

Cite this article as: Lodo V, Italiano EG, Weltert L, Zingarelli E, Pietropaolo C, Buono G *et al.* Transcatheter aortic valve implantation versus surgery in low-risk patients: in-hospital and mid-term outcomes. *Interdiscip CardioVasc Thorac Surg* 2025; doi:10.1093/icvts/ivaf103.

Transcatheter aortic valve implantation versus surgery in low-risk patients: in-hospital and mid-term outcomes

Vittoria Lodo ^{a,*}, Enrico Giuseppe Italiano^a, Luca Weltert^b, Edoardo Zingarelli^a, Claudio Pietropaolo^c, Gabriella Buono^c and Paolo Centofanti^a

^aDepartment of Cardiac Surgery, Azienda Ospedaliera Ordine Mauriziano di Torino, Turin, Italy

^bDepartment of Cardiovascular Sciences, European Hospital, Rome, Italy

^cDepartment of Cardiovascular Anesthesia and Intensive Care, Azienda Ospedaliera Ordine Mauriziano, Turin, Italy

*Corresponding author. Tel: +393475074912; fax: +390115082512; e-mail: vittoria.lodo90@gmail.com (V. Lodo).

Received 16 October 2024; received in revised form 28 January 2025; accepted 25 April 2025

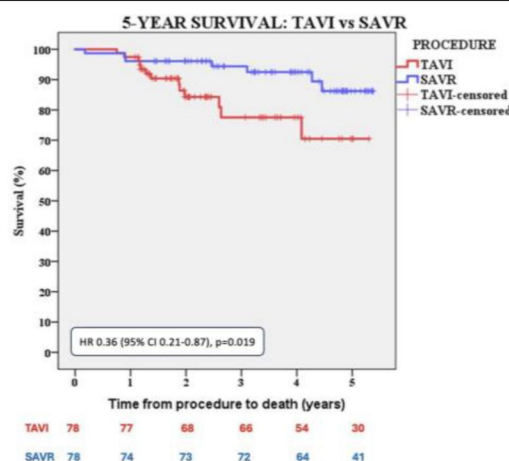
Transcatheter aortic valve implantation versus surgery in low-risk patients: in-hospital and mid-term outcomes.

Summary

In this propensity score-matching study a total of 351 patients undergoing AVR or TAVI were analysed.

78 AVR patients and 78 TAVI patients were compared.

TAVI patients showed a significant higher incidence of LBBB and permanent PM implantation and a higher mid-term mortality (HR 0.36 [95% IC 0.21-0.87], $p=0.019$)



AVR: aortic valve replacement, TAVI: transcatheter aortic valve implantation, LBBB: left bundle branch block, PM: pace-maker.

Abstract

OBJECTIVES: The aim of our study is to compare post-procedural outcomes and mid-term mortality of low-risk patients treated by transfemoral TAVI or surgical aortic valve replacement (AVR) for severe aortic stenosis.

METHODS: Data of consecutive patients undergoing AVR or TAVI from September 2017 to December 2021 were prospectively collected and retrospectively reviewed. Eligible patients were aged between 75 and 85 years with low-surgical risk and isolated severe aortic stenosis. Exclusion criteria were prior heart surgery, valve-in-valve procedure and the need for concomitant procedures. The primary end-point was mid-term all-cause mortality.

RESULTS: Three hundred fifty-one patients were enrolled. Of these, 243 underwent TAVI and 108 underwent AVR. Compared to AVR, TAVI patients were older (82 [78–83] vs 78 [77–80], $P < 0.001$), with higher incidence of advanced chronic kidney disease (33.3% vs 15.7%, $P < 0.001$) and poor mobility (15.6% vs 5.6%, $P = 0.008$) and a higher Euroscore II (2.2 [1.72–2.98] vs 1.9 [1.31–2.46], $P = 0.002$).

AVR patients had a higher incidence of post-procedural AKI (29.6% vs 4.5%, $P < 0.001$), while TAVI patients had a higher incidence of LBBB (23.9% vs 1.8%, $P < 0.001$) and at least mild to moderate PVL (4.5% vs 0%, $P = 0.021$). Mid-term mortality was higher among TAVI patients (HR 0.38 [95% CI 0.23–0.88], $P = 0.020$). In the matched cohort, TAVI had a higher incidence of LBBB (11.5% vs 1.3%, $P = 0.018$) and permanent PM implantation (12.8% vs 5.1%, $P = 0.041$), while AVR patients had a higher incidence of post-procedural AKI (33.3% vs 5.1%, $P < 0.001$). Mid-term mortality was higher in TAVI patients (HR 0.36 [95% CI 0.21–0.87], $P = 0.019$).

CONCLUSIONS: TAVI patients demonstrated a higher mid-term mortality and a higher incidence of post-procedural conduction abnormalities and PVL which remain a concern in low-risk patients.

Keywords: aortic valve replacement • transcatheter aortic valve implantation • low-risk patients

ABBREVIATIONS

AF	Atrial fibrillation
AKI	Acute kidney injury
AS	Aortic stenosis
AVA	Anatomic valve area
AVR	Aortic valve replacement
BMI	Body mass index
CKD	Chronic kidney disease
COPD	Chronic obstructive pulmonary disease
CPB	Cardiopulmonary bypass
CT	Computed tomography
EF	Ejection fraction
LBBB	Left bundle branch block
MI	Myocardial infarction
NYHA	New York Heart Association
PAD	Peripheral artery disease
PM	Pacemaker
PVL	Para-valvular leak
RBBB	Right bundle branch block
RCTs	Randomized clinical trials
RRT	Renal replacement therapy
TAVI	Transcatheter aortic valve implantation
TIA	Transient ischemic attack
ViV	Valve-in-valve

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has been recognized as the gold standard for the treatment of severe aortic valve stenosis (AS) in prohibitive and high-risk patients [1, 2] and a valid option in intermediate risk patients [3, 4].

Most recently, publication of PARTENER 3 [5] and Evolut Low Risk [6] trials, comparing TAVI with surgery in low-risk patients, has provided the basis for an increasing interest in transcatheter approach in this category of patients too.

Nevertheless, current randomized clinical trials (RCTs), based on low-risk patients, provide only short- and mid-term follow-up and do not reflect the real-world population.

Therefore, the data currently available are not sufficient to broaden TAVI indication to low-risk patients who are usually younger and with longer life expectancy when compared to intermediate and high-risk patients.

On the other hand, the long-term durability of bioprosthetic surgical valves has been proved in several studies [7, 8].

Our study aimed to compare post-procedural outcomes and mid-term survival of low-risk patients who underwent surgical aortic valve replacement (AVR) versus transfemoral TAVI at our department.

MATERIALS AND METHODS

The study was conducted in accordance with the ethical principles reported in the Declaration of Helsinki and Declaration of Taipei. Study design was approved by the local Ethics Committee at the Mauriziano Hospital, Turin–Italy (protocol number 260–2022). Informed consent was signed by each patient.

Patient population and study design

From September 2017 to December 2021, data of consecutive patients undergoing TAVI or AVR were prospectively collected and retrospectively reviewed.

Patients were eligible for the inclusion in the study if they had an isolated severe AS, a low surgical risk, defined as Euroscore II $< 4\%$ [9], and were aged between 75 and 85 years.

Exclusion criteria were prior heart surgery, valve-in-valve (ViV) procedure and the need for concomitant surgical or transcatheter procedures.

Each patient was allocated to the most appropriate approach after an accurate Heart Team evaluation based on clinical history, blood tests, electrocardiogram, transthoracic echocardiography, computed tomography (CT) and cardiac catheterization.

Indications for surgery or TAVI changed during the study period according to ESC/EACTS guidelines recommendations [10, 11].

Operative technique

All TAVI procedure were performed by transfemoral approach under conscious sedation, as previously described [12].

Both surgical and percutaneous transfemoral access were performed.

Both new generation balloon expandable (Sapien, Edwards Lifesciences, Irvine, CA, USA) and self-expandable (Evolut [Medtronic, Minneapolis, MN, USA], Portico/Navitor [Abbott, Chicago, IL, USA]) prosthesis were implanted.

AVR was performed using sternotomy or midsternotomy, central aortic cannulation, hypothermic cardiopulmonary bypass (CPB), aortic cross-clamping and myocardial protection with antegrade blood or crystalloid cardioplegia. All patients received a biological aortic valve prosthesis. Both bovine pericardial valves such as Carpentier–Edwards Magna Ease (Edwards Lifesciences, Irvine, CA, USA) and Avalor (Medtronic, Minneapolis, MN, USA), and porcine valve such Epic bioprosthesis (Abbott, Chicago, IL, USA) have been implanted.

End-points

The primary end-point was mid-term all-cause mortality.

The secondary end-points were post-procedural acute kidney injury (AKI), myocardial infarction (MI), stroke, permanent pacemaker (PM) implantation, new-onset persistent atrial fibrillation (AF), new-onset persistent left bundle branch block (LBBB), low cardiac output syndrome, para-valvular leak (PVL) ≥ 2 and prosthesis mean gradient.

AKI definition was based on KIDGO criteria [13].

Haemodynamic valve performance was evaluated by collecting echocardiographic data at three time points: at 6 months, 1 year and 3 years of follow-up.

All patients receive a follow-up visit at 3 months and an annual telephone survey.

The follow-up was completed on 15 June 2024.

Statistical analysis

Continuous data were presented as median and interquartile range (IQR), whereas categorical variables were presented with frequency and percentage. Differences between groups were assessed using paired Student's test for continuous variables and McNemar test for categorical variables. Five-year survival function was assessed and reported using the Kaplan–Meier method and the survival curves were compared using the log-rank test (Mantel–Cox). These methodologies were preferred over restricted mean survival time and stratified tests to ensure consistency with previous publications familiar to the average reader. To reduce possible differences between the two study groups, a matched analysis using propensity score was performed. Only patients with complete information for all covariates and outcomes were considered for the matching. Propensity matching was performed by running a logistic binary regression, with the procedure type as dependent variable, and the probability of the regression was stored and used as matching score by best neighbour matching. The overall efficacy of the match method was then tested re-running the logistic regression and verifying that no variables had significant difference. Impactful variables on univariate analysis in terms of both mortality and morbidity were included in order to avoid heavy preconditioners to be unbalanced in the caseload. The a priori selected variables were as follows: age (SMD 0.1321), gender (SMD 0.0456), Euroscore II (SMD 0.1784), poor mobility (SMD 0.0812), chronic kidney disease (CKD) stage III–IV (SMD 0.0987). Distribution of a priori variables is represented in Fig. 1.

All *P* values were two-sided and a *P* value <0.05 was considered statistically significant. All analyses were performed with SPSS 26.0 (IBM, Chicago, USA).

The mean follow-up period was estimated using the simplified person-time method.

RESULTS

Unmatched patient cohort

During the study period, 959 patients with diagnosis of severe isolated AS underwent AVR ($n=350$, 36.5%) or TAVI ($n=609$, 63.5%) at Mauriziano Hospital in Italy. Among these, 351 patients met the inclusion criteria. One hundred eight (30.8%) of

the selected patients underwent AVR, whereas 243 (69.2%) underwent TAVI.

There were significant differences in baseline characteristics.

Patients in the TAVI group were older (82 [78–83] vs 78 [77–80], $P<0.001$), with higher incidence of advanced CKD (33.3% vs 15.7%, $P<0.001$) and poor mobility (15.6% vs 5.6%, $P=0.008$) and a higher Euroscore II (2.2 [1.72–2.98] vs 1.9 [1.31–2.46], $P=0.002$) when compared to the surgical group.

Further baseline characteristics are given in [Supplementary Table S1](#).

Post-operative outcomes are reported in [Supplementary Table S2](#).

The incidence of post-procedural AKI was significantly higher in the AVR group when compared to the TAVI group (29.6% vs 4.5%, $P<0.001$), with a significant higher need of hemodialysis among surgical patients than in TAVI patients (4.6% vs 0.82%, $P=0.042$).

Post-procedural LBBB occurred in 23.9% of TAVI patients and in 1.8% of surgical patients ($P<0.001$).

The incidence of PVL was significantly higher in the TAVI group than in the surgical group (4.5% vs 0%, $P=0.021$).

No significant differences were reported in terms of in-hospital stroke, in-hospital MI, new-onset persistent AF, permanent PM implantation, low-output syndrome and mean prosthesis gradient.

In TAVI cohort, two patients (0.82%) reported major access site complications.

The mean in-hospital length of stay in AVR and TAVI group was 12.1 ± 11.5 days and 5.71 ± 5.6 days, respectively.

In AVR group, echocardiographic data were available in 92, 83 and 70.4% of survivors at 6 months, 1 year and 3 years, respectively. A slight increase in prosthesis mean gradient from discharge to 6 months was reported (12.5 [9.25–15.75] vs 13.7 [10.2–15.75], $P=0.02$), whereas no further significant increase of mean gradient was found to 6 months to 1 year and from 6 months to 3 years.

In TAVI group, echocardiographic follow-up was available in 90.1, 84 and 68.6% of survivors at 6 months, 1 year and 3 years, respectively. No significant differences have been reported in prosthesis mean gradient.

The 76% of patients reached 3-year follow-up, whereas the 48% of patients completed 5-year follow-up.

In the unmatched cohort the mid-term mortality of TAVI ($n=39/243$, 16%) versus AVR ($n=12/108$, 11%) patients showed a significant difference (HR 0.38 [95% CI 0.23–0.88], $P=0.020$) (Fig. 2).

Matched cohort

Propensity score matching of 108 AVR and 243 TAVI patients resulted in an excellent match of 78 patients in each group (44.4% of study population).

Baseline characteristics of the matched groups are reported in Table 1.

Post-procedural outcomes of the matched patient cohort are reported in Table 2.

AVR patients still had a higher incidence of post-procedural AKI (33.3% vs 5.1%, $P<0.001$) when compared to TAVI cohort, however, no significant difference was reported in terms of need of hemodialysis between the two groups.

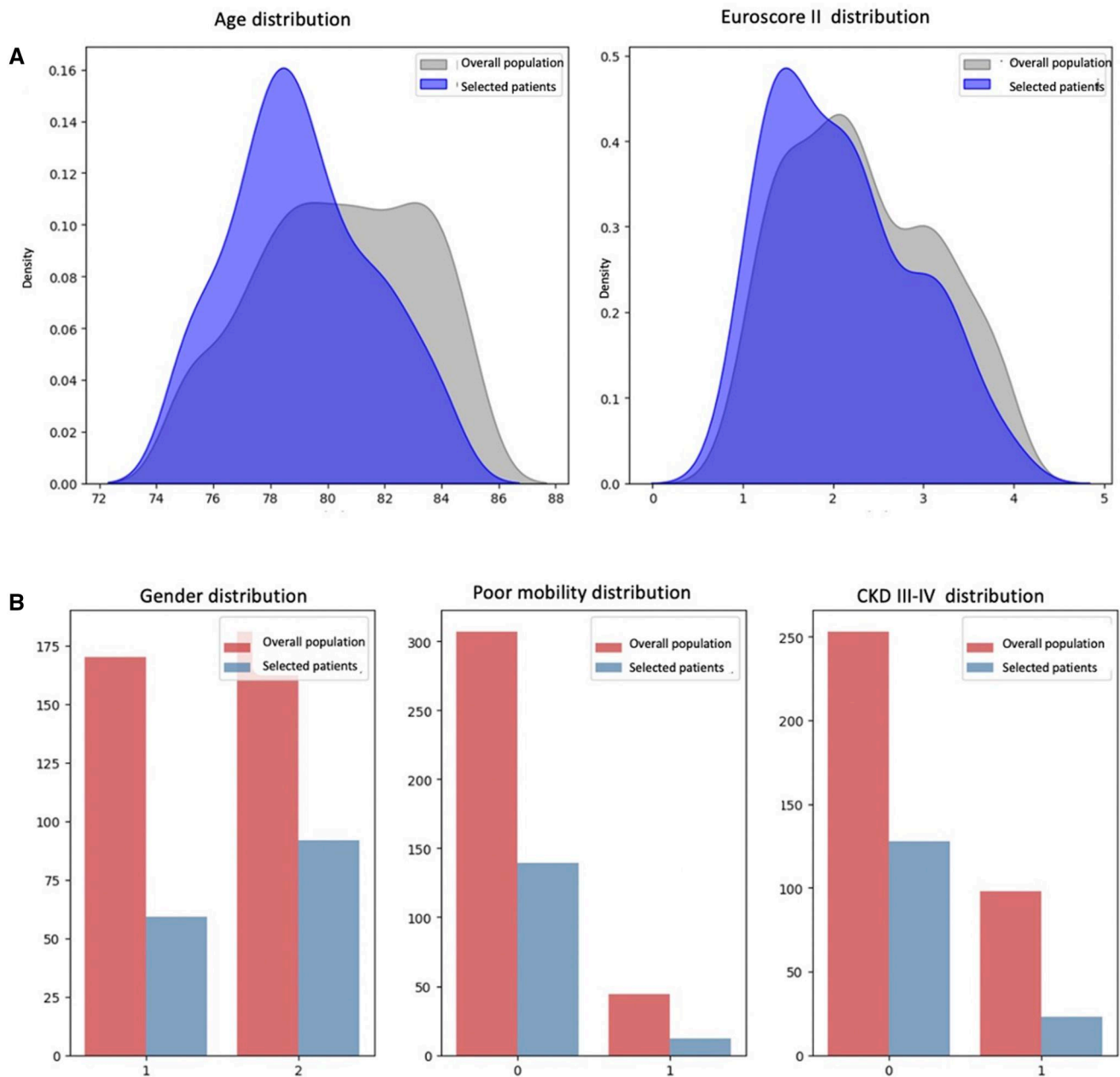


Figure 1: Overlapping plot for continuous **(A)** and categorical **(B)** variables

TAVI patients had a higher incidence of post-procedural LBBB (11.5% vs 1.3%, $P=0.018$) and permanent PM implantation (12.8% vs 5.1%, $P=0.041$).

No cases of femoral complications have been reported among TAVI patients.

There was further no difference between in hospital neurological complications, in-hospital MI, PM implantation, persistent AF, low-output syndrome, mean prosthesis gradient and PVL.

The mean in-hospital length of stay in AVR and TAVI group was 8.45 ± 2.2 days and 4.6 ± 3.4 days, respectively.

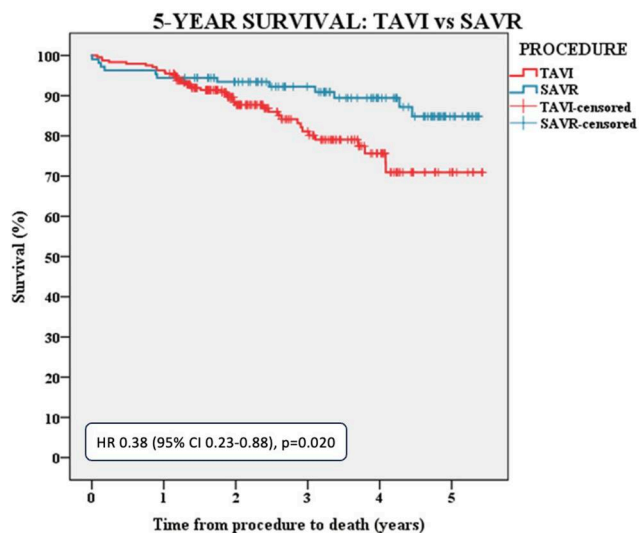
In AVR group, echocardiographic follow-up was completed in 91, 78.6 and 74.4% of survivors at 6 months, 1 year and 3 years, respectively. A mild increase in prosthesis mean gradient from discharge to 6 months was reported ($11 [9-15.75]$ vs 12.5

$[10-15.89]$, $P=0.03$), successively prosthesis mean gradient remained substantially stable from 6 months to 1 year ($12.5 [10-15.89]$ vs $12.62 [10.4-15.71]$, $P=0.88$) and from 6 months to 3 years ($12.5 [10-15.89]$ vs $12.59 [9.8-15.76]$, $P=0.73$).

In TAVI group, echocardiographic follow-up was available in 93.4, 85.5 and 63.6% of survivors at 6 months, 1 year and 3 years, respectively. No significant differences have been reported in prosthesis mean gradient from discharge to 6 months ($9 [7-11]$ vs $9.1 [7.38-11.2]$, $P=0.074$), and from 6 months to 1 year ($9 [7-11]$ vs $9.1 [7.33-11.18]$, $P=0.42$) and from 6 months to 3 years ($9 [7-11]$ vs $9.3 [7.56-11.47]$, $P=0.08$).

The 78% of patients reached 3-year follow-up, whereas the 49% of patients completed 5-year follow-up.

In the propensity matched population, during the follow-up, there were 13 deaths (16.7%) among TAVI patients compared



TAVI	243	234	225	218	136	81
SAVR	108	102	98	96	89	70

Figure 2: Kaplan-Meier survival curves for TAVI vs AVR patients, unmatched cohort

with 7 deaths (8.9%) among AVR patients (HR 0.36 [95% CI 0.21–0.87], $P = 0.019$) (Fig. 3).

DISCUSSION

In this single-centre retrospective analysis evaluating post-procedural outcomes and mid-term survival in patients undergoing TAVI or AVR for severe aortic valve stenosis, we found that AVR patients had a significantly higher mid-term survival in both unmatched and matched cohort and a lower incidence of conduction abnormalities and PVL when compared to TAVI patients.

The encouraging results of recent RCTs [5, 6], comparing TAVI and AVR in low-risk patients, have led to a rapid spread of TAVI indication to younger and lower risk patients.

Consequently, the latest ESC/EACTS guidelines [10] provided a class I recommendation for the use of TAVI in patients older than 75 years or in those with high surgical risk, whereas AVR is recommended in patients younger than 75 years who are low risk for surgery, or in patients who are operable and unsuitable for transfemoral TAVI.

Despite the growing enthusiasm about transcatheter procedures, the widespread use of TAVI among younger and lower risk patients is still a controversial matter in the literature.

TAVI is associated with higher incidence of new PM implantation, LBBB, PVL and stroke. Although these disadvantages may be acceptable in prohibitive-, high- and intermediate-risk patient, their impact in younger lower risk patients is still a source of concern.

In the unmatched cohort, as reported in the literature, TAVI patients had a significantly higher rate of LBBB and PLV when compared to AVR patients. In the matched cohort, TAVI patients showed a higher rate of post-procedural LBBB and PM

implantation than in AVR patients, whereas the incidence of PVL is still higher in TAVI patients but it did not reach the statistical significance.

We supposed that all these factors can overall impact in mid- and long-term survival of TAVI patients.

New-onset LBBB development could lead to cardiovascular events including atrioventricular block, sudden cardiac death, heart failure and rehospitalization [14].

As reported in the literature, permanent PM implantation is associated with an increased risk of heart failure hospitalization and all-cause mortality [15].

PVL is due to incomplete apposition between the aortic annulus and the prosthesis and has a negative impact on both overall mortality and functional class [16, 17].

Before extending TAVI indication to younger and lower risk patients, other two main aspects must be considered: bioprosthesis durability and coronary access.

The long-term durability of bioprosthetic surgical valves and the satisfactory life expectancy after AVR has been confirmed in several studies [8, 18].

Martinsson and colleagues [7] reported outcomes of 8.353 patients older than 60 years who underwent AVR with a bioprosthetic valve between 2001 and 2017. They conclude that the median survival after surgery is considerable, especially in younger and lower risk patients with a good balance between the lifespan of the bioprosthetic valve and the patient life expectancy.

Furthermore, in the last years, new bioprosthesis such as Inspiris Resilia (Edwards Lifesciences LLC, Irvine, CA, USA) have been developed in order to reduce structural valve deterioration and further improve the durability of the bioprosthetic valves.

In a recent review, Sef and colleagues reported encouraging results regarding mid-term safety and haemodynamic performance of this novel bioprosthetic valve [19].

For TAVI, long-term durability beyond 5–8 years is poorly understood [20, 21].

Recently, Thyregod and colleagues published 10-year outcomes of NOTION trial [22]. They concluded that in low-risk patients, the risk of major clinical outcomes was not different 10 years after AVR or TAVI, whereas the risk of severe structural valve deterioration was lower after TAVI. However, NOTION trial presents several limitations. As other RCTs, it enrolled highly selected patients who are not representative of real-world population. Furthermore, it takes into consideration surgical bioprosthesis such as Trifecta and Mitroflow with a well-known poor long-term performance. Finally, only few patients reached 10-year follow-up. All these factors undermined the comparison between TAVI and AVR and consequently data from NOTION trial are not enough to extend TAVI indication to patients with a long life expectancy.

Therefore, before evaluating TAVI in younger lower risk patients, it is important to keep in mind that this category of patients is at high-risk of undergoing further surgical valve replacement or ViV procedure.

Few data are available on the treatment of failed TAVI.

Surgical replacement of a failed TAVI can be complex, potentially requiring an aortic root replacement.

Jawitz and colleagues [23] found that AVR following failed TAVI is related to worse than expected outcomes when compared to similar patients initially undergoing surgery. The operative mortality rate was 17.1% with a longer median operative

Table 1: Baseline characteristics matched cohort

Variables	AVR (n = 78)	TAVI (n = 78)	P value
Age, median (IQR), years	79 (77–81)	79 (78–81)	0.869
Female, n (%)	33 (42.3%)	32 (41.0%)	1.000
BMI, median (IQR), kg/m ²	26.81 (24.54–28.65)	26.72 (24.31–28.54)	0.554
Hypertension, n (%)	76 (97.4%)	76 (97.4%)	1.000
Diabetes, n (%)	24 (30.8%)	23 (29.5%)	1.000
Dyslipidaemia, n (%)	40 (51.3%)	47 (60.2%)	0.337
Smoking habit, n (%)	23 (29.5%)	28 (35.9%)	0.496
COPD, n (%)	11 (14.1%)	17 (21.8%)	0.664
PAD, n (%)	10 (12.8%)	20 (25.6%)	0.067
CKD III–IV, n (%)	16 (20.5%)	10 (12.8%)	0.283
RRT, n (%)	0	2 (2.6%)	0.497
History of cerebrovascular event, n (%)	9 (11.5%)	7 (8.9%)	0.793
History of coronary disease, n (%)	10 (12.8%)	11 (14.1%)	0.635
History of malignancy, n (%)	6 (7.7%)	7 (8.9%)	0.978
Poor mobility, n (%)	6 (7.7%)	8 (10.3%)	0.781
RBBB, n (%)	9 (11.5%)	7 (8.9%)	0.426
Mean gradient, median (IQR), mmHg	47 (42–53.5)	45 (40–52.75)	0.655
AVA, median (IQR), cm ²	0.75 (0.38–0.89)	0.76 (0.37–0.9)	0.788
NYHA III–IV, n (%)	33 (42.3%)	34 (43.6%)	1.000
History of heart failure, n (%)	11 (14.1%)	19 (24.1%)	0.429
EF, median (IQR)	60 (55–65)	60 (60–65)	0.763
Euroscore II, median (IQR)	2.21 (1.56–3.06)	2.19 (1.63–2.94)	0.815

IQR: interquartile range; BMI: body mass index; COPD: chronic obstructive pulmonary disease; PAD: peripheral artery disease; CKD: chronic kidney disease; RRT: renal replacement therapy; RBBB: right bundle branch block; AVA: anatomic valvular area; NYHA: New York Heart Association; EF: ejection fraction.

Table 2: Post-procedural outcomes matched cohort

Variables	AVR (n = 78)	TAVI (n = 78)	P value
AKI, n (%)	26 (33.3%)	4 (5.1%)	<0.001
Haemodialysis, n (%)	1 (1.3%)	0	1.000
Stroke, n (%)	1 (1.3%)	0	1.000
MI, n (%)	1 (1.3%)	1 (1.3%)	1.000
New-onset LBBB, n (%) ^a	1 (1.3%)	9 (11.5%)	0.018
New-onset AF, n (%) ^a	3 (3.8%)	2 (2.6%)	1.000
PM implantation, n (%)	4 (5.1%)	10 (12.8%)	0.041
Low-output cardiac syndrome, n (%)	3 (3.8%)	2 (2.6%)	1.000
Prosthesis gradient, mean, (SD), mmHg	11 (9–15.75)	9 (7–11)	0.154
PVL (at least mild-moderate), n (%)	0	3 (3.8%)	0.245
5-year all-cause mortality, n (%)	7 (8.9%)	13 (16.7%)	0.0019

AKI: acute kidney injury; MI: myocardial infarction; LBBB: left bundle branch block; AF: atrial fibrillation; PM: pacemaker; PVL: paravalvular leak. Bolded values represent significant p values.

time, CBP time and cross-clamp time and a higher incidence of post-operative complications when compared to patients undergoing conventional AVR.

Hawkins *et al.* [24] sought to evaluate the risk of AVR after prior TAVI or AVR. They found that compared with redo AVR after AVR, redo AVR after TAVI is associated with an increased mortality (11.3% vs 6.7%, $P = 0.020$).

TAVI-in-TAVI represent approximately the 0.3% of all TAVI procedures. In their study registry, Landes *et al.* [25] examined outcomes following redo-TAVI. Two hundred twelve consecutive TAVI-in-TAVI procedures were taken into consideration with 2.9% overall mortality, low rate of stroke and coronary obstruction but a 9% incidence of \geq moderate PVL.

When approaching TAVI in younger lower-risk patients, an improvement in our knowledge of long-term TAVI durability is mandatory to choose the best first implanted prosthesis in this category of patients, who must be informed on the potential need for repeat procedures.

Moreover, while in surgical patients' coronary re-access is an easy procedure, in TAVI patients, it may be difficult.

Tang and colleagues [26] found that in 51.4% of cases the TAVI neo-commissures were in the closest proximity to one or both coronary ostia with a potential negative impact on coronary re-access.

The ability to re-access coronary ostia is particularly relevant in younger patients who are more likely to require percutaneous coronary intervention after TAVI.

In our single-centre retrospective analysis, TAVI patients showed a significantly mid-term all-cause mortality in both unmatched and matched cohort.

Similar results were reported in the literature.

Beyersdorf and colleagues reported 5-year outcome data from the German Aortic Valve Registry (GARY) for 18,010 patients underwent TAVI or AVR for severe AS [27]. In the matched cohort, TAVI patients had a higher 5-year mortality than surgical patients (41.9% vs 30.3%, $P < 0.0001$).

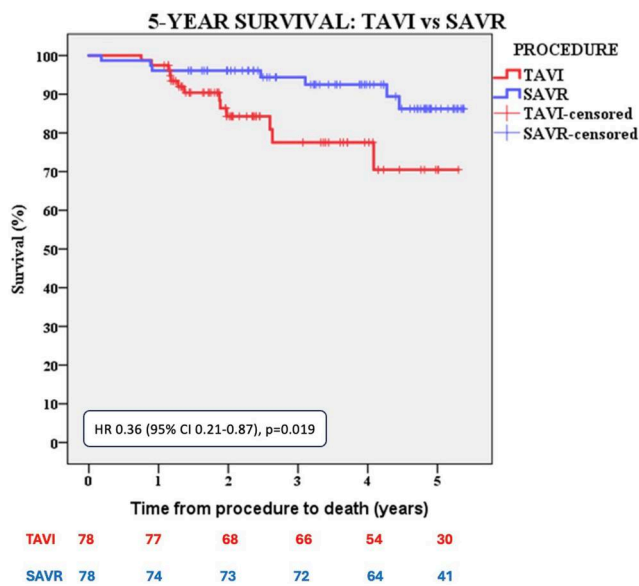


Figure 3: Kaplan-Meier survival curves for TAVI vs AVR patients, matched cohort

A recent propensity score-matching analysis by Krasniqi *et al.* [28] demonstrated that AVR was associated with superior outcomes in terms of 5-year survival and incidence of cerebrovascular events when compared to TAVI.

In a recent meta-analysis by Barili and colleagues [29], TAVI have a protective effect in the short term that disappears after 1 year. TAVI become a risk factor for all-cause mortality after 2 years and for rehospitalization after 6 months.

These results are in contrast with those reported in the major RCTs [1-6].

This difference may be explained by the fact that patients enrolled in RCTs are high selected patients who are not representative of those typically seen in the real-world practice.

At this regard, Takagi *et al.* performed a meta-analysis evaluating mortality, with ≥ 5 years of follow-up, in RCTs and in propensity score matched studies of TAVI versus AVR. TAVI was associated with higher all-cause mortality in propensity score matched studies, whereas no differences between the two procedures were reported in RCTs [30].

The main limitation of the present study lies in its retrospective observational design and in the lack of randomization. Even if we performed a propensity score matching to ensure the comparability and similar risk profiles of the two groups, we cannot exclude that unmeasured confounders may have influenced the study outcomes.

The second limitation of the presents analysis is the small sample size due to its monocentric nature.

Furthermore, the mid-term follow-up is limited, and a longer follow-up period is mandatory to better understand the long-term outcomes in low-risk patients with longer life expectancy.

Finally, another limitation stems from the lack of a standardized echocardiographic follow-up: echocardiographic follow-up was performed by cardiologists of different referring hospitals and only prosthesis mean gradient has been reported. A larger number of echocardiographic data are required to better define haemodynamic prosthesis performance.

CONCLUSION

Compared with AVR, TAVI is associated with a higher mortality at mid-term follow-up and with a higher incidence of post-procedural conduction abnormalities and PVL in low-risk patients.

Our results point out the importance of a longer follow-up period before extending TAVI indication to lower risk patients with long life expectancy.

More data on long-term outcomes following TAVI in low-risk patients are still needed before routinely recommending TAVI for this category of patients.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

FUNDING

None declared.

CONFLICT OF INTEREST

None declared.

DATA AVAILABILITY

The raw data supporting the conclusions of this article will be made available by the authors, without undue revision.

Author contributions

Vittoria Lodo: Conceptualization; Formal analysis; Resources; Writing—original draft. **Enrico Giuseppe Italiano:** Data curation; Writing—review & editing. **Luca Weltert:** Data curation; Writing—review & editing. **Edoardo Zingarelli:** Data curation; Writing—review & editing. **Claudio Pietropaolo:** Data curation; Writing—review & editing. **Gabriella Buono:** Conceptualization; Project administration. **Paolo Centofanti:** Conceptualization; Project administration

Reviewer information

Interdisciplinary CardioVascular and Thoracic Surgery thanks Hüseyin Ayhan, Brian E. Glenville and the other anonymous reviewer(s) for their contribution to the peer review process of this article.

REFERENCES

- [1] Mack MJ, Leon MB, Smith CR *et al.*; PARTNER 1 trial investigators. 5-Year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomized controlled trial. *Lancet* 2015; 385:2477-84.
- [2] Gleason TG, Reardon MJ, Popma JJ *et al.*; CoreValve U.S. Pivotal High Risk Trial Clinical Investigators. 5-Year outcomes of self-expanding transcatheter versus surgical aortic valve replacement in high-risk patients. *J Am Coll Cardiol* 2018;72:2687-96.

- [3] Makkar RR, Thourani VH, Mack MJ *et al.*; PARTNER 2 Investigators. Five-year outcomes of transcatheter or surgical aortic-valve replacement. *N Engl J Med* 2020;382:799–809.
- [4] Reardon MJ, Van Mieghem NM, Popma JJ *et al.*; SURTAVI Investigators. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2017;376:1321–31.
- [5] Mack MJ, Leon MB, Thourani VH *et al.*; PARTNER 3 Investigators. Transcatheter aortic-valve replacement in low-risk patients at five years. *N Engl J Med* 2023;389:1949–60.
- [6] Forrest JK, Deeb GM, Yakubov SJ *et al.* 3-Year outcomes after transcatheter or surgical aortic valve replacement in low-risk patients with aortic stenosis. *J Am Coll Cardiol* 2023;81:1663–74.
- [7] Martinsson A, Nielsen SJ, Milojevic M *et al.* Life expectancy after surgical aortic valve replacement. *J Am Coll Cardiol* 2021;78:2147–57.
- [8] Francica A, Benvegnù L, San Biagio L *et al.* Ten-year clinical and echocardiographic follow-up of third-generation biological prostheses in the aortic position. *J Thorac Cardiovasc Surg* 2024;167:1705–13.e8.
- [9] Nashef SAM, Roques F, Sharples LD *et al.* EuroSCORE II. *Eur J Cardiothorac Surg* 2012;41:734–44.
- [10] Vahanian A, Beyersdorf F, Praz F *et al.*; ESC/EACTS Scientific Document Group. 2021 ESC/EACTS guidelines for the management of valvular heart disease. *Eur J Cardiothorac Surg* 2021;60:727–800. Erratum in: *Eur J Cardiothorac Surg* 2022;61:964.
- [11] Baumgartner H, Falk V, Bax JJ *et al.*; ESC Scientific Document Group. 2017 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J* 2017;38:2739–91.
- [12] Lodo V, Italiano EG, Weltert L *et al.* The influence of gender on outcomes following transcatheter aortic valve implantation. *Front Cardiovasc Med* 2024;11:1417430.
- [13] Levey AS, Eckardt K-U, Tsakamoto Y *et al.* Definition and classification of chronic kidney disease: a position statement from Kidney Disease: improving Global Outcomes (KDIGO). *Kidney Int* 2005;67:2089–100.
- [14] Sasaki K, Izumo M, Kuwata S *et al.* Clinical impact of new-onset left bundle-branch block after transcatheter aortic valve implantation in the Japanese population - a single high-volume center experience. *Circ J* 2020;84:1012–9.
- [15] Faroux L, Chen S, Muntané-Carol G *et al.* Clinical impact of conduction disturbances in transcatheter aortic valve replacement recipients: a systematic review and meta-analysis. *Eur Heart J* 2020;41:2771–81.
- [16] 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* 2022;47:100957.
- [17] Dubois C, Coosemans M, Rega F *et al.* Prospective evaluation of clinical outcomes in all-comer high-risk patients with aortic valve stenosis undergoing medical treatment, transcatheter or surgical aortic valve implantation following heart team assessment. *Interact CardioVasc Thorac Surg* 2013;17:492–500.
- [18] Glaser N, Persson M, Jackson V, Holzmann MJ, Franco-Cereceda A, Sartipy U. Loss in life expectancy after surgical aortic valve replacement: SWEDEHEART study. *J Am Coll Cardiol* 2019;74:26–33.
- [19] Sef D, Thet MS, Klokocovnik T, Luthra S. Early and mid-term outcomes after aortic valve replacement using a novel tissue bioprosthesis: a systematic review. *Eur J Cardiothorac Surg* 2024;65:ezae045.
- [20] Søndergaard L, Ihlemann N, Capodanno D *et al.* Durability of transcatheter and surgical bioprosthetic aortic valves in patients at lower surgical risk. *J Am Coll Cardiol* 2019;73:546–53.
- [21] Barbanti M, Costa G, Zappulla P *et al.* Incidence of long-term structural valve dysfunction and bioprosthetic valve failure after transcatheter aortic valve replacement. *J Am Heart Assoc* 2018;7:e008440.
- [22] Thyregod HGH, Jørgensen TH, Ihlemann N *et al.* Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial. *Eur Heart J* 2024;45:1116–24.
- [23] Jawitz OK, Gulack BC, Grau-Sepulveda MV, Jr, *et al.* Reoperation after transcatheter aortic valve replacement: an analysis of the society of thoracic surgeons database. *JACC Cardiovasc Interv* 2020;13:1515–25.
- [24] Hawkins RB, Deeb GM, Sukul D *et al.* Redo surgical aortic valve replacement after prior transcatheter versus surgical aortic valve replacement. *JACC Cardiovasc Interv* 2023;16:942–53.
- [25] Landes U, Webb JG, De Backer O *et al.* Repeat transcatheter aortic valve replacement for transcatheter prosthesis dysfunction. *J Am Coll Cardiol* 2020;75:1882–93.
- [26] Tang GHL, Zaid S, Ahmad H, Undemir C, Lansman SL. Transcatheter valve neo-commissural overlap with coronary orifices after transcatheter aortic valve replacement. *Circ Cardiovasc Interv* 2018;11:e007263.
- [27] Beyersdorf F, Bauer T, Freemantle N *et al.*; GARY Executive Board. Five-year outcome in 18 010 patients from the German Aortic Valve Registry. *Eur J Cardiothorac Surg* 2021;60:1139–46.
- [28] Krasniqi L, Brandes A, Mortensen PE, Gerke O, Riber L. Severe aortic stenosis treated with transcatheter aortic valve implantation or surgical aortic valve replacement with Perimount in Western Denmark 2016–2022: a nationwide retrospective study. *Interdiscip Cardiovasc Thorac Surg* 2024;39:ivae122.
- [29] 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;6:977–87.
- [30] Takagi H, Hari Y, Nakashima K, Kuno T, Ando T, 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;61:107–16.