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Transcatheter aortic valve implantation versus surgery: 4-year survival according to life expectancy

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ABSTRACT

Background In the last years, transcatheter aortic valve implantation (TAVI) indication has expanded to younger and lower risk patients. Consequently, interest in mid and long-term follow up and in the role of life expectancy, as a key factor for selecting the most tailored treatment, has grown. The aim of this retrospective study is to compare the 4-year survival of patients who underwent aortic valve replacement (AVR) *vs.* TAVI at our department.

Methods From September 2017 to December 2020, 673 consecutive patients with severe aortic valve stenosis were enrolled for AVR (n = 283) or TAVI (n = 390). Inclusion criteria was isolated severe aortic stenosis, while exclusion criteria were redo surgery, valve-in-valve procedure and the need for concomitant surgical procedures. Based on the Lee index, patients were divided into four groups according to their 4-year life expectancy. Four-year survival was assessed and reported using the Kaplan-Meier method. A multivariate regression analysis of risk factors for 4-year mortality was performed.

Results Four years survival is always superior in the AVR patients (89.8% *vs.* 75.6%, P < 0.001). Surgery is associated with a higher incidence of acute kidney injury (23% *vs.* 5.1%, P < 0.001), while TAVI is related to a higher incidence of new onset left bundle branch block (0 *vs.* 23.8%, P < 0.001), pace-maker implantation (2.5% *vs.* 11.8%, P = 0,02) and mild-to-moderate paravalvular leak (0.3% *vs.* 5.4%, P < 0.001). The independent risk factors for 4-years mortality are post-procedural AKI, poor mobility and transcatheter procedure.

Conclusion In our analysis, 4 years survival is always superior in the AVR patients. Life expectancy is a key factor for selecting the most appropriate approach for each patient. A longer follow up is mandatory before extending TAVI indication to patients with a long-life expectancy.

Aortic stenosis (AS) is the most common degenerative valvular disease in developed countries, with a prevalence of 3% among people over the age of 75.[1] Even if surgical aortic valve replacement (AVR) remains the gold standard for the treatment of AS, in the recent years transcatheter aortic valve implantation (TAVI) has been recognized as an attractive alternative to surgery. This process has been accelerated by several randomized clinical trials (RCTs) that have demonstrated similar outcomes comparing AVR and TAVI in high and intermediate-risk patients.[2-5]

Most recently, short and mid-term outcomes from prospective RCTs, comparing surgical and transcatheter approach in low-risk patients have been published.[6,7] These results led to an increased interest in the role of TAVI for the treatment of AS in younger and lower risk patients.

Furthermore, particular attention was paid to the choice of the best treatment option for elderly patients with a good life-expectancy.

Consequently, interest in mid and long-term follow up and in the role of life expectancy, as a key factor for selecting the most tailored treatment, has grown. The aim of this retrospective study is to compare 4-year survival and post procedural outcomes of patients who underwent AVR *vs.* TAVI at our department.

METHODS

The study design was approved by the local Ethics Committee at the Mauriziano Hospital, Turin - Italy (protocol number 260-2022). Informed consent was obtained from all patients.

Patient Population and Study Design

From September 2017 to December 2020, 673 consecutive patients with diagnosis of severe AS were enrolled for AVR or TAVI at our department. Severe AS was defined as a valve area of 1 cm^2 or less, or mean gradient of 40 mmHg or more, or maximal aortic valve velocity of 4.0 m or more per second as assessed by transthoracic echocardiography. Inclusion criteria was isolated severe AS, while exclusion criteria were prior heart surgery, valve-in-valve procedure, and the need for concomitant surgical procedures.

Procedural risk profile was assessed using Euroscore II.[8] Baseline characteristics such as age, sex, body mass index (BMI), hypertension, diabetes, dyslipidemia, kidney function, chronic obstructive pulmonary disease (COPD), peripheral vascular disease (PAD), poor mobility, previous stroke or transient ischemic attack (TIA), New York Heart Association (NYHA) class were evaluated in both groups.

Poor mobility was defined as a severe impairment of mobility secondary to musculoskeletal or neurological dysfunction,[8] and can be considered as an effective indicator of patient frailty.[9] Each patient was allocated to the most appropriate approach after an accurate Heart Team evaluation involving cardiothoracic surgeons, cardiologists, anesthesiologists, and radiologists assessing clinical history, blood tests, electrocardiogram, trans-thoracic echocardiography, computed tomography (CT), and cardiac catheterization of the patients. Particular relevance is given to the pre-operative CT which gives essential information necessary for proper patient selection and procedural success such as aortic annulus size, valvular and subvalvular calcifications, distance from annular plane and coronary ostia, diameter and amount of calcification of access route.

To minimize differences between the two groups, patients were divided into 4 groups according to their 4-year life expectancy based on the Lee index.[10] It is a prognostic index which considers demographic, behavior, comorbidity and functional status variables. It allows to stratify adult patients (50 years or older) into high-, intermediate-, and low-risk groups for 4-year mortality by adding the points for each variable. The points assigned to each of the 12 predictor variables are listed in Table 1.

Following Lee index, patients were divided into 4 groups according to their 4-year life expectancy: (1) 10 points or less: 4-year life expectancy ≥ 75%; (2) 11-12 points: 4-year life expectancy 55%; (3) 13 points: 4-year life expectancy 41%; (4) 14 points or more: 4-year life expectancy ≤ 36%.

Interventios

AVR were performed through full sternotomy or minimally invasive approach, central cannulation, hypothermic cardiopulmonary bypass (CBP), aortic cross clamping and myocardial protection was achieved using anterograde blood or crystalloid cardioplegia. Aortic prosthesis type and size were determined by the surgeon during the procedure. Both bovine pericardial valves such as Carpentier–Edwards Magna Ease™ (Edwards Lifesciences, Irvine, CA, USA) and Avalus™ (Medtronic, Minneapolis, MN, USA), and porcine valve such Epic bioprosthesis (Abbott, Chicago, IL, USA) have been implanted.

TAVI were performed mainly by a transfemoral approach under conscious sedation. Alternative approach such as trans-subclavian, trans-carotid, transapical and transcaval were used only in few cases when the former approach was not feasible. New generation self-expandable (Evolut[Medtronic, Minneapolis, MN, USA], Portico/Navitor [Abbott, Chicago, IL, USA]), and balloon expandable (Sapien, Edwards Lifesciences, Irvine, CA, USA) prosthesis were implanted. Prosthesis type and size and the most appropriate vascular access were established according to pre-procedural computed tomography. Cardiac catheterization was performed before surgery in the AVR group and before or during the procedure in TAVI patients.

Table 1 Points assignment to each of the 12 predictor variables.

Variables	Points
Age, yrs	1
60–64	2
65–69	3
70–74	4
75–79	5
80–84	6
≥ 85	7
Male sex	2
Diabetes mellitus	1
Cancer	2
Lung disease	2
Heart Failure	2
BMI < 25 kg/m^2	1
Current smoker	2
Difficult with bathing	2
Difficult with managing finances	2
Difficult with walking several blocks	2
Difficult with pulling or pushing heavy objects	1

BMI: body mass index.

Outcomes

The primary outcome assessed for the present study was 4-year all-cause mortality. Other outcomes of interest were: 30-day mortality, post procedural acute kidney injury (AKI), neurological events, new pacemaker (PM) implantation, paravalvular leak (PVL), new atrial fibrillation (AF) and left bundle branch block (LBBB). All the patients receive a follow up visit at 3 or 5 months after the procedure and an annual follow up phone call. The mean follow-up period was 1025 ± 378 days.

Statistical Analysis

Data were collected into a dedicated database and retrospectively analyzed. Normal variables and categorical variables were presented as mean and standard deviation (SD) and as frequency and percentage respectively.

In univariate analysis continuous variables were compared using unpaired *t*-test or Wilcoxon-Mann-Whitney according to distribution type. Categorical variables were compared with the use of the Chi-square test or Fisher exact test.

Four-year survival was assessed and reported using the Kaplan-Meier method. A multivariate regression analysis of risk factors for 4-year mortality was performed. Results of the multivariate analysis were expressed by hazard ratio and with a 95% CI. All *P*-values were two - sided and a *P*-values of 0.05 or less were considered statistically significant.

All analyses were performed with SPSS 26.0 (IBM, Chicago, USA).

RESULTS

During the study period, 673 patients with diagnosis of severe AS underwent AVR (n = 283, 42%) or TAVI (n = 390, 58%) at the Mauriziano Hospital in Italy and were enrolled in the present analysis. Preoperative patients' characteristics and comorbidities are reported in Table 2.

Patients in the TAVI group were older (82.6 ± 4.9 *vs.* 71.8 ± 11, $P < 0.001$), with higher incidence of COPD (27.2% *vs.* 17.3%, $P = 0.01$), PAD (17.4% *vs.* 15.9%, $P = 0.03$), with higher Euroscore II (5.12 ± 4.9 % *vs.* 2.4 ± 2.8%, $P < 0.0001$), higher serum creatinine level (1.43 ± 4.28 *vs.* 0.91 ± 0.46, p=0.043)and frailer (poor mobility rate 22% *vs.* 67%, $P < 0.001$) when compared to the AVR group.

Patients in the surgical group had a higher incidence of smoking (45.2% *vs.* 27.7%, $P < 0.001$). Nevertheless, when compare surgical and TAVI patients, divided into the abovementioned subgroups according to their 4-year life expectancy, the differences between the two study populations were minimized (Table 3).

In the subgroup with low 4-year life expectancy the only difference was about patients age, TAVI patients were older (84.3 ± 4.2 *vs.* 73.4 ± 11.9, $P < 0.001$) than surgical patients. In the two subgroups with intermediate 4-year life expectancy TAVI patients were older (82.25 ± 4.27/82.03 ± 4.09 *vs.* 73.15 ± 9.02/ 74.69 ± 11, $P < 0.001$) when compared to the AVR group, while surgical patients had a higher incidence of smoking (65.3/60.3 % *vs.* 20.3/15%, $P < 0.001$). Finally, in the subgroup with high 4-year life expectancy TAVI patients were older (78.78 ± 5.03 *vs.* 69.86 ± 10.9, $P < 0.001$), with higher Scr level (2.68 ± 2.51 *vs.* 0.85 ± 0.24, $P = 0.04$) and higher incidence of NYHA class III-IV (53.6% *vs.* 35.5%, $P = 0.015$) when compared to the surgical group. AVR patients had a higher incidence of smoking (27.7% *vs.* 3.6%, $P < 0.001$).

Table 2 Baseline characteristics and comorbidities of the two groups.

Variables	AVR (*n* = 283)	TAVI (*n* = 390)	*P*-value
Age, yrs	71.8 ± 11	82.6 ± 4.9	< 0.001
Female	126 (44.5%)	212 (54.3%)	0.01
BMI, kg/m^2	26.73 ± 4.58	26.12 ± 4.81	0.08
Hypertension	271 (95.7%)	361 (92.5%)	0.11
Diabetes	69 (24.4%)	113 (28.9%)	0.11
Dyslipidemia	138 (48.7%)	208 (53.3%)	0.24
Smoke	128 (45.2%)	108 (27.7%)	< 0.001
COPD	49 (17.3%)	106 (27.2%)	0.01
PAD	45 (15.9%)	68 (17.4%)	0.03
Serum creatinine, mg/dL	0.91 ± 0.46	1.43 ± 4.28	0.043
Stroke/TIA	20 (7.1%)	39 (9.2%)	0.21
Poor mobility	19 (6.7%)	86 (22%)	< 0.001
NYHA III-IV	114 (40.3%)	192 (49.3%)	0.063
Euroscore II	5.12 ± 4.9	2.42 ± 2.8	0.0001

Data are presented as mean ± SD or *n* (%). BMI: body max index; COPD: chronic obstructive pulmonary disease; PAD: peripheral artery disease; TIA: transient ischemic attack.

Regarding intra-operativa data, less than 5% of the patients did not receive a trasfemoral approach and the 70% of AVR were performed through a minimally invasive approach.

Post-operative outcomes are reported in Table 4. The incidence of death from any cause at 30 days was 2.5% (*n* = 7/283) in the AVR group and 1.8% (*n* = 7/390) in the TAVI group (*P* = 0.24). No significantly differences were recorded in terms of neurological complications, AF at discharge, access site infection and sepsis.

The incidence of post-procedural AKI was significantly higher in the AVR group when compared to the TAVI group (*n* = 66/283 [23%] *vs.* 20/390 [5.1%], *P* < 0.001), whereas permanent PM implantation occurred in 11.8% (*n* = 46/390] of the patients in the TAVI group and in 2.5% (*n* = 7/283) in the surgery group (*P* = 0.02).

The incidence of PVL (at least mild-moderate) was significantly higher in the TAVI group than in the surgical group (*n* = 99/390 [5.4%] *vs.* 1/283 [0.3%], *P* < 0.001). Post-procedural LBBB, persistent at discharge, is a typical complication of transcatheter approach (*n* = 93/390 [23.8%] *vs.* 0/283 [0], *P* < 0.001). Four-year survival was significantly higher in AVR patients when compared to the TAVI group (*n* = 254/283 [89.8%], *vs.* 295/390 [75.6%]; HR = 0.39 [95% CI: 0.26-0.59; *P* < 0.001]) (Figure 1). Post procedural outcomes did not significantly differ in the subgroups based on 4-year life expectancy.

In the subgroup with low 4-year life expectancy, surgical patients had a higher incidence of post-procedural AKI (*n* = 3/34 [8.8%] *vs.* 4/142 [2.8%], *P* = 0.03) and AF (2/34 [5.8%] *vs.* 2/142 [1.4%], *P* = 0.03), while TAVI patients had a higher rate of post procedural LBBB (*n* = 38/142 [26.8%] *vs.* 0, *P* < 0.001), new PM implantation (*n* = 21/142 [16.2%] *vs.* 0, *P* < 0,001) and PVL (*n* = 6/142 [4.2%] *vs.* 0, *P* = 0.04).

In the subgroup with 4-year life-expectancy of 41%, AVR patients showed a higher incidence of post-procedural AKI (*n* = 3/26 [11.5%] *vs.* 1/59 [1.71%], *P* = 0.02), whereas TAVI patients had a higher incidence of LBBB (*n* = 12/59 [20.3%] *vs.* 0, *P* < 0.001) and PVL (*n* = 5/59 [8.4%] *vs.* 0, *P* = 0.02).

In the subgroup with 4-year life-expectancy of 51%, AVR patients had a higher rate of post-procedural kidney damage (*n* = 10/68 [14.7%] *vs.* 1/133 [0.75%], *P* = 0.02), whereas TAVI patients had a higher incidence of LBBB (*n* = 30/133 [22.5%] *vs.* 0, *P* < 0.001), new PM implantation (*n* = 15/133 [11.31%] *vs.* 4/68 [5.9%], *P* = 0.02) and PVL (*n* = 7/133 [5.26%] *vs.* 1/68 [1.47%] , *P* = 0.04).

In the subgroup with higher life-expectancy, surgical patients had a higher rate of post-procedural AKI(*n* = 10/155 [6.4%] *vs.* 0, *P* = 0,02), whereas TAVI patients had a higher incidence of LBBB (*n* =

Table 3 Baseline characteristics and comorbidities according to 4-year life expectancy.

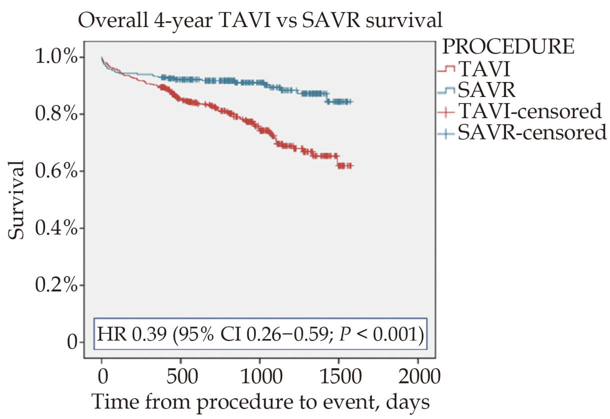
	4-year life expectancy ≤ 36%			4-year life expectancy of 41%			4-year life expectancy of 55%			4-year life expectancy ≥ 75%		
Variables	AVR (n = 34)	TAVI (n = 142)	P-value	AVR (n = 26)	TAVI (n = 59)	P-value	AVR (n = 68)	TAVI (n = 133)	P-value	AVR (n = 155)	TAVI (n = 56)	P-value
Age, yrs	73.4 ± 11.9	84.3 ± 4.2	< 0.001	73.15 ± 9.02	82.25 ± 4.27	< 0.001	74.69± 11	82.03 ± 4.9	< 0.001	69.86 ± 10.9	78.78 ± 5.03	< 0.001
Female	4 (11.8%)	31 (21.8%)	0.18	3 (11.5%)	34 (57.6%)	< 0.001	20 (29.4%)	94 (70.7%)	< 0.001	99 (63.9%)	53 (94.6%)	< 0.001
BMI, kg/m^2	26.52 ± 5.59	25.52 ± 4.2	0.24	27.52 ± 3.74	26.08 ± 4.46	0.15	27.22 ± 4.19	26.52 ± 4.89	0.31	26.46± 4.6	26.73 ± 6.17	0.73
Hypertension	33 (97.1%)	134 (94.4%)	0.52	25 (96.2%)	49 (83%)	0.09	68 (100%)	125 (93.9%)	0.09	144 (92.9%)	54 (96.4%)	0.42
Diabetes	15 (44.1%)	54 (38%)	0.54	6 (23.1%)	17 (28.8%)	0.64	25 (38.6%)	34 (25.6%)	0.2	23 (14.8%)	8 (14.3%)	0.39
Dyslipidemia	16 (47.1%)	75 (52.8%)	0.54	11 (42.3%)	32 (54.2%)	0.31	36 (52.9%)	70 (52.6%)	0.96	75 (48.4%)	32 (57.1%)	0.27
Smoke	16 (47.1%)	76 (53.5%)	0.11	17 (65.3%)	12 (20.3%)	<0.001	41 (60.3%)	20 (15%)	<0.001	43 (27.7%)	2 (3.6%)	< 0.001
COPD	17 (47.2%)	63 (44.3%)	0.55	13 (50%)	18 (30.5%)	0.08	12 (17.6%)	18 (13.5%)	0.41	7 (4.5%)	7 (12.5%)	0.08
PAD	45 (15.9%)	68 (17.4%)	0.43	9 (34.6%)	24 (40.7%)	0.55	16 (23.5%)	26 (19.5%)	0.52	23 (14.8%)	11 (19.6%)	0.4
Serum creatinine. mg/dL	1.27 ± 0.79	0.93 ± 0.21	0.55	0.96 ± 0.24	1.26 ± 0.91	0.09	1.01 ± 0.82	1.14 ± 0.79	0.31	0.85 ± 0.24	2.68 ±2.51	0.04
Stroke/TIA	11 (7.1%)	7 (20.4%)	0.1	1 (3.8%)	5 (8.5%)	0.61	5 (7.3%)	19 (14.3%)	0.32	7 (4.5%)	1 (1.8%)	0.47
Poor mobility	5 (14.7%)	34 (23.9%)	0.24	6 (23.1%)	20 (33.9%)	0.65	8 (11.8%)	25 (18.8%)	0.08	8 (5.1%)	7 (12.5%)	0.66
NYHA III-IV	18 (52.9%)	72 (50.7%)	0.81	9 (34.6%)	26 (44.1%)	0.47	32 (47.1%)	57 (42.9%)	0.57	55 (35.5%)	30 (53.6%)	0.015

Data are presented as mean ± SD or n (%). AVR: aortic valve replacement; COPD: chronic obstructive pulmonary disease; PAD: peripheral vascular disease; TAVI: transcatheter aortic valve implantation; TIA: transient ischemic attack.

Table 4 Main post-operative outcomes.

Variables	AVR (n = 283)	TAVI (n = 390)	P-value
30-day mortality	7 (2.5%)	7 (1.8%)	0.24
AKI	66 (23%)	20 (5.1%)	< 0.001
Stroke	6 (2.1%)	7 (1.8%)	0.7
TIA	2 (0.7%)	6 (1.5%)	0.5
[a]LBBB at discharge	0	93 (23.8%)	0.001
[a]AF at discharge	13 (4.6%)	12 (3.1%)	0.18
PM implantation	7 (2.5%)	46 (11.8%)	0.02
Access site infection	1 (0.3%)	2 (0.51%)	0.7
Sepsis	5 (1.8%)	7 (1.8%)	0.8
PVL (at least mild-moderate)	1 (0.3%)	21 (5.4%)	P < 0.001
4-year mortality	29 (10.2%)	95 (24.4%)	P < 0.001

Data are presented as n (%). [a]For LBBB and AF at discharge percentages, the denominator was the number of patients who developed post-procedural LBBB and AF in each group. AF: atrial fibrillation; AKI: acute kidney injury; LBBB: left bundle branch block; PM: pacemaker; PVL: paravalvular leak.



No. at risk	Baseline	1-year	2-year	3-year	4-year
AVR	283	266	264	182	101
TAVI	390	352	328	206	102

Figure 1 Overall 4-year Kaplan-Meier survival curves for AVR and TAVI patients. AVR: aortic valve replacement; TAVI: transcatheter aortic valve implantation; SAVR: surgical aortic valve replacement.

13/56 [23.2%] *vs.* 0, P < 0.001), new PM implantation(n = 4/56 [71%] *vs.* 3/155 [1.9%], P = 0.02) and PVL (n = 4/56 [7.14%] *vs.* 0, P = 0.02).

A multivariate model revealed three independent predictors of 4-year mortality: post procedural AKI (HR = 3.4, 95% CI: 1.97-5.98, P < 0.0001), poor mobility (HR = 3.6, 95% CI: 2.13-6.29, P < 0.0001) and transcatheter approach (HR 0.38, 95% CI 0.17–0.84, P = 0.017). PVL almost reached statistically significancy (HR = 1.32, 95% CI: 0.97–1.79, P = 0.074) (Table 5). In the subgroup with low 4-year life expectancy, the Kaplan-Meier 4-year estimate survival was 70.9% for patients in the TAVI group and 82.4% for patients in the surgical group (HR = 0.37 [95% CI: 0.23–0.85; P = 0.024]) (Figure 2).

Table 5 Multivariate analysis of risk factors for 4-year mortality.

Variables	P-value	HR	95% CI
Age	0.75	0.99	0.95–1.03
PM implantation	0.326	0.64	0.27–1.5
AKI	0.0001	3.4	1.97-5.98
Poor mobility	0.0001	3.6	2.13–6.29
PVL mild-moderate	0.074	1.32	0.97–1.79
TAVI	0.017	0.38	0.17–0.84

AKI: acute kidney injury; PM: pacemaker; PVL: paravalvular leak; TAVI: transcatheter aortic valve implantation.

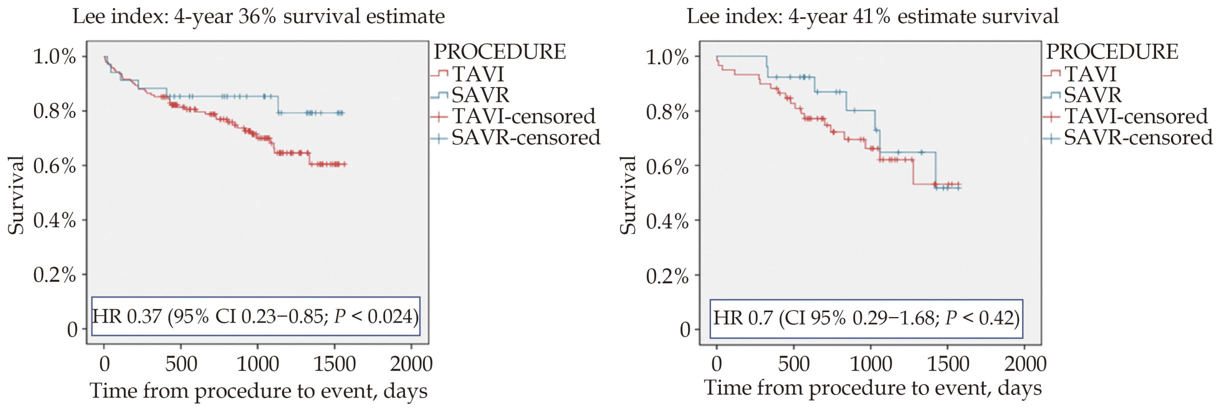
In the subgroup with intermediate life expectancy (41%), the Kaplan-Meier 4-year estimate survival was 67.8% for TAVI patients and 73.1% for AVR patients (HR = 0.7 [95% CI: 0.29–1.68; P < 0.42]) (Figure 2).

In the other subgroup with intermediate life expectancy (55%), the Kaplan-Meier 4-year estimate survival was 79.7% in the transcatheter group and 92.6% in the surgical group (HR = 0.31 [95% CI: 0.12–0.81; P < 0.01]) (Figure 2). In the subgroup with high life expectancy, the Kaplan-Meier 4-year estimate survival was 85.7% for TAVI patients and 92.9% for AVR patients (HR = 0.53 [95% CI: 0.21–1.32; P < 0.17]) (Figure 2).

DISCUSSION

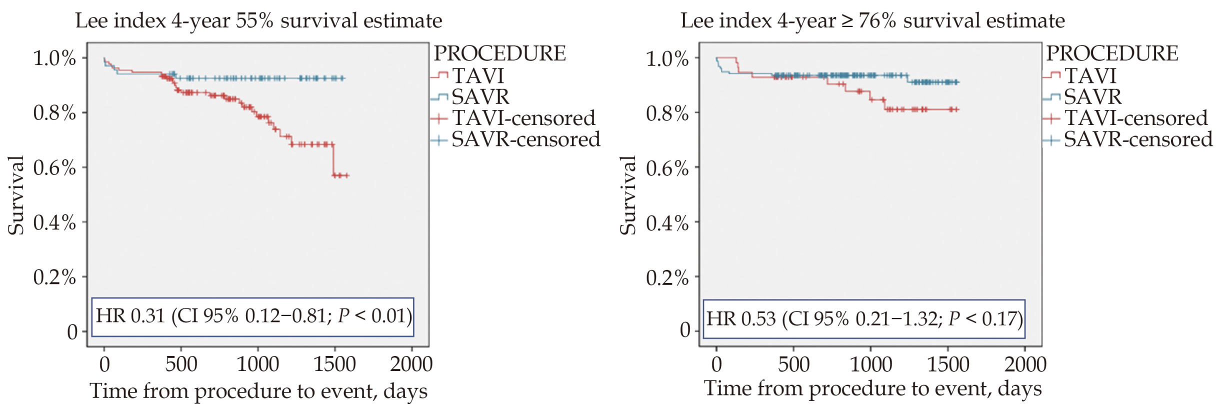
Since the first procedure was performed in a human in 2002,[11] TAVI has been recognized as an attractive alternative treatment of severe AS. Over the last years, TAVI has become the treatment of choice of AS in prohibitive[12] and high-risk patients[2,3] and a valid therapeutic option in intermediate-risk patients.[4,5] Recently, encouraged results have emerged from RCTs comparing TAVI and AVR in low-risk patients.[6,7]

Nowadays there is controversy in the literature about the widespread use of TAVI among these categories of patients, given the unknown prosthesis long-term durability and the impact on long-term



No. at risk	Baseline	1-year	2-year	3-year	4-year
AVR	34	30	30	21	11
TAVI	142	122	115	72	29

No. at risk	Baseline	1-year	2-year	3-year	4-year
AVR	26	25	23	13	8
TAVI	59	52	47	25	9



No. at risk	Baseline	1-year	2-year	3-year	4-year
AVR	68	64	62	44	23
TAVI	133	126	115	67	30

No. at risk	Baseline	1-year	2-year	3-year	4-year
AVR	155	144	143	92	40
TAVI	56	52	51	34	23

Figure 2 Kaplan-Meier survival curves for AVR and TAVI patients according to their 4-year 466 life expectancy. AVR: aortic valve replacement; TAVI: transcatheter aortic valve implantation.

outcomes of TAVI complications such as PVL, conduction abnormalities, neurological and vascular complications.

Even if recent data from RCTs demonstrated that TAVI is a feasible and safe procedure also in low-risk patients,[7,8,13] we must bear in mind that RCTs usually include high selected patients, not corresponding to the daily clinical practice. In this regard, Takagi and collogues performed a meta-analysis of mortality with ≥ 5 years of follow up in RCTs and in propensity score matched (PSM) studies of TAVI versus AVR. TAVI was associated with higher all-cause mortality in PSM studies, while no differences between the two procedures were reported in RCTs.[14]

Similar results have been reported in another meta-analysis by Witberg and collogues, in low-risk patients TAVI was significantly associated with increased midterm mortality in PMS studies, whereas no differences between the two approaches were reported in RCTs [15] These findings can be explained by the fact that patients enrolled in RCTs may not be representative of those typically seen in the real-world practice.

Beyersdorf and collogues have confirmed the better long-term survival rate of surgical patient.[16] They analyzed 5-year outcome data from the German Aortic Valve Registry (GARY) for 18010 patients underwent TAVI or AVR for severe AS. After propensity score matching TAVI was associated with significantly greater 5-year mortality than AVR (41.9% *vs.* 30.3%, $P < 0.0001$). According to literature, in our single-center retrospective analysis, TAVI patients had a higher 4-year mortality when compared to surgical patients (24.4% *vs.* 10.2%, $P < 0.001$). The higher mortality rate in TAVI patients is not unexpected, they are usually older, frailer and with more comorbidities than surgical patients, as reported in the overall baseline characteristics of our study population.

However, to make a meaningful comparison between the two study populations, patients were divided into 4 subgroups according to their 4-year life expectancy based on Lee index; the midterm survival remained superior in surgical patients and this difference resulted statistically significant in two subgroups.

One of the most interesting findings of our study was that TAVI was an independent risk factor of 4-year mortality. This result is in line with the literature; Barili and collogues demonstrated that TAVI has a protective effect in the short time that reverses over the time and after 2 years TAVI becomes a risk factor for all-cause mortality.[17]

In our analysis, as reported in literature, TAVI patients had a significantly higher incidence of postprocedural conduction abnormalities and PVL and these complications can overall impact on mid- and long-term survival. New-onset LBBB is a specific concern of TAVI and the development of LBBB could lead to cardiovascular events including AV block, sudden cardiac death, heart failure and rehospitalization.[18] Permanent pace-maker implantation leads to mechanical dyssinchrony and may decrease ventricular function.[19] Finally, PVL after TAVI has a negative impact on both overall survival and functional class.[20]

Furthermore, as reported by the STS-ACC Registry in 2020 stroke and new pace-maker implantation rates had just a small decline over the years despite technology improvements.[21] It is mandatory to reflect if these complications rates are still reasonable in lower risk patients too. In our analysis, the difference in terms of 4-year survival reached the statistical significancy in the subgroups with low and intermediate life-expectancy. This result may be explained by the fact that the abovementioned TAVI complications probably had a greater impact on frailer patients. We suppose that, if we prolonged the follow up period, we would get the same results in healthier patients too.

All these factors should be considered before extending routine clinical use of TAVI in younger and lower risk patients. Finally, considering the other post-procedural outcomes, despite several trials reported higher incidence of new onset of AF in surgical patients,[4,22] in our study it was mostly a transient complication whereas no significantly differences were reported in terms of AF rate at discharge.

Post-procedural AKI is a feared complication of both surgical and transcatheter procedures. In our analysis AKI had a higher incidence in surgical patients. However, in a further sub analysis we found out that despite the higher AKI incidence in AVR patients, kidney injury lasted longer in TAVI patients and had a greater impact on mid-term outcomes.[23]

The single-center non-randomized study design is clearly the main limitation. Results herein presented are specific to a single - center and may not be easily applied across all hospitals and geographic settings. Finally, a longer follow up and a larger study population are mandatory to confirm these findings.

In conclusion, despite TAVI has become a well-established alternative to surgery in high- and intermediate-risk patients, its indication in lower-risk patients is still controversial. In our analysis 4-year survival was always superior in surgical patients and TAVI has been recognized as an independent risk factor of mid-term mortality. Our results stress the importance of a longer follow up before extending TAVI indication to lower risk patients. Life expectancy, more than age, is a key factor for selecting the most appropriate approach in this patient category. TAVI should be reserved to patients with lower life expectancy who can benefit from the early protective effect of TAVI.

DISCLOSURE

Fundings

None.

Conflicts of Interests

None.

REFERENCES

[1] Iung B, Delgado V, Rosenhek R, *et al*. EORP VHD II Investigators. Contemporary Presentation and Manage-

ment of Valvular Heart Disease: The EURObservational Research Programme Valvular Heart Disease II Survey. *Circulation* 2019; 140: 1156−1169.
[2] Popma JJ, Adams DH, Reardon MJ, *et al*. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. *J Am Coll Cardiol* 2014; 631972-631981.
[3] Smith CR, Leon MB, Mack MJ, *et al*. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011; 364: 2187−2198.
[4] Reardon MJ, Van Mieghem NM, Popma JJ, *et al*. Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med* 2017; 376: 1321−1331.
[5] Leon MB, Smith CR, Mack MJ, *et al*. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2016; 374: 1609−1620.
[6] Mack MJ, Leon MB, Thourani VH, *et al*. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N Engl J Med* 2019; 380: 1695−1705.
[7] Popma JJ, Deeb GM, Yakubov SJ, *et al*. Evolut Low Risk Trial Investigators. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. *N Engl J Med* 2019; 380: 1706−1715.
[8] Nashef SA, Roques F, Sharples LD, *et al*. EuroSCORE II. *Eur J Cardiothorac Surg* 2012; 41: 734−744.
[9] Chandrasekhar J, Mehran R. Poor mobility independently predicts mortality in TAVI: Are we closer to a universal definition for frailty? *Catheter Cardiovasc Interv* 2015; 86: 1278-1279.
[10] Lee SJ, Lindquist K, Segal MR, Covinsky KE. Development and validation of a prognostic index for 4-year mortality in older adults. *JAMA* 2006; 295: 801−808.
[11] Cribier A, Eltchaninoff H, Bash A, *et al*. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation* 2002; 106: 3006−3008.
[12] Leon MB, Smith CR, Mack M, *et al*. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010; 363: 1597−1607.
[13] Jørgensen TH, Thyregod HGH, Ihlemann N, *et al*. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter *vs*. surgical aortic valve replacement. *Eur Heart J* 2021; 422912-422919.
[14] Takagi H, Hari Y, Nakashima K; All-Literature Investigation of Cardiovascular Evidence (ALICE) Group. A meta-analysis of ≥ 5-year mortality after transcatheter versus surgical aortic valve replacement. *J Cardiovasc Surg (Torino)* 2020; 61107-61116.
[15] Witberg G, Lador A, Yahav D, Kornowski R. Transcatheter versus surgical aortic valve replacement in patients at low surgical risk: A meta-analysis of randomized trials and propensity score matched observational studies. *Catheter Cardiovasc Interv* 2018; 92: 408−416.
[16] Beyersdorf F, Bauer T, Freemantle N, *et al*. Five-year outcome in 18010 patients from the German Aortic Valve Registry. *Eur J Cardiothorac Surg* 2021; 60: 1139−1146.
[17] Barili F, Freemantle N, Musumeci F, *et al*. Five-year outcomes in trials comparing transcatheter aortic valve implantation versus surgical aortic valve replacement: a pooled meta-analysis of reconstructed time-to-event data. *Eur J Cardiothorac Surg* 2022; 61: 977−987.
[18] Megaly M, Abraham B, Abdelsalam M, *et al*. Short- and Long-Term Outcomes in Patients With New-Onset Persistent Left Bundle Branch Block After Transcatheter Aortic Valve Replacement. *Cardiovasc Revasc Med* 2020; 21: 1299−1304.
[19] Urena M, Webb JG, Tamburino C, *et al*. Permanent pacemaker implantation after transcatheter aortic valve implantation: impact on late clinical outcomes and left ventricular function. *Circulation* 2014; 129: 1233−1243.
[20] Bhushan S, Huang X, Li Y, *et al*. Paravalvular Leak After Transcatheter Aortic Valve Implantation Its Incidence, Diagnosis, Clinical Implications, Prevention, Management, and Future Perspectives: A Review Article. *Curr Probl Cardiol* 2021: 100957.
[21] Carroll JD, Mack MJ, Vemulapalli S, *et al*. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol* 2020; 76: 2492−2516.
[22] Adams DH, Popma JJ, Reardon MJ, *et al*. Transcatheter aortic valve replacement with a self-expanding prosthesis. *N Engl J Med* 2014; 370: 1790−1798.
[23] Lodo V, Audisio K, Zingarelli E, *et al*. Impact of Post-Procedural Acute Kidney Injury in Patients Undergoing Surgical Aortic Valve Replacement Versus Transcatheter Aortic Valve Implantation. *J Surg* 2023; 8: 1769.

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