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ORIGINAL RESEARCH

Outcome of Patients with Mixed Aortic Valve Disease Undergoing Transfemoral Aortic Valve Replacement

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ABSTRACT

Background: Data on transfemoral aortic valve replacement (TAVR) in patients with mixed aortic valve disease (MAVD) compared with aortic stenosis (AS) are missing. The aims of this study were to assess feasibility of TAVR in MAVD and evaluate the impact on short- and long-term outcome. The primary endpoint was all-cause mortality or disabling stroke within 12 months.

Methods: Between 2014 and 2016, 734 patients were enrolled (clinicaltrials.gov NCT02162069), 665 had AS, 69 presented with MAVD. Mixed aortic valve disease was defined as coexistence of severe aortic stenosis and moderate to severe aortic regurgitation (AR).

Results: VARC-2 early safety endpoint at 30 days was 8.1% in isolated AS and 10.1% in MAVD ($p = 0.57$) with no significant differences in all-cause mortality (AS 1.8%, MAVD 4.3%, $p = 0.16$) and rate of disabling stroke (AS 1.7%, MAVD 1.4%, $p = 0.89$). There was no difference in residual aortic regurgitation between groups. The primary endpoint at 12 months was comparable (AS 18.3%, MAVD 19.9%, $p = 0.87$). Within 24 months (AS 26.9%, MAVD 19.9%, $p = 0.10$) there was no significant difference in all-cause mortality or disabling stroke. Rate of rehospitalization for congestive heart failure did not differ between groups. In multivariate analyses STS for mortality ($p < 0.01$) and atrial fibrillation ($p = 0.02$) were independent predictors for the primary endpoint at 12 months. In a propensity matched population outcomes were not different within 12 and 24 months.

Conclusion: TAVR in patients with MAVD is associated with a comparable 30 days, 12- and 24-month clinical outcome compared to patients undergoing TAVR for aortic stenosis.

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KEYWORDS Mixed aortic valve disease; outcome; transfemoral aortic valve replacement

Introduction

Transfemoral aortic valve replacement (TAVR) in severe aortic stenosis (AS) has been shown to be superior to surgical aortic valve replacement in patients at high and intermediate surgical risk.[1–3] Data on outcome of TAVR in mixed aortic valve disease are scarce. Mixed aortic valve disease, a combination of aortic stenosis (AS) and aortic regurgitation (AR), means a pressure as well as volume load to the left ventricle.[4] Pressure load in aortic stenosis is known to be associated with concentric hypertrophy, whereas the increased stroke volume in aortic regurgitation leads to an eccentric hypertrophy. Recent data on mixed aortic valve disease suggested a left ventricular dysfunction associated with the combination of pressure and volume overload.[5,6] Egbe and colleagues recently reported adverse event rates in patients with moderate mixed aortic valve disease, similar to those in severe aortic stenosis.[7] In TAVR postprocedural aortic regurgitation, exposing the hypertrophied left ventricle to an acute AR volume, is also known to be associated with worse outcome.[8] Current guidelines give a class IIb indication for TAVR in severe AS and moderate but not severe coexisting AR, emphasizing treatment determined by the predominant lesion.[9,10] Data on acute and long-term outcome in patients undergoing TAVR with new generation devices for mixed aortic valve disease are missing. In the large randomized PARTNER trials[1–3] patients with mixed aortic valve disease have been excluded. We evaluated 30 days, 12- and 24-month outcomes in patients undergoing TAVR for mixed aortic valve disease compared to aortic stenosis.

Materials and methods

Patients were prospectively enrolled in the Coronary and Structural Interventions Ulm–Transcatheter Aortic Valve Replacement registry at the University of Ulm, Germany. Symptomatic severe aortic stenosis was confirmed by echocardiography and cardiac catheterization with an aortic valve area (AVA) ≤ 1 cm^2 or an indexed AVA ≤ 0.6 cm^2/m^2. Aortic regurgitation was assessed and graded by echocardiography as described elsewhere.[11] Mixed aortic valve disease was defined as coexisting severe aortic stenosis and moderate or severe aortic regurgitation. Moderate AR was defined as a jet width 25–64% of the left ventricular outflow tract (LVOT), a vena contracta of 0.3–0.6 cm, an effective regurgitation orifice (ERO) of 0.10–0.29 cm^2 and a pressure half-time <500 ms and >200 ms. Severe AR was defined as a jet width > 65% of the LVOT, a vena contracta of > 0.6 cm, an ERO ≥ 0.3 cm^2 and a pressure half time < 200 ms in transthoracic and transesophageal

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Supplemental data for this article can be accessed publisher's website.

echocardiography. There were no exclusion criteria, apart from valve-in-valve procedures, bicuspid valves and pure aortic insufficiency. Patients underwent diagnostic evaluation with routine laboratory testing, medical history with current medication, Society of Thoracic Surgeons (STS)-Score, logistic EuroScore, New York Heart Association (NYHA) classification, electrocardiography (ECG), echocardiography, heart catheterization and a multislice computed tomography (MSCT). MSCT was used for sizing and evaluated for aortic annulus, left ventricular outflow tract (LVOT), distance from annulus to coronary ostia and area at ostia with a dedicated software (3mensio software, Pie medical Imaging, Maastricht, the Netherlands) according to present guidelines.[12,13] Calcification of aortic cusps was assessed according to Rosenhek.[14]

Decision regarding suitability for transfemoral TAVR was assessed by the heart team. Intermediate to high surgical risk was defined based on Society of Thoracic Surgeons (STS) Score for mortality, frailty and relevant comorbidities including contraindications for surgical valve replacement as chest radiation or porcelain aorta. The study complies with the Declaration of Helsinki and was approved by the ethics committee of the University of Ulm and written informed consent was obtained from all patients (clinicaltrials.gov NCT02162069). Procedures were performed via transfemoral access using local anesthesia under conscious sedation as described elsewhere.[12,13,15,16] For TAVR the Edwards Sapien 3 (Edwards Lifesciences Corporation, Irvine, CA, USA), Boston Lotus (Boston Scientific Corporation, Marlborough, MA, USA) and Medtronic Evolut R (Medtronic Inc, Minneapolis, MN, USA) were used. In all patients, the Perclose Proglide vascular closure device was used.[13] There was no surgical cut-down.

Clinical outcomes were assessed according to the Valve Academic Research Consortium (VARC)-2 criteria.[17] Standardized aortography was done to analyze postprocedural AR.[12,18] Pressure gradients and AR were assessed by transthoracic echocardiography after the procedure. AR was graded as described elsewhere.[11–13] Follow-up was done at 12 and 24 months, assessing the early safety endpoint according to VARC-2 criteria and the combined endpoint of all-cause mortality or disabling stroke at 12 and 24 months.

Statistical analysis

Categorical parameters are presented as counts and percentages and were compared by Pearson's chi-square test. Continuous variables are presented as mean ± SD and were compared with the *t*-test. Early safety endpoint at 30 days was defined according to VARC-2 as a composite of all-cause mortality, all stroke, life-threatening bleeding, acute kidney injury, coronary obstruction, major vascular complication and valve dysfunction requiring reintervention. Primary outcome measure was a composite of all-cause mortality or disabling stroke. Survival analyses were done with the use of Kaplan-Meier estimates based on available follow-up and were compared with the log-rank test and Cox proportional regression hazard ratio. To account for differences between the two non-randomized groups we performed propensity score analysis based on an optimal matching attempt (SAS 9.4, SAS Institute GmbH, Heidelberg, Germany). Matching was done for STS score, history of stroke and previous permanent pacemaker (see Supplemental Figure 1, available online). Multivariable analyses using stepwise forward regression were performed to evaluate independent predictors for mortality and disabling stroke. Factors with a $p < 0.2$ in univariate anlaysis were included (STS for mortality, history of stroke) as well as factors having been shown previously in larger randomized trials to have an impact on morbidity and mortality. The following variables were included for multivariable analysis regarding the primary outcome measure: gender, STS score, diabetes mellitus, predilation, history of stroke, history of CAGB, atrial fibrillation and a left ventricular ejection fraction < 40% and AS versus MAVD. A *p*-value < 0.05 was considered to be statistically significant. Statistical analysis was performed using Statistica release 10 (StatSoft, Tulsa, OK, USA).

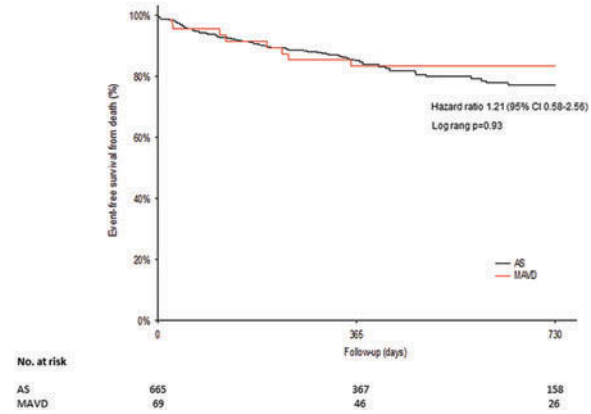

Figure 1. Kaplan-Meier curves for event-free survival from death. The rate of mortality did not differ within 30 days, 12- and 24-months in patients undergoing TAVR for aortic stenosis (AS) or mixed aortic valve disease (MAVD). CI, confidence interval.

Results

Patient population and baseline parameters

Between 2014 and 2016 a total of 734 consecutive patients with severe aortic stenosis were enrolled. Moderate to severe aortic regurgitation was additionally present in 69 (9.4%) patients. In 665 (90.6%) patients there was no more than mild coexisting aortic regurgitation at baseline. Patients presented with multiple comorbidities (Table 1). Baseline characteristics between groups did not differ. Cardiac catheterization and transthoracic echocardiography demonstrated severe aortic stenosis (Table 2). Analyses of MSCT for the two groups are detailed in Table 2. Diameters of LVOT, aortic annulus and sinotubular junction as well as calcifications of aortic cusps and LVOT were comparable between groups. In the propensity score matched population including 138 patients baseline data did not differ between groups (Supplemental Tables 1 and 2, available online).

Procedural results and outcome

All patients were successfully treated with a single valve. Procedural data and outcome did not differ between groups (Table 3). There was no significant difference in valve size ($p = 0.77$). There was no moderate or severe AR

Table 1. Patient baseline characteristics.

	AS $N = 665$	MAVD $N = 69$	p-value
Age, years	80.7 ± 5.8	79.9 ± 6.9	0.33
Female, *n* (%)	349 (52.5%)	38 (55.1%)	0.68
NYHA-class III/IV, *n* (%)	532 (80.0%)	51 (73.9%)	0.34
STS Score for mortality	6.5 ± 4.6	7.4 ± 5.7	0.11
Diabetes mellitus, *n* (%)	199 (29.9%)	21 (30.4%)	0.87
Chronic renal failure, *n* (%)	218 (32.8%)	23 (33.3%)	0.93
Coronary artery disease, *n* (%)	551 (82.9%)	53 (76.8%)	0.86
History of myocardial infarction, *n* (%)	94 (14.1%)	9 (13.0%)	0.80
History of CABG, *n* (%)	55 (8.3%)	4 (5.8%)	0.56
Peripheral or cerebral vascular disease, *n* (%)	556 (83.6%)	54 (78.3%)	0.65
History of stroke/intracerebral bleeding, *n* (%)	65 (9.8%)	13 (18.8%)	0.06
Atrial fibrillation, *n* (%)	252 (37.9%)	25 (36.2%)	0.89
Permanent pacemaker, *n* (%)	48 (7.2%)	8 (11.6%)	0.19
Porcelain aorta, *n* (%)	24 (3.6%)	3 (4.3%)	0.78
Left ventricular ejection fraction <40%, *n* (%)	98 (14.7%)	8 (11.6%)	0.48

Note. Values are mean ± standard deviation (SD).
AS, aortic stenosis; CABG, coronary artery bypass graft; MAVD, mixed aortic valve disease; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons.

Table 2. Baseline aortic valve parameters.

	AS $N = 665$	MAVD $N = 69$	p-value
Transthoracic echocardiography			
Aortic valve area, cm^2	0.76 ± 0.21	0.77 ± 0.23	0.81
Maximum gradient, mmHg	64 ± 23	66 ± 22	0.56
Cardiac catheterization			
Indexed aortic valve area, cm^2/m^2	0.24 ± 0.07	0.24 ± 0.11	0.86
Aortic annulus diameter (computed tomography)			
Area derived diameter, mm	24.8 ± 2.3	24.7 ± 2.6	0.82
Area, mm^2	485 ± 90	484 ± 102	0.89
Perimeter, mm	79.6 ± 7.3	79.4 ± 8.3	0.91
Moderate/severe aortic cusp calcification, *n* (%)	609 (91.6%)	60 (87.0%)	0.19
Distance annulus to ostium of coronary ostia			
Left coronary artery, mm	14.3 ± 3.1	14.6 ± 3.4	0.41
Right coronary artery, mm	17.3 ± 3.0	17.2 ± 3.2	0.71
Left ventricular outflow tract			
Area derived diameter, mm	24.5 ± 2.7	24.6 ± 2.9	0.81
Area, mm^2	478 ± 105	482 ± 113	0.78
Perimeter, mm	79.8 ± 8.6	81.1 ± 9.5	0.24
Sinutubular junction			
Area derived diameter, mm	28.8 ± 3.3	29.6 ± 4.3	0.09

Note. Values are mean ± standard deviation.
AS, aortic stenosis; MAVD, mixed aortic valve disease.

after TAVR in both groups. Contrast amount was low. There was one coronary obstruction in a patient in the MAVD group treated with a Boston Scientific Lotus valve due to embolized calcium, which needed hemodynamic support by extracorporal membrane oxygenation for stenting of left main occlusion. One annular rupture occurred in a patient without coexisting aortic regurgitation after implantation of an Edwards Sapien 3 valve (Table 3). Regarding hemodynamic stability during valve implantation procedure, there was no difference between both groups in terms of need for inotropes (24.6% in AS vs. 22.6% in MAVD, $p = 0.80$) or respiratory support (0.6% in AS vs. 0% in MAVD, $p = 0.77$). There was no significant difference in procedural results in the propensity matched population (Supplemental Table 3, available online).

Follow-up for 30 days was available in 100% of patients. Early safety endpoint at 30 days (Table 4) was low in both groups with 8.1% without AR and a rate of 10.1% in MAVD patients ($p = 0.57$). Rates were statistically not different between groups for all-cause mortality (1.8% in AS and 4.3% with MAVD, $p = 0.16$), major vascular complications (3.5% in AS and 5.8% with MAVD, $p = 0.32$; Table 4) and acute kidney injury (0.9% in AS versus 2.9% with MAVD, $p = 0.13$). In the propensity matched population rates of all-cause mortality were also not significantly different with 1.5% ($n = 1$) in AS and 4.3% ($n = 3$); $p = 0.31$ in MAVD patients (Supplemental Table 4, available online).

Follow-up for 12 months was available in 413 patients (100% of eligible patients). The composite endpoint of all-cause mortality or disabling stroke after 12 months follow-up was statistically not different with 18.3% in AS and 19.9% in

Table 3. Procedural data and outcome.

	AS $N = 665$	MAVD $N = 69$	p-value
Balloon predilation, *n* (%)	606 (91.1%)	59 (85.5%)	0.73
Valve size mean, mm	26.0 ± 2.1	25.9 ± 2.3	0.77
Angiographic aortic regurgitation after valve replacement, *n* (%)			
None/trace	637 (95.8%)	65 (94.2%)	0.54
Mild	28 (4.2%)	4 (5.8%)	0.54
Moderate	0 (0%)	0 (0%)	–
Severe	0 (0%)	0 (0%)	–
Implantation of >1 valve, *n* (%)	0 (0%)	0 (0%)	–
Adjunctive PCI, *n* (%)	15 (2.3%)	0 (0%)	0.21
Contrast amount, ml	86 ± 30	88 ± 31	0.65
Immediate procedural death, *n* (%)	1 (0.3%)	0 (0%)	0.44
Coronary obstruction, *n* (%)	0 (0%)	1 (0.5%)	0.19
Annular rupture, *n* (%)	1 (0.3%)	0 (0%)	0.44
Device success, *n* (%)	618 (92.9%)	63 (91.3%)	0.62
Echocardiographic aortic regurgitation post TAVR, *n* (%)			
None/trace	525 (78.9%)	55 (79.9%)	0.88
Mild	140 (21.1%)	14 (20.3%)	0.88
Moderate/severe	0 (0%)	0 (0%)	–

Note. Values are mean ± standard deviation. AS, aortic stenosis; MAVD, mixed aortic valve disease; immediate procedural death according to VARC-2 within 72 hours post TAVR.

MAVD ($p = 0.87$, Table 5). There was no repeat procedure for valve-related dysfunction in either group. Need for rehospitalization for congestive heart failure (CHF) did not significantly differ between groups.

Left ventricular enddiastolic diameter (LVEDD) as continuous echo surrogate and marker of cardiac remodeling was assessed at baseline and during follow-up. In the overall study population, left ventricular enddiastolic diameter was 52.7 ± 7.6 mm at baseline in AS patients, compared to 56.3 ± 7.2 mm in MAVD ($p = 0.10$). During 12 months of follow-up left ventricular enddiastolic diameters did not differ in AS patients (52.7 ± 7.6 mm at baseline vs. 51.8 ± 9.6 mm at 12 months ($p = 0.40$), in MAVD patients there was a trend towards a reduction in LVEDD after TAVR within 12 months of follow-up (56.3 ± 7.2mm at baseline vs. 53.2 ± 8.8 mm at 12 months ($p = 0.09$).

Of the 734 patients included, 189 were eligible for 24 months follow-up. In 184 patients follow-up was available (97.4% follow-up rate). Within 24 months the outcome was not statistically different independent of degree of preexisting AR (Table 6). Rate of all-cause mortality was 22.1% without AR versus 17.9% with MAVD ($p = 0.93$). There was no significant difference in rate of rehospitalization for CHF over 24 months of follow-up ($p = 0.94$). Event-free survival from death did not differ significantly between groups as shown in Figure 1 for the overall population (1.21 [95% CI 0.58–2.56], $p = 0.93$) and Supplemental Figure 2 (available online) for the propensity matched population (1.92 [95% CI 0.60–6.11], $p = 0.26$). In multivariate analyses STS for mortality ($p < 0.01$) and atrial fibrillation ($p = 0.02$) were independent predictors for the primary outcome measure of all-cause mortality and all stroke within 12 months of follow-up. In addition, STS for mortality was also an independent predictor ($p < 0.01$) for the occurrence of all-cause mortality and stroke within 24 months. Gender, prior stroke, history of coronary bypass surgery, predilation, reduced left ventricular function, diabetes and AS or MAVD were not predictive for 12 and 24 months outcome. In the propensity matched population there was no significant difference in all-cause mortality at 12 months (5.8% in AS vs. 17.2% in MAVD, $p = 0.07$) and 24 months (14.5% in AS vs. 17.9%, $p = 0.26$; Supplemental Figure 1, available online).

Discussion

Data on outcome in patients undergoing TAVR for mixed aortic valve disease—severe aortic stenosis and moderate or severe aortic regurgitation—are limited. We compared the outcome of patients undergoing TAVR for mixed aortic valve disease with patients treated for severe aortic stenosis including 734 patients. The main findings were: (1) TAVR with new generation devices in mixed aortic valve disease is

Table 4. Thirty days outcome.

	AS $N = 665$	MAVD $N = 69$	p-value
All-cause mortality, *n* (%)	12 (1.8%)	3 (4.3%)	0.16
Disabling stroke, *n* (%)	11 (1.7%)	1 (1.4%)	0.89
Major vascular complication, *n* (%)	23 (3.5%)	4 (5.8%)	0.32
Life-threatening bleeding, *n* (%)	15 (2.3%)	1 (1.5%)	0.66
Acute kidney injury stage 2/3, *n* (%)	6 (0.9%)	2 (2.9%)	0.13
Repeat procedure, *n* (%)	0 (0%)	0 (0%)	–
Early safety endpoint, *n* (%)	54 (8.1%)	7 (10.1%)	0.57

Note. AS, aortic stenosis; MAVD, mixed aortic valve disease.

Table 5. Twelve months outcome.

	AS	MAVD	*p*-value
All-cause mortality, *n* (%)	61 (14.7%)	9 (17.2%)	0.57
Stroke disabling, *n* (%)	15 (3.6%)	1 (1.9%)	0.53
Repeat procedure, *n* (%)	0 (0%)	0 (0%)	–
Myocardial infarction, *n* (%)	2 (0.5%)	0 (0%)	0.53
Endocarditis, *n* (%)	1 (0.2%)	0 (0%)	0.71
Rehospitalization for CHF, *n* (%)	51 (12.3%)	6 (11.5%)	0.77
All-cause mortality or disabling stroke, *n* (%)	76 (18.3%)	10 (19.9%)	0.87

Note. Values are mean ± standard deviation. Given are Kaplan-Meier estimates, *p*-values are for point-in-time comparison.
AS, aortic stenosis, CHF, congestive heart failure; MAVD, mixed aortic valve disease.

Table 6. Twenty-four-months outcome.

	AS	MAVD	*p*-value
All-cause mortality, *n* (%)	73 (22.1%)	9 (17.9%)	0.93
Stroke disabling, *n* (%)	16 (4.8%)	1 (2.0%)	0.31
Repeat procedure, *n* (%)	0 (0%)	0 (0%)	–
Myocardial infarction	2 (0.6%)	0 (0%)	0.56
All-cause mortality or disabling stroke	89 (26.9%)	10 (19.9%)	0.10
Rehospitalization for CHF, *n* (%)	56 (16.9%)	9 (17.9%)	0.94

Note. Given are Kaplan-Meier estimates, *p*-values are for point-in-time comparison.
AS, aortic stenosis; CHF, congestive heart failure; MAVD, mixed aortic valve disease.

feasible and associated with no moderate or severe paravalvular AR and a low 30 days early safety endpoint; (2) within 12 and 24 months follow-up clinical outcome was comparable between patients treated for mixed aortic valve disease and isolated aortic stenosis; (3) multivariable analysis revealed STS score for mortality and presence of atrial fibrillation as significant predictors for the combined endpoint all-cause mortality or all stroke within 12 months.

Mixed aortic valve disease is associated with a high rate of adverse events. Egbe and colleagues recently demonstrated event-free survival rates of 71, 42 and 30% at 1, 3 and 5 years of follow-up[5] with conservative therapy in mixed aortic valve disease in a relatively young patient cohort with a mean age of 69 years. Patients with mixed aortic valve disease were more likely to become symptomatic and require aortic valve replacement than patients with isolated aortic stenosis.[5,6] Moreover mixed aortic valve disease was associated with early and late left ventricular dysfunction after surgical aortic valve replacement in 179 patients,[6] most likely associated with hypertrophy due to a pressure and volume overload of the left ventricle in coexisting AS and AR. Current guidelines recommend treatment according to the predominant lesion. Timing and modality of treatment however are unclear. There is a class IIb recommendation for TAVR in patients with severe AS and no more than moderate AR.[9,10]

Impact of mixed aortic valve disease on outcome after TAVR is unknown since patients with mixed aortic valve disease were excluded in large randomized trials.[1–3,19–21] In 734 patients we are able to demonstrate a prevalence of 9.4% (n = 69) of mixed aortic valve disease. Patients' baseline and aortic valve characteristics did not differ compared to AS. With the use of new generation TAVR devices there was a significant reduction of AR in MAVD and no moderate or severe aortic regurgitation after valve replacement. There was no difference in device success between groups. Early safety endpoint at 30 days did not significantly differ with 8.1% for AS and 10.1% in MAVD with comparable outcomes for all-cause mortality and disabling stroke. Within 30 days rate of disabling stroke was 1.7% in AS and 1.4% in mixed aortic valve disease (p = 0.89). In the PARTNER-2 trial[1] in intermediate-risk patients, rate of disabling stroke at 30 days was 2.2% for the transfemoral route, thus comparable to our population. In addition, rate of all-cause mortality was statistically not different between patients with mixed aortic valve disease and patients with aortic stenosis (4.3% vs. 1.8%, p = 0.16). We did not observe a difference in all-cause mortality and stroke between patients with AS or MAVD within 12 and 24 months. In addition, echocardiographic follow-up showed a trend towards a reduction in LVEDD in MAVD patients during follow-up. Need for rehospitalization for CHF was comparable between groups over 12 (12.3% in AS and 11.5% in MAVD, p = 0.77) and 24 months (16.9% in AS and 17.9% in MAVD, p = 0.94) of follow-up. These rates are quite comparable to the outcome in the PARTNER-2 trial with 14.8% at 12 months and 19.6% at 24 months of follow-up.[2]

Comparing long-term results over 24 months of follow-up there was no significant difference in rate of all-cause mortality or stroke between both groups. Event-free survival from death did not differ for patients undergoing TAVR for aortic stenosis or mixed aortic valve disease (hazard ratio 1.21, 95% CI 0.58–2.56) over 24 months of follow-up. In multivariate analyses STS for mortality and the presence of atrial fibrillation were independent predictors for the primary endpoint of all-cause mortality or stroke within 12 months of follow-up. In patients undergoing TAVR for severe aortic stenosis atrial fibrillation is known to be associated with an increased all-cause mortality and rehospitalization.[22] STS score has been shown previously to be predictive for mortality at 30 days and 1 year in transfemoral TAVR.[23,24] STS score remained an independent predictor (p < 0.01) for the occurrence of all-

cause mortality and stroke within 24 months of follow-up in patients with aortic stenosis and patients with MAVD. Diabetes mellitus, aortic stenosis or MAVD, history of bypass surgery, prior stroke, gender, predilation or reduced left ventricular ejection fraction were not predictive within 12 or 24 months.

Limitations

This is no randomized controlled trial, though a large single center experience comparing 30 days, 12 and 24 months outcome in patients undergoing transfemoral TAVR for severe aortic stenosis or mixed aortic valve disease including the standardized VARC-2 criteria. The study was not powered to show differences in the endpoints of stroke or mortality. Findings should be considered hypotheses generating.

Conclusion

TAVR in patients with mixed aortic valve disease is associated with comparable 30 days, 12- and 24-month clinical outcome compared to patients undergoing TAVR for severe aortic stenosis.

Clinical trials registration

clinicaltrials.gov NCT02162069

Disclosure statement

The authors report no conflict of interest. The authors alone are responsible for the writing and content of this article.

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