,68 times higher risk of death (Table IV).

Independent variable	**1 year all-causes mortality after TAVI**	
Univariate analysis in the Chi-square test		
	OR (95% PU)	**p**
STS score before TAVI	4,24 (0,71-16,17)	**≤ 0,01**
Gender	1,65 (0,59-6,72)	> 0,05
Asymptomatic patients	5,23 (0,34-26,56)	**≤ 0,05**
Katz frailty score	6,69 (0,83-32,43)	**≤ 0,01**
NT-proBNP before TAVI	1,000159 (1,0-1,0)	> 0,05

Multivariate logistic regression (p ≤ 0,05)		
	OR (95% PU)	
STS score before TAVI	3,8 (0,58-15,79)	> 0,05
Katz frailty score	13,68 (1,83-102,48)	**≤ 0,05**
Symptomatic patients	4,8 (0,21-24,82)	> 0,05

Table IV: *Logistic regression analysis for 1 year all-causes mortality after TAVI*

a) 1-year mortality from cardiovascular causes after TAVI and the Katz frailty syndrome

The multivariate logistic regression model indicated the Katz frailty syndrome and the STS risk score before TAVI were prognostically significant factors of cardiovascular death in patients undergoing TAVI (p ≤ 0,01). Patients with moderate and severe Katz frailty syndrome (values ≤ 4) had a risk of cardiovascular death 3,28 times higher than those with Katz frailty scores ≥ 5 (p > 0,05). When switching the surgical STS risk category before TAVI from low to intermediate, the risk of death from cardiovascular causes increased 4,60 times, while if the surgical STS risk category was changed from intermediate to high, the risk of death from cardiovascular causes was higher 21,16 times (p ≤ 0,05) after TAVI (Table V).

Independent variable	**1 year cardiovascular mortality after TAVI**	
Univariate analysis in the Chi-square test		
	OR (95% PU)	**p**
STS score before TAVI	5,33 (1,41-20,19)	**≤ 0,05**
Katz frailty score	7,78 (0,85-65,13)	**≤ 0,05**
Gender	01,77 (0,41-7,71)	>0,05
Asymptomatic patients	4,46 (0,52-38,95)	>0,05
NT-proBNP before TAVI	1,000221 (1,0-1,0)	>0,05
Multivariate logistic regression (p ≤ 0,01)		
	OR (95% PU)	
STS score before TAVI	4,6 (1,13-18,78)	**≤ 0,05**
Katz frailty score	3,28 (0,25-30,95)	**≤ 0,05**

Table V: *Logistic regression analysis for 1-year cardiovascular mortality after TAVI*

Discussion

The optimal selection of patients with severe aortic stenosis for the TAVI procedure, taking into the frailty syndrome, remains the subject of many studies and analyzes [5-8,11–14,16]. Our study shows that the stage of Katz frailty syndrome is an important parameter in the assessment of patients before TAVI and has a prognostic value in assessing the risk of death after TAVI, also in depending on the risk in STS score. Our analysis indicate that the Katz frailty score had a significant prognostic value, especially in intermediate- and high risk patients, but no in low-risk patients. Moreover, together with the STS risk scale predicts the risk of death from cardiovascular causes after TAVI.

Our data confirm that the Katz frailty syndrome is a significant indicator of mortality in patients after TAVI and these data are consistent with the results presented in previous publications and meta-analysis [11,13-16,18-20]. At the same time, we showed that 1-year all-causes mortality after TAVI in high-risk and intermediate-risk patients was a significantly dependent on Katz frailty score.

In recently published studies, survival after TAVI was significantly associated with the advancement of the Katz frailty syndrome, and the frailty turned out to be an independent predictor of mortality [20-26]. Moreover, in a study by Rogers et al. it was shown that the frailty syndrome, both independently and by adding it to the risk assessment on the classic STS scale, predicted an all-causes 30-days and one-year mortality after TAVI [9].

There are single studies analyzed the effect of the frailty syndrome on cardiovascular mortality after TAVI. In the Li et al. study, the assessed of geriatric parameters, including the Katz frailty scale, were significantly associated with all-causes and cardiovascular mortality one year after TAVI [18]. Frailty was one of the most important predictors of all-causes mortality, but also of myocardial infarction and stroke in a 9-month follow-up. In our study, we showed that patients with severe SA and the stage of Katz frailty scale ≤ 4 show significantly higher cardiovascular mortality in one-year follow-up after TAVI. Additionally, multivariate regression analysis indicated that the model of the Katz frailty score and the STS risk scores was a prognostic factor of cardiovascular death in frailty patients undergoing TAVI (p ≤ 0,01).

The use of the Katz frailty scale before TAVI to assess high-risk patients in the STS risk scale allows us to further refine the prognosis of patients undergoing TAVI. This has been demonstrated in the above-cited works as well as in the present publication. Interestingly, the Katz frailty scale allows us to differentiate the prognosis of patients with moderate risk in the STS risk score, reaching statistical significance in 1 year follow-up (p≤ 0,05). In contrast, patients with low risk of STS scale showed no differences in prognosis depending on the Katz frailty scale. In low-risk patients in our study, regardless of the Katz frailty scale, no deaths were observed either in one-month or one-year follow-up. Other researchers, such as Bo et al. also showed the best prognosis of patients with low risk of STS scale, and the Katz score ≤ 4 did not differentiate the prognosis despite the fact that deaths were reported in this group (3% vs. 0% and 4% vs. 0%, respectively) [27].

Frailty syndrome may be a consequence of severe SA, but also severe SA seems to exacerbate the symptoms of frailty. We observed a statistically significant reduction in the symptoms of the Katz frailty syndrome in a 30-day and one-year observation **(Figure 1).** Our data indicate the possibility of interrupting the progressive impairment of mobility and loss of independence in elderly patients, which may have a significant impact on improving the quality of life in TAVI population of patients.

Our study complements the growing amounts of evidence supporting the need to assess the frailty syndrome in patients undergoing TAVI. However, in future post-TAVI mortality prediction tools, a standardized assessment of the frailty scores should be largely considered.

Limitations

The strength of our study is assessment of the relationship of the Katz frailty syndrome with the classical STS risk score and their impact on the clinical results after TAVI. However, there are a few limitations to consider. First, we had a small population. Second, the observation time was relatively short. Third, in the study population, different types of bioprotheses were used during TAVI procedure, which may affect the results obtained.

Conclusions

The stage of the Katz frailty syndrome turned out to be significantly associated with one-year mortality after TAVI, both all-causes and cardiovascular. The demonstrated reduction in the number of patients with moderate and severe frailty syndrome, as well as the reduction of the symptoms of the frailty syndrome indicate the possibility of interrupting the progressive limitation of mobility in patients with severe aortic stenosis treated with TAVI. Therefore, the TAVI procedure can be considered an appropriate therapeutic intervention. The predictive value and compliance of the risk stratification at the patient level was significantly improved by considering the simultaneous STS and Katz frailty scores. The Katz frailty score had a significant prognostic value, especially in intermediate- and high-risk patients, but no in low-risk patients. Therefore, estimating the stage of the Katz frailty syndrome before TAVI qualification can`t help stratify risk in low-risk patients.

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