Performance and short-term outcomes of three different transcatheter aortic valve replacement devices in patients with aortic stenosis: A single-center experience

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Abstract

Background: Data on whether different transcatheter aortic valve replacement (TAVR) devices and delivery approaches can achieve equally favorable outcomes when performed by a single heart team are scarce. We sought to compare the performance and short-term outcomes of three different TAVR devices—self-expanding Medtronic CoreValve (MCV), mechanically expanded Lotus valve, and balloon-expandable Edwards SAPIEN XT (SXT)—for the treatment of severe aortic stenosis (AS) in a single large-volume center in Taiwan.

Methods: We retrospectively reviewed consecutive patients who underwent TAVR for the treatment of severe AS. Clinical outcomes were reported following Valve Academic Research Consortium 2 (VARC-2) criteria. The composite primary endpoint was combined all-cause mortality, myocardial infarction (MI), or disabling stroke within 180 days.

Results: A total of 231 patients (MCV n=112, Lotus n=18, and SXT n=101) were included. The device and procedural success rates were similar among all three TAVR devices. At 30 days, there was no significant difference in all-cause mortality, cardiovascular mortality, periprocedural MI, stroke, major vascular complications, life-threatening bleeding, acute kidney injury (AKI, stage 2/3), or VARC-2 composite early safety endpoints. There was no difference among groups in the rate of primary endpoint within 180 days. Lack of procedural success, presence of acute coronary occlusion during TAVR, and presence of AKI (stage 3) after TAVR were independent predictors of adverse outcomes.

Conclusion: TAVR using MCV, Lotus, or SXT was associated with similar 30- and 180-day clinical outcomes. The presence of periprocedural complications was one of the main determinants of short-term adverse outcomes.

Keywords: Balloon-expandable valve; Mechanically expanded valve; Outcomes; Self-expanding valve; Transcatheter aortic valve replacement

1. INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is a rapidly evolving technique providing robust treatment of severe aortic stenosis (AS) in high-risk patients.[1–5] The main valve technologies available since 2010 have been the self-expanding Medtronic CoreValve (MCV) prosthesis (Medtronic Inc., Minneapolis, MN, USA), the mechanically expanded Lotus (Boston Scientific, Natick, MA, USA), and the balloon-expandable SAPIEN XT (SXT; Edwards Lifesciences, Irvine, CA, USA), which were approved by the Taiwan Food and Drug Administration for clinical use in 2012, 2015, and 2016, respectively. Whether these commonly used earlier generation TAVR prostheses are associated with different key limitations that can potentially impact patient outcomes still needs to be resolved.[6,7] These limitations appear to be partially patient specific, but might also be specific to each TAVR system.

As a single approach may not fit all patients, the "tailored TAVR approach" has been proposed.[8] Since centers with access to only one type of TAVR device may only be able to offer treatment to a limited portion of the eligible patient population, our TAVR team has striven to be skilled in multiple TAVR devices and delivery approaches so treatment can be offered to the vast

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Conflicts of interest: Prof. Wei-Hsian Yin and Dr. Yung-Tsai Lee are proctors of transcatheter aortic valve replacement (TAVR) devices of the Medtronic, Edwards, and Boston Scientific companies. Dr. Kuo-Chen Lee, Dr. Tien-Ping Tsao, and Prof. Jeng Wei are proctors of Edwards TAVR devices. The other authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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majority of patients who are eligible for this procedure. However, data on whether multiple TAVR devices and delivery approaches performed by a single heart team can achieve equally favorable outcomes are scarce.[9]

Therefore, we evaluated the performance and outcomes of three different TAVR devices (MCV, Lotus, and SXT) for the treatment of severe AS at our center since 2013 to determine whether adverse events after TAVR were patient, device, and/or procedure specific.

2. METHODS

2.1. Study population and TAVR procedures

From March 2013 when the TAVR program was first introduced at Cheng-Hsin General Hospital to August 2017, 231 consecutive patients underwent TAVR at the institution. All patients with severe AS at high risk for conventional cardiac surgery were referred to the TAVR multidisciplinary team composed of interventional cardiologists, imaging cardiologists, cardiothoracic surgeons, radiologists, and anesthesiologists. The MCV device was used in 112 (48.5%) patients, the Lotus valve in 18 (7.8%) patients, and the SXT valve in 101 (43.7%) patients.

The MCV, Lotus, and SXT devices were introduced to our institution in 2013, 2015, and 2016, respectively. For all patients, the choice of access was based on pre-procedural imaging diagnostics, including computed tomography (CT) scan, angiography, and transesophageal and transthoracic echocardiography. In our institution, the default strategy for all patients is the transfemoral (TF) approach. If the first-choice TF access is not feasible due to diseased peripheral vessels, a trans-subclavian, transaortic, or transapical implantation would be considered.

All patients in the study population underwent implantation performed in a hybrid theater, and nearly all patients were treated under general anesthesia. TF TAVR was performed with the use of percutaneous closure devices or surgical cut down of the femoral artery in cases of vessel calcifications or severe obesity. In the trans-subclavian approach, the subclavian artery was dissected free for access through a 4- to 5-cm left infraclavicular incision. For transaortic access, an upper median mini-sternotomy was performed. Concurrent anterolateral mini-thoracotomy was performed in the fifth or sixth intercostal space to obtain straight access to the left ventricular apex in the transapical approach. In most cases, after balloon valvuloplasty during rapid ventricular pacing, valve deployment was performed under fluoroscopy.

After TAVR, all patients were monitored in the intensive care unit for at least 1 day, and heart rate monitoring was continued until discharge. All patients received treatment for platelet inhibition with aspirin 100 mg daily. Postoperatively, most patients were also prescribed clopidogrel 75 mg daily for 3 months. Patients with an indication for anticoagulant therapy received clopidogrel and warfarin or a direct oral anticoagulant without aspirin.

2.2. Follow-up and data collection

Echocardiography and clinical monitoring by the heart valve team were performed before and after the procedure for all patients. Follow-up included telephone interviews and office visits. Cases were censored at death or upon completion of 6 months of follow-up, whichever occurred first.

Prediction of patient operative mortality after TAVR was calculated, using the Society of Thoracic Surgeons' (STS) Online Risk Calculator (http://riskcalc.sts.org/stswebriskcalc/calculate). Echocardiographic studies performed at baseline and at 30 days after TAVR were evaluated according to the criteria of the American Society of Echocardiography.[10]

According to the Valve Academic Research Consortium-2 (VARC-2) consensus document, device success was defined as (1) the absence of procedural mortality, (2) the correct positioning of a single prosthetic heart valve into the proper anatomical location, and (3) the intended performance of the prosthetic heart valve (no prosthesis–patient mismatch with mean aortic valve gradient <20 mmHg or peak velocity <3 m/s and no moderate or severe prosthetic valve regurgitation).[15] Procedural success was defined as the achievement of successful deployment of the TAVR device and retrieval of the delivery system in the absence of mortality, conversion to surgical aortic valve replacement, or myocardial infarction (MI).

The composite primary endpoint of this study was major cardiac and cerebral adverse event (MACCE) in terms of combined all-cause death, nonfatal MI, and disabling stroke within 180 days following TAVR. Early 30-day safety endpoints included New York Heart Association (NYHA) functional class III/IV heart failure, life-threatening bleeding, acute kidney injury (AKI, stage 3), major vascular complication, paravalvular leakage, and need for permanent pacemaker implantation for complete heart block. AKI (stage 3) was defined as a ≥3.0-fold increase in serum creatinine (SCr) from baseline or increase to SCr ≥4.0 mg/dL (≥354 mmol/L) within 72 hours according to VARC-2 criteria.[11]

2.3. Statistical analysis

Univariate analyses were conducted to compare demographic, procedural, and outcome parameters of patients grouped by the type of TAVR device implanted. Continuous variables are expressed as mean ± SD and were compared using the Student's *t* test or the Wilcoxon rank sum test. Categorical variables are presented as number and percent frequency and were compared using the Pearson's chi-square test or the Fisher's exact test.

For the survival analysis, patients were divided into two groups depending upon whether or not MACCE (primary endpoint) occurred by the 180-day follow-up. Univariate comparisons of clinical characteristics and laboratory measurements between the two groups were made with appropriate tests. In the multivariate Cox proportional hazards analyses, the independent predictors of MACCE at 180 days were determined using variables including device types and those variables associated with the MACCE in the univariate analysis.

A two-sided p-value of <0.05 was considered statistically significant for all analyses. All statistical analyses were carried out using commercially available software (IBM SPSS for Windows, version 22.0; IBM Corp., New York, NY, USA).

3. RESULTS

Baseline demographic and clinical characteristics among the three groups of patients according to TAVR device are summarized in Table 1. The groups were generally well matched, although patients in the MCV group tended to be older (mean ages of MCV, Lotus, and SXT groups were 80±8, 78±8, and 78±9 years, respectively; p=0.056). Peripheral artery disease was less frequent in the Lotus group (17%) than in the MCV group (29%) and the SXT group (40%) (p=0.068), and end-stage renal disease needing dialysis was less frequent in the MCV group (5%) than in the Lotus (11%) and SXT (13%) groups (p=0.078), although the differences were not significant. There was no significant difference in mean STS score or the proportion of patients with NYHA functional class III/IV heart failure at presentation among the three groups.

Although the type and size of the prosthesis to be used for each patient was chosen based on echocardiographic and CT findings, the baseline echocardiography and CT measurements

Table 1

Baseline characteristics of the study patients

	CoreValve (n=112)	Lotus (n=18)	SXT (n=101)	*p*
Age, y	80±8	78±9	78±8	0.056
Male, n (%)	54 (47)	9 (50)	47 (47)	0.963
Body mass index, kg/m^2	24.1±3.7	23.6±2.9	24.2±4.1	0.876
Systemic hypertension, n (%)	80 (71)	13 (72)	66 (65)	0.601
Diabetes mellitus, n (%)	42 (38)	6 (33)	42 (42)	0.728
Dyslipidemia, n (%)	61 (55)	6 (33)	51 (51)	0.242
Current smoker, n (%)	8 (7)	1 (6)	6 (6)	0.925
Coronary artery disease, n (%)	75 (67)	12 (67)	65 (64)	0.920
Previous MI, n (%)	6 (5)	2 (11)	11 (11)	0.297
Previous percutaneous coronary intervention, n (%)	43 (38)	6 (33)	38 (38)	0.918
Previous coronary artery bypass grafting, n (%)	12 (11)	1 (6)	6 (6)	0.406
Previous valve surgery, n (%)	6 (5)	0 (0)	1 (1)	0.094
Carotid artery disease, n (%)	25 (22)	5 (28)	13 (13)	0.118
Previous stroke, n (%)	17 (15)	1 (6)	14 (14)	0.482
Peripheral vascular disease, n (%)	32 (29)	3 (17)	40 (40)	0.068
Previous atrial fibrillation, n (%)	36 (32)	5 (28)	33 (33)	0.917
Previous permanent pacemaker implantation, n (%)	10 (9)	1 (6)	12 (12)	0.610
Chronic obstructive pulmonary disease, n (%)	21 (19)	2 (11)	13 (13)	0.427
Chronic kidney disease ≥ stage 3, n (%)	64 (57)	9 (50)	53 (53)	0.730
End-stage renal disease needing dialysis, n (%)	5 (5)	2 (11)	13 (13)	0.078
Porcelain aorta, n (%)	4 (4)	1 (6)	7 (7)	0.539
Heart failure, NYHA functional class III/IV, n (%)	111 (99)	17 (94)	96 (95)	0.183
Syncope, n (%)	23 (21)	5 (28)	12 (12)	0.118
STS score, %	12.2±10.2	8.3±6.3	11.1±9.8	0.253

MI = myocardial infarction; NYHA = New York Heart Association; STS = Society of Thoracic Surgeon; SXT = SAPIEN XT.

Table 2

Baseline echocardiographic/computed tomographic measurements of the study patients

	CoreValve (n=112)	Lotus (n=18)	SXT (n=101)	*p*
Baseline CT				
Perimeter of aortic annulus, mm	73.1±10.6	73.8±8.5	74.4±6.3	0.734
Aortic annulus diameter (P), mm	23.3±3.4	23.5±2.0	23.7±2.9	0.730
Area of aortic annulus, mm^2	413.1±128.0	420.5±99.5	428.5±70.9	0.782
Aortic annulus diameter (A), mm	22.7±3.3	23.0±2.6	23.3±1.9	0.643
Bicuspid morphology, n (%)	16 (14)	3 (17)	17 (17)	0.870
Sino-tubular junction diameter, mm	27.7±3.4	27.5±3.6	27.2±3.1	0.875
Sinus of Valsalva diameter, mm	29.1±2.9	30.2±2.6	31.2±3.0	0.380
Left coronary height, mm	13.3±3.2	13.2±2.6	13.3±2.4	0.865
Right coronary height, mm	13.9±2.9	14.9±3.6	15.9±4.0	0.227
Left common iliac artery (MLD), mm	7.1±2.7	7.0±2.6	6.9±2.0	0.707
Left external iliac artery (MLD), mm	6.7±1.4	6.5±1.6	6.3±1.5	0.720
Left common femoral artery (MLD), mm	6.6±1.8	6.4±1.6	6.1±1.2	0.148
Right common iliac artery (MLD), mm	8.0±1.5	7.9±2.0	7.4±1.9	0.505
Right external iliac artery (MLD), mm	6.6±2.0	6.6±1.6	6.7±1.2	0.912
Right common femoral artery (MLD), mm	7.3±1.9	6.9±1.8	6.6±1.6	0.504

A = area-derived; CT = computed tomography; MLD = minimal luminal diameter; P = perimeter-derived; SXT = SAPIEN XT.

showed no significant differences among the three groups, as shown in Table 2.

Technical aspects of the procedure and procedural outcomes are presented in Table 3. Valve sizes ranged from 23 to 31 mm for MCV, 23 to 27 mm for Lotus, and 23 to 29 mm for SXT. Compared with the other two groups, mean valve size used in the Lotus group was significantly smaller (p<0.001), and a greater proportion of the implanted devices were sized ≤26 mm (Lotus: 94%, MCV: 55%, and SXT: 84%; p<0.001). TAVR procedure was performed via TF (91%), trans-subclavian (4%), or transaortic (5%) approach with MCV. TF access was the only approach applied for Lotus valve implantation. The balloon-expandable transcatheter SXT valves were implanted via TF, transapical, or transaortic access in 85%, 10%, and 5% of patients, respectively. In addition, balloon valvuloplasty for pre-dilatation was less frequently required with Lotus implantation compared with MCV and SXT (Lotus: 50%, MCV: 71%, and SXT: 97%; p<0.001), whereas balloon valvuloplasty for post-dilatation was needed more frequently with SXT (SXT: 29%, MCV: 13%, and Lotus: 11%; p=0.008). The mean final

Table 3

Procedural characteristics and immediate complications of the study patients

	CoreValve (n=112)	Lotus (n=18)	SXT (n=101)	*p*
THV valve size, mm				
≦26, n (%)	62 (55)	17 (94)	85 (84)	<0.001
>26, n (%)	50 (45)	1 (6)	16 (16)	<0.001
Vascular access				
TF, n (%)	102 (91)	18 (100%)	86 (85)	0.047
Pre-dilatation, n (%)	80 (71)	9 (50)	98 (97)	<0.001
Post-dilation, n (%)	14 (13)	2 (11)	29 (29)	0.008
Implantation depth from annulus, mm	5.3±2.5	1.9±1.1	2.3±1.1	<0.001
Device success, n (%)	96 (86)	15 (83)	91 (90)	0.424
Paravalvular leakage ≧ moderate, n (%)	4 (4)	1 (6)	2 (2)	0.660
Second device needed, n (%)	10 (9)	0 (0)	4 (4)	0.102
Post-TAVR transvalvular PG > 20 mmHg	2 (2)	2 (11)	2 (2)	0.318
Procedural success, n (%)	111 (99)	18 (100)	99 (98)	0.623
Conversion to SAVR, n (%)	0 (0)	0 (0)	0 (0)	–
Coronary obstruction, n (%)	1 (1)	0 (0)	3 (3)	0.379
Annulus rupture, n (%)	1 (1)	0 (0)	1 (1)	0.847
Left ventricular rupture, n (%)	0 (0)	0 (0)	0 (0)	–
Emergency CPB/ECMO, n (%)	6 (5)	0 (0)	3 (3)	0.324
Total procedure time, min	45.3±29.0	46.6±29.8	41.4±23.2	0.470
Total fluoroscopic time, min	27.8±14.6	26.8±13.3	24.1±11.0	0.120
Total contrast volume, min	112.1±40.2	132.7±58.4	142.1±59.2	<0.001

CPB/ECMO = cardiopulmonary bypass/extracorporeal membrane oxygenation; PG = pressure gradient; SAVR = surgical aortic valve replacement; SXT = SAPIEN XT; TAVR = transcatheter aortic valve replacement; TF = transfemoral; THV = transcatheter heart valve.

Table 4

Hemodynamic performance of the three TAVR devices

	CoreValve (n=112)	Lotus (n=18)	SXT (n=101)	*p*
Baseline echocardiography				
Mean PG, mmHg	45.6±20.5	43.9±23.1	43.7±19.2	0.795
AVA, cm^2	0.7±0.2	0.7±0.2	0.7±0.2	0.798
Left ventricular ejection fraction, %	53.7±12.7	57.2±13.1	52.5±14.3	0.377
Right ventricular systolic pressure, mmHg	43.8±14.0	38.6±14.1	45.0±17.2	0.273
Aortic regurgitation ≧moderate, n (%)	47 (42)	4 (22)	39 (39)	0.244
Echocardiography at 30 d				
Mean PG, mmHg	8.1±3.5*	14.0±6.7*	8.2±3.6*	<0.001
AVA, cm^2	1.8±0.3*	1.7±0.2*	2.0±0.3*	<0.001
Left ventricular ejection fraction, %	57.3±9.1*	58.7±11.0	57.2±9.4*	0.833
Right ventricular systolic pressure, mmHg	37.6±9.7*	32.8±8.4*	38.6±14.2*	0.221
Paravalvular leakage ≧moderate, n (%)	8 (7)	1 (6)	3 (3)	0.352

*$p<0.05$, 30 d vs baseline.

AVA = aortic valve area; PG = pressure gradient; SXT = SAPIEN XT; TAVR = transcatheter aortic valve replacement.

implantation depth below annulus was significantly deeper in patients of the MCV group (MCV: 5.3±2.5 mm, Lotus: 1.9±1.1 mm, and SXT: 2.3±1.1 mm; $p<0.001$). Implantation depth is assessed routinely by fluoroscopy in our institution. The distance from the zero level to the ventricular edge of the TAVR frame was measured using Siemens software (Syngo.via^{T-M}VB20A, Siemens Healthcare, Forchheim, Germany) for distance measurements. The bottom of the TAVR frame was first aligned with the axis of the device. Then, the distances between the lower edges of the TAVR frame and the non-coronary cusp and the left coronary cusp were acquired and averaged.

Ten (9%) patients with MCV and four (4%) patients with SXT required implantation of a second valve due to initial implant embolization to the ascending aorta or malpositioning (p=NS; non-significant). Moderate or more severe paravalvular leakage after TAVR procedure was found in four (4%) patients with MCV, one (6%) patient with Lotus, and two (2%) patients with SXT (p=NS). Two patients in each group had a post-procedural transvalvular gradient of >20 mmHg (p=NS). Overall, the device success rate was 86% for MCV, 83% for Lotus, and 90% for SXT (p=NS).

Rates of major intraoperative complications, including emergency conversion to open-heart surgery, annular or left ventricular rupture, coronary occlusion, or need for emergent hemodynamic support, were similar among the three groups, and the procedural success rate was 99% for MCV, 100% for Lotus, and 98% for SXT (p=NS). Mean procedure and fluoroscopic times were also similar among the three groups. However, the MCV group received lower mean contrast volume (MCV: 112.1±40.2 mL, Lotus: 132.7±58.4 mL, and SXT: 142.1±59.2 mL; $p<0.001$).

Table 4 shows the hemodynamic performance of the three TAVR devices. A significant reduction in prosthetic valvular

pressure gradient (PG) and increase in prosthetic aortic valve area (AVA) at 30 days were observed in all patients who underwent successful TAVR. However, in patients receiving a Lotus valve, a significantly higher mean transaortic valve PG (Lotus: 14.0±6.7 mmHg, MCV: 8.1±3.5 mmHg, and SXT: 8.2±3.6 mmHg; $p<0.001$) and smaller AVA (Lotus: 1.7±0.2 cm^2, MCV: 1.8±0.3 cm^2, and SXT: 2.0±0.3 cm^2; $p<0.001$) were observed. Follow-up echocardiography revealed significant improvements in left ventricular ejection fraction and right ventricular systolic pressure at 30 days post TAVR in nearly all patients with no significant difference among groups. Incidence of moderate or severe aortic regurgitation (AR) was low overall and not statistically different among the three devices used (MCV: 7%, Lotus: 6%, and SXT: 3%; $p=0.352$).

Clinical outcomes of the study cohort are shown in Table 5. Mean duration of stay in the intensive care unit did not differ among the three groups. Significant improvement in NYHA functional class was observed in all groups. At 30 days post TAVR, there were no significant difference in rates of all-cause mortality (MCV: 3%, Lotus: 0%, and SXT: 3%; $p=0.605$), cardiovascular mortality (MCV: 2%, Lotus: 0%, and SXT: 3%; $p=0.564$), periprocedural MI (0% in all groups; p=NS), stroke (MCV: 2%, Lotus: 0%, and SXT: 1%; $p=0.691$), major or life-threatening bleeding (MCV: 2%, Lotus: 0%, and SXT: 5%; $p=0.239$), major vascular complications (MCV: 11%, Lotus: 17%, and SXT: 5%; $p=0.388$), or AKI (stage 3) (MCV: 9%, Lotus: 0%, and SXT: 3%; $p=0.130$). Notably, patients in the Lotus group had a significantly higher rate of need for a permanent pacemaker (Lotus: 22%, MCV: 13%, and SXT: 3%; $p=0.004$).

At 180 days, no significant difference among groups in the rate of MACCE, including all-cause death, cardiovascular death, recurrent nonfatal MI, and stroke, was found. Multivariate analysis identified the lack of procedural success ($p=0.023$), presence of AKI (stage 3; $p=0.037$), and presence of coronary obstruction ($p=0.05$) to be independently associated with the primary composite endpoint within 180 days after TAVR (Table 6).

4. DISCUSSION

The main findings of our study are: (1) the three types of TAVR devices studied demonstrated favorable and comparable safety and efficacy outcomes at 30 and 180 days in this real-world cohort; (2) the Lotus device was associated with higher post-TAVR transaortic valve PG and greater need for permanent pacemaker implantation; and (3) the presence of acute coronary occlusion during TAVR, AKI, and persistent refractory heart failure after TAVR were independent predictors of adverse outcomes at 180 days.

In line with the results of the CHOICE trial, device success rate was somewhat lower with MCV at 86% than with the other two devices in this study, which can be mainly attributed to higher rates of embolization/migration and moderate or severe AR.[12,13] Compared with SXT, which was associated with a device success rate of 90%, device success rate was also lower with the Lotus valve at 83%, which is even lower than that reported in the REPRISE III trial.[14] This was mainly driven by a higher rate of patient–prosthesis mismatch. Comparable to the findings of the REPRISE III study, we found a similar higher mean post-TAVR transaortic valve PG of 12 mmHg and smaller mean AVA of 1.59 cm^2 with the Lotus valve compared to the other devices.[14] In the present study, despite well-matched baseline annular dimensions, a significantly larger number of small prostheses were inserted in the Lotus cohort in following with the manufacturer's recommendations of less oversizing with this device, possibly relating to the valve design. It is possible that the smaller average device size contributed to a higher mean gradient. However, severe patient–prosthesis mismatch after TAVR is rare and can be predicted by larger body surface area and does not seem to affect midterm mortality or composite clinical outcome. Larger studies are needed to identify different independent predictors of PPM and to elucidate its impact in terms of device durability and long-term clinical efficacy. Moreover, the lower device success rates with MCV and Lotus valves in our study may have occurred by chance, as our study was underpowered for that event, but it could also have been related to the learning curve specific to those prostheses. Previous studies have shown that MCV implantation, having the advantage of supra-annular valve positioning, led to a higher AVA and lower MPG in comparison to SXT.[12,13] In our study, however, MCV was associated with a smaller AVA, possibly related to deeper implantation, less frequent pre-dilatation, and slightly smaller baseline annulus diameter.

Table 5

Thirty- and 180-d clinical outcomes of the study patients

	CoreValve (n=112)	Lotus (n=18)	SXT (n=101)	*p*
Intensive care unit stay, d	5±10	2±1	3±7	0.119
30-d NYHA functional class I/II, n (%)	85 (77)	14 (78)	78 (78)	0.942
30-d MACCE, n (%)	5 (5)	0 (0)	4 (4)	0.467
All-cause mortality, n (%)	3 (3)	0 (0)	3 (3)	0.605
Cardiac mortality, n (%)	2 (2)	0 (0)	3(3)	0.564
Nonfatal MI, n (%)	0 (0)	0 (0)	0 (0)	–
Nonfatal stroke, n (%)	2 (2)	0 (0)	1 (1)	0.691
Other 30-d VARC complications				
Major or life-threatening bleeding, n (%)	2 (2)	0 (0)	5 (5)	0.239
Major vascular access complication, n (%)	12 (11)	3 (17)	5 (5)	0.388
AKI, stage 3, n (%)	10 (9)	0 (0)	3 (3)	0.130
Permanent pacemaker for CAVB, n (%)	15 (13)	4 (22)	3 (3)	0.004
31–180-d MACCE, n (%)	13 (12)	1 (6)	9 (9)	0.635
All-cause mortality, n (%)	11 (10)	1 (6)	7 (7)	0.676
Cardiac mortality, n (%)	3 (3)	1 (6)	5 (5)	0.641
Nonfatal MI, n (%)	0 (0)	0 (0)	0 (0)	–
Nonfatal stroke, n (%)	1 (1)	0 (0)	2 (2)	0.717

AKI = acute kidney injury; CAVB = complete atrioventricular block; MACCE = major cardiac and cerebral adverse event; MI = myocardial infarction; NYHA = New York Heart Association; SXT = SAPIEN XT; VARC = Valve Academic Research Consortium.

Table 6

Independent prognostic determinants of composite MACCEs at 180 d by univariate and multivariate analysis

	MACCE (+) (n=23)	MACCE (–) (n=208)	Univariate *p*	Multivariate *p*
Baseline characteristics				
Age, y	81±6	79±8	0.160	
Male, n (%)	11 (48)	98 (47)	0.998	
Body mass index, kg/m^2	23.2±4.1	24.2±3.8	0.258	
Systemic hypertension, n (%)	18 (78)	141 (68)	0.429	
Diabetes mellitus, n (%)	12 (52)	78 (38)	0.253	
Dyslipidemia, n (%)	11 (48)	107 (51)	0.913	
Current smoker, n (%)	2 (9)	13 (6)	0.995	
Coronary artery disease, n (%)	17 (74)	135 (65)	0.527	
Previous MI, n (%)	3 (13)	16 (8)	0.627	
Previous percutaneous coronary intervention, n (%)	11 (48)	76 (37)	0.405	
Previous coronary artery bypass grafting, n (%)	3 (13)	16 (8)	0.627	
Previous valve surgery, n (%)	0 (0)	7 (3)	0.801	
Carotid artery disease, n (%)	7 (30)	36 (17)	0.210	
Previous stroke, n (%)	2 (9)	30 (14)	0.663	
Peripheral vascular disease, n (%)	13 (57)	62 (30)	0.018	0.682
Previous atrial fibrillation, n (%)	7 (30)	67 (32)	0.999	
Previous permanent pacemaker implantation, n (%)	3 (13)	20 (10)	0.878	
Chronic obstructive pulmonary disease, n (%)	6 (26)	30 (14)	0.246	
Chronic kidney disease ≧ stage 3, n (%)	16 (70)	110 (53)	0.192	
End-stage renal disease needing dialysis, n (%)	3 (13)	17 (8)	0.691	
Porcelain aorta, n (%)	0 (0)	12 (6)	0.491	
Heart failure, NYHA functional class III/IV, n (%)	23 (100)	201 (97)	0.801	
Syncope, n (%)	2 (9)	38 (18)	0.389	
STS score, %	18.9±10.4	10.6±9.4	<0.001	0.351
Baseline echocardiography				
Mean PG, mmHg	45.1±27.7	44.6±19.1	0.925	
AVA, cm^2	0.6±0.2	0.7±0.2	0.565	
Left ventricular ejection fraction, %	49.2±15.5	53.9±13.2	0.113	
Right ventricular systolic pressure, mmHg	46.4±10.0	43.6±15.4	0.414	
Aortic regurgitation ≧ moderate, n (%)	10 (44)	80 (39)	0.882	
Mitral regurgitation ≧ moderate, n (%)	13 (57)	98 (47)	0.538	
Device characteristics				
Transcatheter heart valve type				
CoreValve, n (%)	13 (57)	99 (48)	0.553	
Lotus, n (%)	1 (4)	17 (8)	0.811	
SXT, n (%)	9 (39)	92 (44)	0.805	
Transcatheter heart valve type				
23 mm, n (%)	5 (22)	58 (28)	0.703	
25 or 26 mm, n (%)	13 (56)	88 (42)	0.279	
27, 29, or 31 mm, n (%)	5 (22)	62 (30)	0.571	
Procedural characteristics				
Vascular access				
TF access	18 (78)	188 (90)	0.155	
Pre-dilatation, n (%)	17 (74)	170 (82)	0.531	
Post-dilatation, n (%)	3 (13)	42 (20)	0.586	
Device success, n (%)	19 (83)	188 (90)	0.424	
Paravalvular leakage ≧ moderate, n (%)	0 (0)	7 (3)	0.825	
Second device needed, n (%)	2 (9)	12 (6)	0.922	
Procedural success, n (%)	21 (91)	207 (99)	0.020	0.024
Coronary obstruction, n (%)	2 (9)	2 (1)	0.063	0.050
Annulus rupture, n (%)	1 (4)	1 (1)	0.475	
Emergency CPB/ECMO, n (%)	2 (9)	7 (3)	0.493	
New left bundle branch block, n (%)	6 (26)	69 (33)	0.650	
Newly developed complete heart block, n (%)	1 (4)	10 (5)	0.998	
Total procedure time, min	41.3±27.9	44.1±26.5	0.631	
Total fluoroscopic time, min	27.3±17.2	26.0±12.6	0.650	
Total contrast volume, min	120.0±46.0	127.6±53.3	0.510	

(*Continued*)

Table 6 (Continued)

	MACCE (+) (n=23)	MACCE (–) (n=208)	Univariate *p*	Multivariate *p*
30-d VARC complications				
Major or life-threatening bleeding, n (%)	1 (4)	6 (3)	0.996	
Major vascular access complication, n (%)	5 (22)	14 (7)	0.037	0.834
AKI, stage 3, n (%)	7 (35)	6 (3)	<0.001	0.037
Permanent pacemaker for CAVB, n (%)	5 (22)	26 (13)	0.362	
30-d NYHA functional class III/IV, n (%)	17 (74)	37 (18)	<0.001	0.066
Echocardiography at 30 –d				
Mean PG, mmHg	8.7±6.5	8.6±4.0	0.900	
AVA, cm^2	1.9±0.3	1.9±0.3	0.419	
Left ventricular ejection fraction, %	56.2±6.0	57.4±9.5	0.669	
Right ventricular systolic pressure, mmHg	39.9±15.0	37.6±11.7	0.528	
Paravalvular leakage ≥ moderate, n (%)	1 (9)	11 (6)	0.995	

AKI = acute kidney injury; AVA = aortic valve area; CAVB = complete atrioventricular block; CPB/ECMO = cardiopulmonary bypass/extracorporeal membrane oxygenation; MACCE = major cardiac and cerebral adverse event; MI = myocardial infarction; NYHA = New York Heart Association; PG = pressure gradient; STS = Society of Thoracic Surgeon; SXT = SAPIEN XT; TF = transfemoral; VARC = Valve Academic Research Consortium.

It is worth noting that the necessity for permanent pacemaker implantation was significantly higher with MCV (13%) and Lotus valve (22%) than with STX (3%) in this study, as has been shown in many previous publications.[5,12,14] In the head-to-head comparison REPRISE III study, the use of Lotus was associated with low rates of death, stroke, and paravalvular leakage, but the rate of pacemaker implantation at 30 days was nearly doubled in Lotus-treated vs MCV-treated patients (35.5% vs 19.6%; $p<0.001$).[14] It has been well shown that pacemaker implantation leads to greater ventricular dysfunction and increased hospitalization costs, despite having no impact on mortality in TAVR patients.[15] Hence, even though the Lotus device is expected to return to market as the newer-generation Lotus Edge, whether the higher post-TAVR PG and pacemaker implantation rate would compromise long-term outcomes remains uncertain. As for MCV, the higher pacemaker implantation rate may be related to deeper implantation of the device. Fortunately, the next generation of the MCV device, the Evolut-R valve, allows retrieval and repositioning. Recently launched in Taiwan, the new device is expected to result in a lower pacemaker implantation rate compared with the earlier MCV valve. The Evolut-R valve may also improve device success rate through reduction in embolization/migration and moderate or severe AR.

Among uncommon but clinically relevant complications following the TAVR procedure, acute coronary obstruction during valve implantation or delayed coronary obstruction occurring in the early or late (≥60 days) post-procedural phase may occur.[16,17] In the present study, the development of coronary obstruction within 30 days was one of the main determinants of adverse outcome at 180 days. In this regard, the possibility of coronary obstruction should be considered during the prosthesis selection process. For example, the Evolut-PRO valve has a longer frame that extends beyond the coronary ostia, thereby likely lowering risk of coronary obstruction.[18] On the other hand, valves with a larger stent cell size and shorter frame may facilitate future access to the coronary orifices.[19] Moreover, certain newer-generation TAVR devices are fixed in place via direct anchoring to either calcified native leaflets or surgical valve leaflets, which mitigates the risk of future valve tissue prolapse and coronary obstruction.[20] In addition, to optimize future coronary reaccess, implantation depth is critical, especially if the ostia is <10 mm.[18]

In our series, the presence of stage 3 AKI was a significant predictor of adverse events. The etiology of post-TAVR AKI is multifactorial, but the principle procedural issues are contrast-induced nephropathy and renal hypoperfusion secondary to intra-procedural hypotension.[21] Although the mean amounts of contrast used in our study were similar to those reported in previous publications, there is still room for improvement. For those patients with preexisting chronic renal impairment, the use of a self-expandable or mechanically expandable valve that features retrievability and repositionability under the guidance of echocardiography or fluoroscopy–echocardiography fusion imaging may allow more accurate valve placement without the need for contrast aortography.[22]

4.1. Study limitations

First, although the three groups of patients according to prosthesis used were similar in terms of comorbidities and pre-procedural risk, this was not a randomized trial; therefore, the study is subject to selection bias and unmeasured confounders. Second, it was performed at a single center including a relatively small number of patients. Third, as follow-up was restricted to 180 days, further research on longer-term outcomes of these three devices is warranted.

In conclusion, our data clearly demonstrated that there were no differences in VARC-2 combined early safety endpoints at 30 days or the primary endpoint at 180 days among patients receiving MCV, Lotus, or SXT devices. Results suggest that once a heart team achieves technical proficiency in the implantation of a specific device, post-TAVR adverse events seem to be mainly patient specific. This study compared the technical success rate, hemodynamic performance, and VARC-2 outcomes of three different TAVR devices in a single center in Asia. The findings could serve as valuable benchmarks for guiding patient selection for specific TAVR devices and assessing the performance of newer-generation TAVR devices in the future.

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