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Transcatheter aortic valve implantation versus surgical aortic valve replacement in patients over 85 years old†

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Abstract

OBJECTIVES: Surgical aortic valve replacement (SAVR) for the treatment of in very old patients with severe aortic stenosis is associated with a high risk of morbidity and mortality. Transcatheter aortic valve implantation (TAVI) has become the preferred alternative. Therefore, we sought to evaluate outcomes in very old patients who underwent SAVR versus TAVI.

METHODS: A total of 169 consecutive patients aged ≥85 years underwent TAVI ($n = 68$) or SAVR ($n = 101$). A propensity score adjustment was used to compare outcomes including cost analysis.

RESULTS: The propensity score generated 40 pairs of patients with similar baseline characteristics. The TAVI group experienced atrioventricular block (37.5% vs 5%, $P < 0.01$) more frequently, a longer stay in the intensive care unit (median 5 days, range 1–35 vs median 2 days, range 1–6, $P < 0.01$) but a lower rate of new-onset atrial fibrillation (15% vs 47.5%, $P < 0.01$). The 30-day mortality rate was similar in the unmatched and matched cohorts (8.8% vs 5.0%, $P = 0.32$; 10% vs 7.5%, $P = 0.69$). One, 3- and 5-year overall survival rates (80% vs 90%, 56% vs 79%, 37% vs 71%, $P < 0.01$) and freedom from major adverse cardiac and cardiovascular events (72% vs 90%, 46% vs 76%, 17% vs 68%, $P < 0.01$) were lower in the TAVI group. An overall cost analysis indicated that TAVI was more expensive (€2084 vs €19 891).

CONCLUSIONS: In patients 85 years and older, SAVR seems to offer good short- and mid-term clinical outcomes compared to TAVI. Advanced age alone would not be an indication for TAVI in old–old patients.

Keywords: Over 85 • Aortic valve replacement • TAVI • Elderly • Aortic stenosis

BACKGROUND

Aortic stenosis is the most common valvular disease in the elderly [1, 2]. It is a frequent cause of morbidity and mortality [3], with a 2-year 90% mortality rate in symptomatic patients without surgery [4, 5]. Notably, improving surgical techniques and postoperative care resulted in a low-operative mortality rate after surgical aortic valve replacement (SAVR) and improved survival rates in the elderly population [1–6]. However, referring physicians still have the perception of a poor outcome after SAVR [3]; consequently, there is an increased likelihood of elderly patients being managed conservatively. In fact, although older age is not a contraindication for SAVR [6, 7], it is a common clinical practice to recommend TAVI for old–old patients even though the preoperative risk is not prohibitive or particularly high [7, 8]. Hence, we evaluated outcomes in old–old patients who underwent SAVR versus TAVI.

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METHODS

Patient population

Between 2007 and 2015, 169 consecutive patients ≥85 years with severe symptomatic aortic stenosis underwent SAVR or TAVI at the University Hospital of Udine, Italy. Patient selection and determination of further indications for TAVI or SAVR were performed by the heart team: cardiac surgeon, clinical cardiologist, interventional cardiologist, radiologist and anaesthesiologist. During the study period, there was a progressive shift to TAVI for patients who were considered inoperable to patients considered at high risk based on a logistic EuroSCORE [9] or the presence of porcelain aorta or frailty.

Procedures

For SAVR, stented and stentless biological prostheses were implanted using a full sternotomy and cardiopulmonary bypass. In patients with severe coronary artery disease, coronary artery bypass graft was performed concomitantly. For TAVI, the balloon-expandable Edwards SAPIEN-XT or SAPIEN-3 (Edwards Lifesciences, Irvine, CA, USA) or self-expandable CoreValve (Medtronic, Inc., Minneapolis, MN, USA) bioprostheses were implanted. The type of TAVI access, transfemoral, transaortic or transapical, was selected based on assessment using a pre-TAVI multi-imaging model. Whenever possible, the transfemoral approach was considered the first option. In patients with severe coronary artery disease affecting major vessels, the patients were treated with angioplasty 2–4 weeks before the TAVI procedure.

Outcomes

Early and late outcomes of SAVR and TAVI patients were compared using several perioperative end points according to the Valve Academic Research Consortium-2 guidelines [10]. Overall survival was defined as freedom from all-cause mortality. A major adverse cardiovascular and cerebral event (MACCE) was defined as a compound of all-cause mortality, myocardial infarction, major stroke (modified Rankin score ≥2) and valve-related rehospitalization.

Economic analysis was performed according to the regional cost reported by the health department grossly as follows: TAVI prosthesis, €20 000; surgical bioprostheses, €2500; catheterisation laboratory equipment expenses including equipment and doctors and nurses, €2520; operating room expenses including cardiopulmonary bypass, doctors and nurses €1966; reoperation for bleeding, €291; coronary angiography, €750; angioplasty with stent implantation, €1665; pacemaker implantation, €2991; intra-aortic balloon pump insertion, €1640; haemodialysis, €230; blood transfusions, €136; intensive care unit stay, €1400 per day; intermediate care stay, €1000 per day; ward stay, €650 per day; computed tomography scans, €120; echocardiogram, €70.

STATISTICAL ANALYSIS

Continuous variables were expressed as mean ± standard deviation or median and range, according to the data distribution. The data were analysed using the Shapiro–Wilk test to verify the normal distribution. Categorical variables were presented as absolute numbers and percentages.

The Student *t*-test or the Mann–Whitney *U* test was used to compare continuous variables between groups, as appropriate. Comparison of categorical variables was performed by χ^2 analysis or the Fisher exact test, as appropriate.

Due to imbalances in baseline characteristics between the TAVI and SAVR cohorts, a propensity score analysis was performed. Propensity scores were generated from a multivariable logistic regression model in which TAVI/SAVR status regressed on the baseline variables [age, New York Heart Association (NYHA) class, atrial fibrillation, logistic EuroSCORE, preoperative myocardial infarction, mitral regurgitation > moderate, frailty, previous angioplasty and cardiac surgery]. The matching method used to generate balanced cohorts was the single nearest neighbour, without replacement. [11].

Overall survival was defined as freedom from all-cause mortality. MACCE was defined as a compound of all-cause mortality, myocardial infarction, major stroke (modified Rankin score ≥2) and valve-related rehospitalization.

Overall survival and MACCE-free survival were determined using the Kaplan–Meier approach for unmatched and matched TAVI and SAVR cohorts. Comparisons between survival distributions were performed using the log-rank test, with estimation of the hazard ratio (HR) from a Cox regression model, after the proportional hazards assumption had been verified. Univariate and multivariate Cox regression analyses were also performed to determine the prognostic implications of each variable on overall survival and MACCE. Multivariate stepwise analyses included all variables significant at $P \leq 0.10$ in univariate analysis. Retention in the stepwise model required that the variable be significant at $P < 0.05$ in a multivariate analysis. Results are presented as HRs and 95% confidence intervals.

Analyses were performed with the Stata/SE 14.1 program for the Mac computer.

ADULT CARDIAC

RESULTS

The baseline clinical and echocardiographic characteristics of the study populations are presented in Table 1. TAVI patients were older (median age 87.8 years, range 85–94 years vs median age 85.9 years, range 85–89.6 years; $P < 0.01$) and more symptomatic in terms of NYHA functional class (median NYHA class 3, range 2–4 vs median NYHA class 2, range 1–4, $P < 0.01$). They also presented more frequently with atrial fibrillation (52.9% vs 29.7%, $P < 0.01$), previous angioplasty (29.9% vs 4.0%, $P < 0.01$) or a cardiac surgical procedure (16.2% vs 1% $P < 0.01$), frailty (7.4% vs 0%, $P < 0.01$), porcelain aorta (13.2% vs 0%, $P < 0.01$), mitral regurgitation > moderate (10.3% vs 2% $P = 0.02$), a higher logistic EuroSCORE (median logistic EuroSCORE 22%, range 5–63% vs median logistic EuroSCORE 15.5%, range 5.1–62.8%, $P < 0.01$) and a higher EuroSCORE II (median EuroSCORE II 3.4%, range 1.1–22.6% vs median EuroSCORE II 2.6%, range 1.2–20.5%, $P < 0.01$).

Procedures

In the TAVI group, there were 51 (75%) transfemoral procedures, 15 (22%) transapical procedures and 2 (3%) transaortic procedures. The balloon-expandable SAPIEN-XT or SAPIEN-3 bioprosthesis was used in 29 patients (43%), and the self-expanding CoreValve was used in 39 (57%) patients. The median implanted size was 26 (21–31) mm. Ten patients (15%) underwent further postimplantation dilatation because of residual aortic regurgitation. TAVI was performed following coronary angioplasty in 20 cases (29%), and 13 patients (19%) received an incomplete revascularization.

In the SAVR group, different bioprostheses were used: Magna (Edwards Lifesciences, Irvine, CA, USA) in 37 cases, Mitroflow (Livanova, London, UK) in 11, Hancock II (Medtronic, Minneapolis, MA, USA) in 11, Solo (Livanova, London, UK) in 11, others in 41. The median implanted size was 23 (19–27) mm. Seventy-two patients (71%) underwent combined procedures, coronary artery bypass graft being the most frequent one

Table 1: Baseline clinical and echocardiographic data

	Full cohort (n = 169)			Propensity score matched cohort (n = 80)		
	TAVI (n = 68)	SAVR (n = 101)	P-value	TAVI (n = 40)	SAVR (n = 40)	P-value
Clinical variables						
Age (years, median, range)	87.8 (85–94)	85.9 (85–89.6)	<0.01	87.6 (85–92.6)	86.7 (85–91.6)	0.08
Female sex	36 (52.9%)	54 (53.5%)	0.95	22 (55%)	27 (67.5%)	0.25
NYHA (median, range)	3 (2–4)	2 (1–4)	<0.01	3 (2–4)	3 (1–4)	0.40
Diabetes	16 (23.5%)	17 (16.8%)	0.28	6 (15%)	6 (15%)	1.00
COPD	14 (20.6%)	16 (15.8%)	0.43	12 (30%)	9 (22.5%)	0.45
Renal failure (GFR <30)	18 (26.5%)	20 (20.0%)	0.33	7 (17.5%)	8 (20.5%)	0.73
Hypertension	52 (76.5%)	81 (80.2%)	0.56	28 (70%)	32 (80%)	0.30
Peripheral vascular disease	18 (26.5%)	25 (24.8%)	0.80	9 (22.5%)	8 (20%)	0.79
Cerebrovascular disease	7 (10.3%)	5 (5%)	0.19	2 (5%)	0 (0%)	0.15
Atrial fibrillation	36 (52.9%)	30 (29.7%)	<0.01	19 (47.5%)	17 (42.5%)	0.65
Previous myocardial infarction	16 (23.5%)	10 (9.9%)	0.02	7 (17.5%)	8 (20%)	0.78
Previous PTCA	20 (29.9%)	4 (4.0%)	<0.01	7 (17.5%)	3 (7.5%)	0.18
Previous cardiac surgery	11 (16.2%)	1 (1%)	<0.01	5 (12.5%)	1 (2.5%)	0.09
Coronary artery disease	36 (52.9%)	61 (60.4%)	0.34	15 (37.5%)	23 (57.5%)	0.07
Frailty	5 (7.4%)	0 (0%)	<0.01	0 (0%)	0 (0%)	1.00
Porcelain aorta	9 (13.2%)	0 (0%)	<0.01	0 (0%)	0 (0%)	1.00
Logistic EuroSCORE (median, range)	22 (5–63)	15.5 (5.1–62.8)	<0.01	21.6 (5–63)	18.7 (5.1–62.8)	0.11
EuroSCORE II (median, range)	3.4 (1.1–22.6)	2.6 (1.2–20.5)	<0.01	3.2 (1.1–14.8)	3.2 (1.4–22.6)	0.67
Echocardiographic data						
LVEF (%)	56.9 (12.1%)	59.2 (11.7)	0.22	57 ± 12.3	58.5 ± 13	0.58
Aortic valve area (cm^2, mean ± SD)	0.65 ± 0.48	0.72 ± 0.21	0.29	0.58 ± 0.5	0.7 ± 0.2	0.20
Mean gradient (mmHg, mean ± SD)	42.7 ± 14.8	45.9 ± 17.2	0.26	43.8 ± 16	46.4 ± 18.8	0.55
Mitral regurgitation >moderate	7 (10.3%)	2 (2%)	0.02	3 (7.5%)	1 (2.5%)	0.31
Pulmonary hypertension	22 (32.4%)	24 (23.8%)	0.22	11 (27.5%)	12 (30%)	0.81

TAVI: transcatheter aortic valve implantation; SAVR: surgical aortic valve replacement; NYHA: New York Heart Association; COPD: chronic obstructive pulmonary disease; GFR: glomerular filtration rate; LVEF: left ventricular ejection fraction; PTCA: percutaneous transluminal coronary angioplasty; SD: standard deviation.

(60 patients). Other surgical procedures included radiofrequency ablation (4 patients), septal myectomy (3 patients), mitral valve repair (2 patients) and others (3 patients).

Outcomes

The postoperative clinical and echocardiographic characteristics of the study populations are presented in Table 2. The TAVI group showed more atrioventricular blocks (33.8% vs 3.0%, P < 0.01), major vascular complications (7.4% vs 0%, P < 0.01) and longer stays in the intensive care unit (median stay 4 days, range 0–35 vs median stay 2 days, range 1–60, P < 0.01); the TAVI group had a lower rate of acute kidney injury (7.4% vs 21.8%, P = 0.01) and new-onset atrial fibrillation (14.7% vs 47.5%, P < 0.01) compared with SAVR group. Importantly, the 30-day mortality rate was similar in both groups (8.8% vs 5.0%, P = 0.32). Echocardiography at hospital discharge showed similar peak and mean gradients (16.6 ± 7 mmHg vs 17.9 ± 6.5, P = 0.35; 9.8 ± 4.9 mmHg vs 9.3 ± 3.9 mmHg, P = 0.59, respectively) but TAVI patients showed higher rates of paravalvular leak ≥ moderate (10.5% vs 0%, P < 0.01).

The median follow-up period was 28 months (range 0.1–84) in the TAVI group and 47 months (range 0.1–108) in SAVR group.

The estimated 1-, 3- and 5-year overall survival rates were 81%, 61% and 40% in the TAVI group and 91%, 79% and 71% in the SAVR group, P < 0.01 (Fig. 1). The estimated 1, 3- and 5-year MACCE-free survival rates were 63%, 41% and 21% in TAVI group and 88%, 75% and 67% in the SAVR group, respectively, P < 0.01 (Fig. 2).

Multivariate Cox regression analysis showed that risk factors for mortality were mitral regurgitation >moderate (HR 3.571, 1.598–7.977, P < 0.01) and renal failure (HR 2.045, 1.199–3.489, P = 0.01), whereas systemic hypertension was a protective factor (HR 0.529, 0.316–0.888, P = 0.02). Prognostic variables that have been shown to be risk factors for MACCE in the multivariate Cox proportional hazards model were TAVI group (HR 2.917, 1.802–4.721, P < 0.01), mitral regurgitation > moderate (HR 3.156, 1.435–6.941, P < 0.01) and renal failure (HR 2.088, 1.281–3.403, P < 0.01), whereas systemic hypertension was a protective factor (HR 0.604, 0.375–0.976, P = 0.04).

Propensity score analysis

The propensity score matching process resulted in 40 pairs of patients with similar baseline characteristics. Baseline characteristics of the matched populations are summarized in Table 1. The early outcomes of the matched population according to the type of treatment are reported in Table 2. In the TAVI group, there were more atrioventricular blocks (37.5% vs 5%, P < 0.01), longer time in the intensive care unit (median 5 days, range 1–35 vs median 2 days, range 1–6, P < 0.01) but a lower rate of new-onset atrial fibrillation (15% vs 47.5%, P < 0.01). Postoperative echocardiographic findings (Table 2) were similar in the 2 groups but indicated a higher rate of mild (46.2% vs 3.9%, P < 0.01) and ≥ moderate paravalvular leak (10.3% vs 0%, P = 0.04) among TAVI patients.

The 30-day mortality rate was similar in the 2 groups (10% vs 7.5%, P = 0.69). The estimated 1, 3- and 5-year overall survival

Table 2: Perioperative outcomes

	Full cohort (*n* = 169)			Propensity score matched cohort (*n* = 80)		
Variables	TAVI (*n* = 68)	SAVR (*n* = 101)	*P*-value	TAVI (*n* = 40)	SAVR (*n* = 40)	*P*-value
Acute kidney injury	5 (7.4%)	22 (21.8)	0.01	4 (10%)	7 (17.5%)	0.33
Bleeding	2 (2.9%)	3 (3.0%)	0.99	1 (2.5%)	2 (5%)	0.56
Stroke	0 (0%)	0 (0%)	1.00	0 (0%)	0 (0%)	1.00
Wound infection	2 (2.9%)	1 (1%)	0.30	1 (2.5%)	1 (2.5%)	1.00
Atrioventricular block	23 (33.8%)	3 (3.0%)	< 0.01	15 (37.5%)	2 (5%)	<0.01
Atrial fibrillation	10 (14.7%)	48 (47.5%)	< 0.01	6 (15%)	19 (47.5%)	<0.01
Major vascular complications	5 (7.4%)	0 (0%)	<0.01	3 (7.5%)	0 (0%)	0.08
LVEF (%, mean ± SD)	58 ± 11	63.6 ± 10	<0.01	59.9 ± 11.3	63.3 ± 9.4	0.19
Peak gradient (mmHg, mean ± SD)	16.6 ± 7	17.9 ± 6.5	0.35	15.9 ± 5.8	17.3 ± 6.2	0.46
Mean gradient (mmHg, mean ± SD)	9.8 ± 4.9	9.3 ± 3.9	0.59	10.4 ± 4.9	9.3 ± 3.8	0.39
Paravalvular leak >2	7 (10.5%)	0 (0%)	<0.01	4 (10.3%)	0 (0%)	0.04
ICU stay (days, median, range)	4 (0–35)	2 (1–60)	< 0.01	5 (1–35)	2 (1–6)	<0.01
Hospital stay (days, median, range)	12 (3–95)	12 (7–19)	0.71	12 (5–9)	14.5 (7–19)	0.95
30-Day mortality rate	6 (8.8%)	5 (5.0%)	0.32	4 (10%)	3 (7.5%)	0.69

TAVI: transcatheter aortic valve implantation; SAVR: surgical aortic valve replacement; LVEF: left ventricular ejection fraction; ICU: intensive care unit.

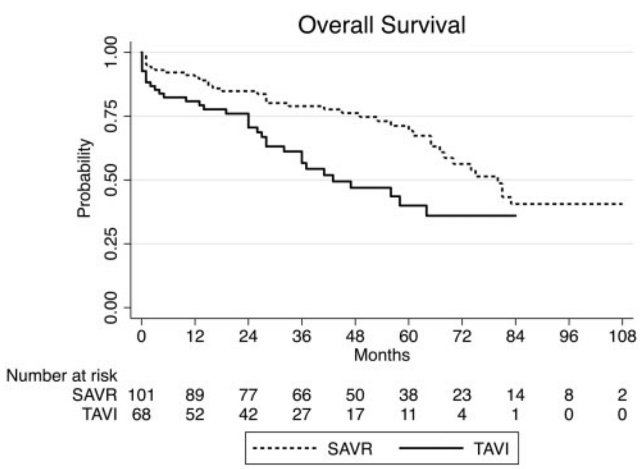

Figure 1: Overall actuarial survival.

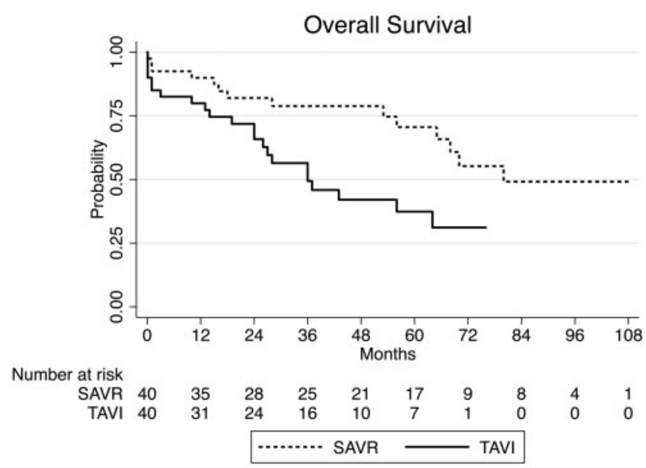

Figure 3: Overall survival after propensity matching.

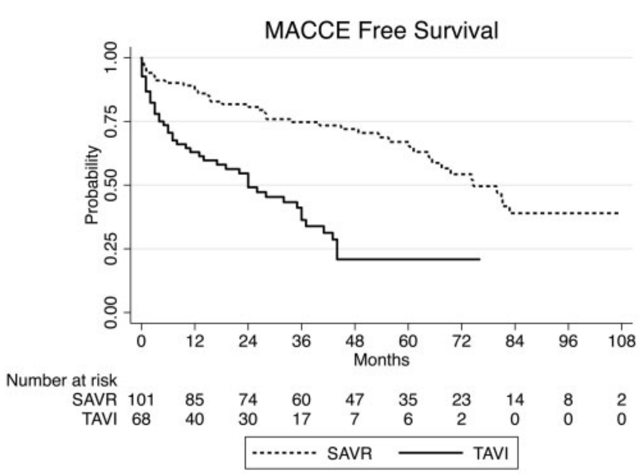

Figure 2: Major adverse cardiovascular and cerebral event-free survival.

rates in the matched groups were 80%, 56% and 37% in the TAVI group and 90%, 79% and 71% in the SAVR group (Fig. 3). In the TAVI group, the causes of death during the follow-up period were cardiac in 7 patients (41%), infective in 7 (41%), neoplastic in 1 (6%) and other in 2 (12%). In the SAVR group, 2 patients (20%) died of cardiac causes, 1 (10%) of infection, 2 (20%) of neoplasms and 5 (50%) of other causes. The estimated 1, 3- and 5-year MACCE-free survival rates were 72%, 46% and 17% in the TAVI group and 90%, 76% and 68% in the SAVR group, respectively (Fig. 4). There was a statistically significant difference in terms of overall survival and freedom from MACCE between the TAVI and SAVR groups (both $P < 0.01$). After multivariate Cox proportional hazards model analysis, the TAVI approach had the only independent predictive factor for mortality (HR 2.510, 1.238–5.089, $P = 0.01$), whereas the TAVI approach (HR 3.073, 1.539–6.135, $P < 0.01$) and chronic obstructive pulmonary disease (HR 2.576, 1.295–5.124, $P < 0.01$) were independent predictors for MACCE (Tables 3 and 4).

Cost analysis

The mean cost in the TAVI group was much higher than that in the SAVR group (€42 084 vs €19 891). This significant difference might be explained by a more complex preoperative patient screening (for coronary angiography, CT scan, prolonged hospitalization, €2140 vs €820), longer hospital stay in the intermediate care unit (€16 390 vs €13 950) and higher rate of postoperative complications including pacemaker implantation (€1034 vs €155) in addition to the higher cost of the TAVI prosthesis itself.

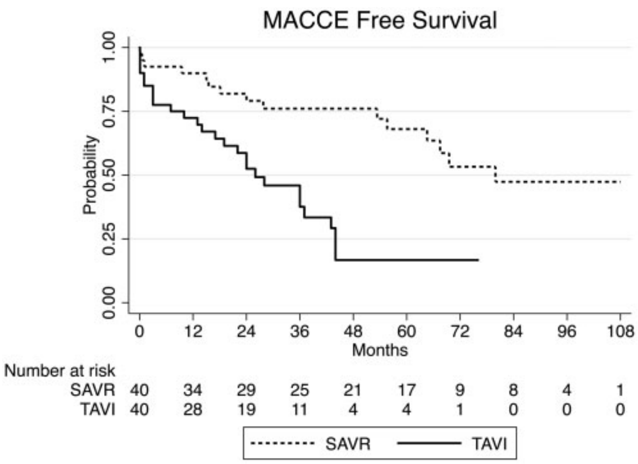

Figure 4: Major adverse cardiovascular and cerebral event-free survival after propensity matching.

DISCUSSION

The main message of this study is that patients with severe aortic stenosis aged ≥85 years can be effectively treated with SAVR or TAVI, obtaining satisfactory rates of morbidity and mortality with either approach. TAVI seems to have worse mid-term outcomes in terms of survival and freedom from MACCE even after propensity matching, and its costs appear to be double those with SAVR.

Clinical outcomes

In old–old patients, a higher surgical risk is generally accepted because of multiple comorbid conditions. Vasques *et al.* [1] performed a meta-analysis of 13 216 contemporary octogenarian patients that showed a postoperative mortality rate of 6.7% for SAVR, and a previous nonagenarians series reported a short-term mortality rate of 11.1–17.1%, showing an increased risk in cases of concomitant myocardial revascularization [12, 13]. Transcatheter aortic valve implantation in a series of old–old patients showed a 30-day mortality rate between 3.2% and 6.9% [14, 15]. Our 30-day mortality rate in the SAVR group was 5% (7.5% after matching), whereas in the TAVI group, it was 8.8% (10% after matching), which could be partially explained by the learning curve because we included all patients who were over 85 years old by the beginning of the TAVI program. Recently, a comparison between SAVR and TAVI showed similar 30-day mortality rates (6% vs 7.9%, $P = 0.35$) in nonagenarians [16], but few studies so far have analysed the long-term survival rates of old–old patients undergoing TAVI and SAVR. Even after propensity matching, our results showed a better survival rate and

Table 3: Risk factors in score matched cohort for long-term mortality and major adverse cardiac and cardiovascular events at univariate Cox regression

	Overall survival			MACCE		
	HR	95% CI	*P*-value	HR	95% CI	*P*-value
TAVI group	2.510	1.238–5.089	0.01	3.436	1.749–6.750	<0.01
Age	1.021	0.824–1.265	0.85	1.074	0.889–1.299	0.46
Female sex	0.925	0.468–1.829	0.82	1.179	0.636–2.188	0.60
NYHA	1.095	0.597–2.010	0.77	1.191	0.679–2.089	0.54
Diabetes	0.833	0.323–2.147	0.71	0.699	0.274–1.783	0.45
COPD	1.948	0.954–3.976	0.07	2.528	1.305–4.898	<0.01
Renal failure	1.240	0.541–2.842	0.61	1.171	0.541–2.539	0.69
Hypertension	0.479	0.242–0.950	0.04	0.493	0.261–0.931	0.03
Peripheral vascular disease	0.418	0.148–1.183	0.10	1.061	0.507–2.222	0.88
Atrial fibrillation	1.409	0.730–2.721	0.31	1.311	0.711–2.451	0.39
Logistic EuroSCORE	1.001	0.979–1.024	0.92	1.008	0.988–1.028	0.43
EuroSCORE II	0.963	0.881–1.052	0.40	0.980	0.910–1.055	0.58
Left ventricular ejection fraction	0.997	0.970–1.026	0.86	0.988	0.963–1.013	0.35
Mean gradient	0.991	0.968–1.016	0.50	0.992	0.971–1.014	0.47
Previous myocardial infarction	0.691	0.287–1.666	0.41	0.707	0.313–1.596	0.40
Previous PTCA	0.693	0.212–2.269	0.55	1.260	0.492–3.227	0.63
Previous cardiac surgery	0.655	0.157–2.730	0.56	0.806	0.248–2.612	0.72
Coronary disease	1.020	0.530–1.963	0.95	1.025	0.559–1.880	0.94
Mitral regurgitation > moderate	3.361	1.170–9.654	0.02	4.788	1.612–14.22	<0.01
Paravalvular leak >2	1.033	0.247–4.318	0.96	1.622	0.499–5.270	0.42

MACCE: major adverse cardiac and cardiovascular events; TAVI: transcatheter aortic valve implantation; NYHA: New York Heart Association; COPD: chronic obstructive pulmonary disease; PTCA: percutaneous transluminal coronary angioplasty; HR: hazard ratio; CI: confidence interval.

Table 4: Risk factors in score matched cohort for long-term mortality rates and major adverse cardiac and cardiovascular events with multivariate Cox regression

	Overall survival			MACCE		
	HR	95% CI	*P*-value	HR	95% CI	*P*-value
TAVI group	2.510	1.238–5.089	0.01	3.331	1.683–6.596	<0.01
COPD				2.375	1.211–4.658	0.01

MACCE: major adverse cardiac and cardiovascular events; HR: hazard ratio; CI: confidence interval; TAVI: transcatheter aortic valve implantation; COPD: chronic obstructive pulmonary disease.

freedom from MACCE in SAVR group. The OBSERVANT study showed no difference in mortality rate and freedom from MACCE at 1 and 3 years in octogenarians [17], whereas the US Pivotal Trial showed a superiority in terms of death from any cause at 1 year in the TAVI group (14.2% vs 19.1%); similar results seem to be confirmed at 3 years [8].

Given the low levels of early deaths and the satisfactory long-term survival rates obtained with SAVR, as well as the excellent quality of life [4, 18], exclusion from surgical intervention based solely on age may hamper patients from receiving the best standard of care. In clinical practice, older patients are more frequently referred for TAVI instead of SAVR because of a perceived lower risk of intervention and shorter recovery time. But determination of surgical risk should not depend on patient age alone; rather, the presence of significant comorbidities, such as renal failure, stroke, urgent status and frailty [7] should also be considered. Moreover, old patients are more frequently affected by additional heart diseases such as diffuse coronary disease and mitral regurgitation [19] that can also be treated surgically. In fact, in the SAVR group, moderate or severe mitral regurgitation was treated concomitantly, and coronary artery bypass graft permitted complete revascularization. In the TAVI group, occluded coronary vessels could not be stented, and percutaneous transluminal coronary angioplasty was performed only in major coronary arteries. The incomplete revascularization and the untreated mitral regurgitation could have influenced the high rate of hospital readmissions for heart failure as well as deaths of cardiac reasons. Therefore, even in old patients, whenever possible, completeness should be preferred to the less invasiveness of TAVI.

Complications and postoperative morbidity can have a significant effect on survival and quality of life of extremely elderly patients [18, 20–22]. Our experience confirms the different distribution of complications with TAVI and SAVR shown in previous studies: The need for permanent pacemaker implantation, the incidence of moderate or severe paravalvular regurgitation and major vascular complications are higher in the TAVI patient population. Conversely, patients treated with TAVI are at significantly lower risk for periprocedural bleeding and acute kidney injury [18, 20].

Cost-effectiveness

The increased costs of highly technical cardiovascular treatments and the progressively insufficient economic resources force health care organizations to optimize cost-effectiveness in health care strategies. Therefore, econometric analysis plays an important role in the evaluation of any novel cardiovascular therapy.

In accordance with a systematic review of the literature, TAVI seems to be more expensive and less effective for high-risk patients, with a mean total cost of US$81 638 and US$43 974 for TAVI and SAVR, respectively ($P < 0.01$) [23]. In our experience, the costs associated with TAVI were double those associated with SAVR, mainly due to the high cost of the prosthesis and the higher demand for preoperative investigations. On the other hand, such increased costs are not balanced by a lower rate of postoperative complications and thus a shorter hospital stay, as expected. In fact, TAVI patients needed a longer stay in intermediate care and a high rate of pacemaker implantation (that led to even longer hospital stays). In both groups, hospitalization was longer than that described in the literature because of the lack of rehabilitation centres in our region to which we could rapidly transfer the patients.

Limitations

The present study has several limitations. The retrospective and observational natures of the study are certainly associated with selection bias. Nonagenarians are less likely to comply with a structured follow-up program. Therefore, echocardiographic findings and mid-term data were available only for those patients requiring hospital readmission, so the needed data were not collected. The limited number of matched patients did not permit us to make definitive conclusions. Larger studies are necessary.

CONCLUSIONS

In patients 85 years and older, SAVR offers satisfactory short- and mid-term clinical outcomes compared to TAVI. Our results suggest that in this subset of old–old patients, advanced age alone would not be an indication for TAVI. An individual, patient-centred strategy should be paramount in the decision-making process.

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