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Original article

Comparison of Edwards SAPIEN 3 versus SAPIEN XT in transfemoral transcatheter aortic valve implantation: Difference of valve selection in the real world

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ABSTRACT

Background: The SAPIEN 3 (S3; Edwards Lifescience, Irvine, CA, USA) is a new-generation percutaneous aortic valve with better profile, more precise handling and positioning, designed to reduce the risk of post-procedural paravalvular aortic leak (PVL). The aim of this study was to compare the S3 valve and SAPIEN XT valve (SXT).

Methods: The last 89 transfemoral transcatheter aortic valve implantation (TAVI) cases using SXT were compared to the first 111 cases using the S3.

Results: Patient age and logistic EuroSCORE were similar (83.1 years vs 83.0 years and 18.2% vs 16.6%) in the S3 and SXT groups, respectively as were other baseline characteristics. The ratio of valve diameter/calculated annulus average diameter (CAAD) by multi-detector row computed tomography was significantly lower in the S3 group (1.06 vs 1.09, $p < 0.001$) as was the annular area oversizing percentage (11.3% vs 20.5%, $p < 0.001$). Furthermore, a smaller valve was selected in S3 cases with borderline CAAD compared to SXT cases. Nevertheless, the frequency of paravalvular aortic leakage (PVL) $\geq$2 tended to be reduced in the S3 group (5% vs 9%, $p = 0.339$). The rate of major vascular complications was significantly lower with S3 (3% vs 12%, $p = 0.013$). In addition, 30-day mortality was significantly lower in the S3 group (0% vs 5%, $p = 0.044$).

Conclusions: Although TAVI using S3 tended to be carried out with a less oversized valve compared to TAVI using SXT, the frequency of post-procedural PVL $\geq$2 tended to be lower in the S3 group. The outcomes including vascular complications and 30-day mortality showed a trend in favor of the S3 group.

Introduction

Transcatheter aortic valve implantation (TAVI) has gained increasing acceptance as a treatment option for patients with severe symptomatic aortic stenosis (AS) who are considered at high risk for surgical aortic valve replacement [1–7]. Despite its minimally invasive nature, TAVI is invariably associated with complications such as paravalvular aortic leak (PVL) and access site complications, which remain limiting factors potentially affecting the outcome of this treatment strategy [2,8–10]. In order to overcome these problems, the balloon-expandable SAPIEN 3 prosthesis (S3; Edwards Lifescience, Irvine, CA, USA) was designed to reduce post-procedural PVL by adding an outer skirt at the distal part of the prosthesis. In addition, the S3 sheath size was reduced

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in order to improve the feasibility and safety of the transfemoral approach [11]. However, there are currently only limited data focusing on the differences between the two prosthesis generations.

The aim of this study was, therefore, to compare the two valves, especially regarding PVL and vascular complications.

Materials and methods

Study design

From October 2006, all consecutive high-risk patients, with severe symptomatic AS treated with TAVI in Massy, France, were prospectively included in our dedicated TAVI database. Patients with severe AS were considered candidates for TAVI if they were deemed ineligible or high risk for surgical aortic valve replacement. The decision to proceed with TAVI was made by a dedicated heart team composed of experienced clinical and interventional cardiologists, imaging specialists, cardiovascular surgeons, and anesthesiologists. The analysis reported here included the first 111 TF-TAVI procedures using the S3, which were performed between June 2013 and March 2015, and the last 89 using the SAPIEN XT valve (SXT), performed between June 2013 and August 2014. Written informed consent was obtained from all patients.

Vascular access and valve selection

Patients were selected to undergo TAVI via the transfemoral approach (TF) or alternative approaches depending on the size, calcification, and tortuosity of the ilio-femoral arterial access. The type and size of valve prosthesis was mainly selected according to the team's and main operator's preference. In all cases, the aortic root was assessed by multi-detector row computed tomography (MDCT) before the procedure in terms of calcification volume and location, distance between annulus and coronary arteries, and annulus diameter, which was the calculated annulus average diameter (CAAD) derived from the annulus area. The nominal external valve area of an expanded S3 prosthesis is 409 mm (23 mm), 519 mm (26 mm), and 649 mm (29 mm), as previously described [12]. The percentage of oversizing or undersizing was calculated using the following formula: (prosthesis nominal area/MDCT annular area $-$ 1) $\times$ 100.

Procedures

Aspirin (75 mg) and clopidogrel (75 mg) daily were recommended prior to TAVI. A loading dose of clopidogrel (300–600 mg) was administered to patients who were not already on clopidogrel before or immediately after the procedure. Only one antiplatelet therapy (aspirin or clopidogrel) was used in combination with warfarin in the majority of patients on long-term anticoagulant therapy. A bolus of heparin (70 IU kg^{-1}) was administered at the start of the procedure to achieve an activated clotting time of 250–300 s, and the activated clotting time was measured every 30 min thereafter. All procedures were performed by an experienced team according to our standard operating procedures, as previously described [13].

Post-procedural assessment of PVL

After the procedure, semi-quantitative grading of PVL was performed using transthoracic echocardiography and aortography. Echocardiography was performed in all patients by experienced echocardiographers using a multi-parametric approach was as follows: 0 = absent, 1 = trace, 2 = mild, 3 = moderate, and 4 = severe.

Post-procedural care

All patients were observed in the intensive care unit for at least 24 h after valve implantation. Dual antiplatelet therapy was continued for 1–3 months and, thereafter, aspirin was continued indefinitely. In patients on warfarin, aspirin or clopidogrel was stopped after 1 month.

Endpoints

The main endpoints of this study were the frequency of PVL $\geq$2 after the procedure, major vascular complications, combined 30-day safety endpoint, and all-cause mortality at 30 days. The combined 30-day safety endpoint included all-cause mortality, major stroke, life-threatening bleeding, acute kidney injury (AKI)-stage 3, major vascular complications, and further intervention due to valve dysfunction, according to the valve academic research consortium (VARC)-2 criteria [15]. AKI-stage 3 was defined as a change in serum creatinine (SCr) up to 72 h compared with baseline: $\geq$3.0-fold increase in SCr or ΔSCr $\geq$4.0 mg/dl ($\geq$354 μmol/l) according to VARC-2 criteria.

Statistical analysis

All statistical analyses were performed using SPSS version 21.0 (Chicago, IL, USA). Continuous variables are expressed as mean $\pm$ SD or with the corresponding interquartile range. Dichotomous variables are expressed as counts and percentages. Comparisons between the two groups were performed using Pearson's bivariate test and the chi-square test for categorical covariates, and unpaired Student t test for continuous covariates. A value of $p < 0.05$ was considered significant.

Results

Baseline characteristics stratified by prosthesis type

The main characteristics of the two groups are summarized in Table 1. Patient age, 83.1 years vs 83.0 years (p = 0.940) and logistic EuroSCORE 18.2% vs 16.6% (p = 0.385) were similar in the S3 and SXT groups, respectively. Other baseline characteristics were also similar between the two groups.

Annular assessment by MDCT and procedural characteristics stratified by prosthesis type

Annular assessment by MDCT and procedural characteristics are summarized in Table 2. The CAAD by MDCT was similar (23.7 mm vs 23.9 mm, p = 0.534) as was the annular area by MDCT (450 mm^2 vs 458 mm^2, p = 0.556). On the other hand, the valve size was smaller in the S3 group compared to the SXT group (25.1 $\pm$ 2.3 mm vs 26.2 $\pm$ 2.2 mm, p = 0.002) as were the valve diameter/CAAD ratio (1.06 vs 1.09, $p < 0.001$) and the % of annular area oversizing (11% vs 20%, $p < 0.001$). The sheath size was also significantly smaller in the S3 group (14.3 mm vs 18.1 mm, $p < 0.001$).

Annular assessment by MDCT stratified by valve size

Annular assessment by MDCT stratified by valve size is summarized in Table 3. In recipients of 23-mm and 26-mm prostheses, the valve diameter/CAAD ratio was significantly lower

Table 1
Baseline clinical characteristics stratified by prosthesis type.

	SXT ($n=89$)	S3 ($n=111$)	p-Value
Baseline characteristics			
Age (years)	83.0 ± 7.4	83.1 ± 6.1	0.940
Gender, male	44 (49%)	47 (42%)	0.319
BMI (kg/m^2)	27.0 ± 5.2	26.2 ± 5.2	0.307
BSA (m^2)	1.77 ± 0.21	1.72 ± 0.21	0.154
NYHA classification (III/IV)	85 (96%)	109 (98%)	0.292
Prior MI, *n*	1 (1%)	0 (0%)	0.456
Prior PCI, *n*	19 (21%)	17 (15%)	0.220
Prior CABG, *n*	3 (4%)	8 (7%)	0.416
Prior stroke, *n*	1 (1%)	1 (1%)	0.881
Diabetes mellitus, *n*	18 (20%)	31 (27%)	0.205
Hypertension, *n*	61 (69%)	77 (69%)	0.900
Dyslipidemia, *n*	46 (52%)	51 (45%)	0.422
COPD, *n*	4 (5%)	3 (3%)	0.504
Logistic EuroSCORE (%)	16.6 ± 11.7	18.2 ± 12.1	0.385
Creatinine clearance (ml/min)	58.5 ± 23.2	60.5 ± 29.6	0.599
Echocardiographic data			
LVEF (%)	51.1 ± 15.5	54.9 ± 11.3	0.057
AVA (cm^2)	0.64 ± 0.14	0.65 ± 0.15	0.721
Mean gradient (mmHg)	48.0 ± 15.5	50.7 ± 14.7	0.288
AR grade (0–4)	0.80 ± 0.83	1.03 ± 0.63	0.074
MR grade (0–4)	1.08 ± 0.93	1.16 ± 0.77	0.533
PAP (mmHg)	47.9 ± 13.1	44.1 ± 14.5	0.111
Diameter of femoral artery (mm)	7.7 ± 1.2	7.5 ± 1.2	0.443

Values are number (%) or mean ± SD.
BMI, body mass index; BSA, body surface area; NYHA, New York Heart Association; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; LVEF, left ventricle ejection fraction; AVA, aortic valve area; AR, aortic regurgitation; MR, mitral regurgitation; PAP, pulmonary artery pressure; SXT, SAPIEN XT valve; S3, SAPIEN 3 valve. Diameter of femoral artery was assessed by angiography.

patients treated with 29-mm prostheses, the valve diameter/CAAD ratio tended to be lower in the S3 group as was the annular area oversizing percentage.

Valve selection trends for cases with borderline annulus

The valve selection trends for cases with borderline annulus are summarized in Fig. 1A (CAAD: 22–23.5 mm) and Fig. 1B (CAAD: 25–26.5 mm). A significantly smaller valve size was selected in S3 cases with borderline annulus.

Table 2
Annular assessment by MDCT and procedural characteristics stratified by prosthesis type.

	SXT ($n=89$)	S3 ($n=111$)	p-Value
MDCT-guided valve sizing	89 (100%)	111 (100%)	1.000
Short-axis diameter of annulus by MDCT (mm)	22.1 ± 2.2	21.7 ± 2.1	0.242
Long-axis diameter of annulus by MDCT (mm)	26.7 ± 2.8	26.4 ± 2.7	0.523
CAAD by MDCT	23.9 ± 2.3	23.7 ± 2.4	0.534
Annular area by MDCT (mm^2)	458.7 ± 87.3	450.4 ± 94.6	0.556
Aortic valve calcium volume (mm^3)	561.2 ± 570.0	634.0 ± 363.3	0.630
Procedural characteristics			
Sheath size (Fr)	18.1 ± 1.6	14.3 ± 0.8	<0.001
Size of valve (mm)	26.2 ± 2.2	25.1 ± 2.3	0.002
Valve/CAAD	1.09 ± 0.04	1.06 ± 0.04	<0.001
Nominal area oversizing (%)	20.5 ± 10.0	11.3 ± 10.0	<0.001
Contrast underfilling	8 (9%)	8 (7%)	0.646
Contrast overfilling	8 (9%)	6 (5%)	0.326

Values are number (%) or mean ± SD.
MDCT, multi-detector computed tomography; CAAD, calculated aortic annulus diameter; SXT, SAPIEN XT valve; S3, SAPIEN 3 valve.

Table 3
Annular assessment by MDCT stratified by valve size.

	SXT ($n=89$)	S3 ($n=111$)	p-Value
23 mm	21	52	
CAAD by MDCT	20.9 ± 0.9	21.7 ± 0.9	0.004
Annular area by MDCT (mm^2)	348.4 ± 30.1	372.1 ± 32.5	0.012
Valve/CAAD	1.09 ± 0.05	1.05 ± 0.04	0.003
Nominal area oversizing (%)	20.0 ± 11.1	10.7 ± 10.2	0.003
26 mm	41	37	
CAAD by MDCT	23.5 ± 0.9	24.3 ± 1.0	0.003
Annular area by MDCT (mm^2)	439.4 ± 36.1	463.8 ± 37.6	0.009
Valve/CAAD	1.10 ± 0.04	1.07 ± 0.04	0.003
Nominal area oversizing (%)	21.5 ± 9.1	12.6 ± 9.2	<0.001
29 mm	27	22	
CAAD by MDCT	26.6 ± 1.3	27.4 ± 1.4	0.079
Annular area by MDCT (mm^2)	556.6 ± 48.5	593.3 ± 62.7	0.031
Valve/CAAD	1.09 ± 0.05	1.06 ± 0.05	0.074
Nominal area oversizing (%)	19.6 ± 10.8	10.5 ± 11.1	0.007

Values are number (%) or mean ± SD.
MDCT, multi-detector computed tomography; CAAD, calculated aortic annulus diameter; SXT, SAPIEN XT valve; S3, SAPIEN 3 valve.

Post-procedural characteristics stratified by prosthesis type

Post-procedural characteristics are summarized in Table 4. The frequency of paravalvular aortic leakage (PVL) ≥2 tended to be lower in the S3 group (5% vs 9%, $p = 0.339$). The rate of major vascular complications was significantly lower in recipients of the S3 (3% vs 12%, $p = 0.013$), while the need for pacemaker implantation was not increased (7% vs 4%, $p = 0.341$). In addition, 30-day mortality was significantly lower in the S3 group (0% vs 5%, $p = 0.044$).

Impact of prosthesis type on 2-month survival after TAVI

The median follow-up period of this cohort was 82 days. Cumulative survival rates were calculated using the Kaplan–Meier method and compared with the log-rank test (Fig. 2). Although, the 2-month survival rate was not significantly different between the two groups, there was a trend in favor of the S3 group (log-rank $p = 0.053$).

Discussion

The present study shows that compared to the SXT, the frequency of PVL ≥2 tended to be decreased in the S3 group. Furthermore, device downsizing and more precise valve positioning may reduce the risk of 30-day mortality.

Amat-Santos et al. reported that the frequency of PVL decreased with S3 compared to SXT in a small series of 27 S3 compared to 50 SXT [16]. Yang et al. also reported that the frequency of PVL decreased with S3 compared to SXT in a series of 61 S3 compared to 92 SXT [12]. Moderate to severe PVL after TAVI has been reported to be associated with poor outcomes [17] and even mild PVL may lead to unfavorable outcomes as shown by an increasing volume of data [18,19]. In order to address this issue, the S3 was designed to reduce PVL after the procedure by means of an additional outer skirt at the distal part of the prosthesis. Our study clearly shows that the use of the S3 valve is associated with a lower risk of PVL despite a relatively small ratio between valve diameter and CAAD.

We recently reported the importance of the valve diameter/CAAD ratio for predicting the risk of post-procedural PVL after implantation of the SAPIEN valve [20] with a mean valve diameter/CAAD ratio of 1.09 in patients with PVL <2 and 1.05 in patients with PVL ≥2. In the present study, this ratio was significantly lower in the S3 group compared to SXT (1.06 vs 1.10), while the risk of

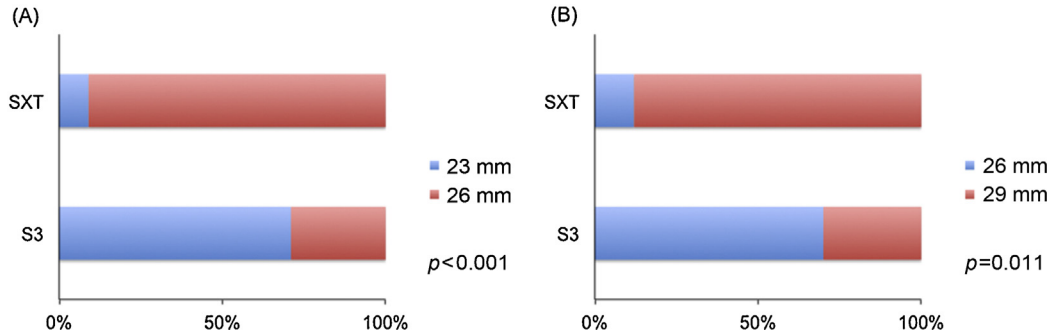

Fig. 1. (A) Valve selection trends (valve selection patterns) for cases with borderline annulus (CAAD: 22–23.5 mm). (B) Valve selection trends (valve selection patterns) for cases with borderline annulus (CAAD: 25–26.5 mm). CAAD, calculated annulus average diameter; SXT, SAPIEN XT valve; S3, SAPIEN 3 valve.

Table 4
Post-procedural characteristics stratified by prosthesis type.

	SXT ($n=89$)	S3 ($n=111$)	p-Value
Post-procedural variables			
Procedural success	85 (96%)	110 (99%)	0.083
30-Day mortality	4 (5%)	0 (0%)	0.044
30-Day combined safety endpoint	8 (10%)	5 (4%)	0.160
Major stroke	0 (0%)	0 (0%)	–
AKI	2 (4%)	2 (2%)	0.946
Major vascular complication	11 (12%)	3 (3%)	0.013
Life-threatening bleeding	0 (0%)	0 (0%)	–
Annulus rupture	1 (2%)	0 (0%)	0.320
Pacemaker implantation	3 (4%)	8 (7%)	0.341
2-Valve implantation	0 (0%)	1 (1%)	0.321
Post-procedural PVL ≥grade 2	8 (9%)	6 (5%)	0.339
Mean gradient by TTE (mmHg)	9.6 ± 3.6	11.0 ± 5.4	0.319

Values are number (%) or mean ± SD. AKI, acute kidney injury; PVL, paravalvular aortic leakage; TTE, transthoracic echocardiography; SXT, SAPIEN XT valve; S3, SAPIEN 3 valve.

ratio was applied in order to limit the risk of PVL ≥2, which can potentially lead to an increased risk of annulus rupture or perforation. The possibility of decreasing this ratio, while reducing the risk of PVL ≥2, is clearly a major technological advancement, which could lower the risk of not only 30-day but also longer-term mortality.

Another improved feature of the S3 seems to be the reduced profile of the delivery system. The 14 Fr E-sheath can accommodate a 23- and 26-mm valve and the 16Fr E-sheath a 29-mm valve. It has been reported that using a larger sheath can lead to a higher risk of vascular complications, which are considered major

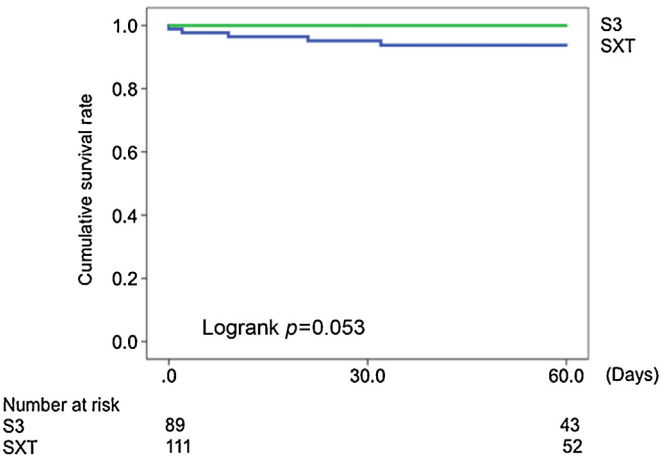

Fig. 2. Survival curves stratified by prosthesis type among all patients. SXT, SAPIEN

complications likely to affect the outcome of TAVI patients [21,22]. This study showed that the sheath size was significantly reduced, and the incidence of major vascular complications tended to be lower with the S3 valve.

Tarantini et al. reported that the frequency of post-procedural pacemaker implantation was higher in recipients of the S3 valve compared to the SXT (20.7% vs 3.4%, $p < 0.0001$) and that deep valve implantation was associated with a higher need for permanent pacemaker implantation [23]. In the study presented here, the valve was positioned sufficiently high according to the recommendations provided by experts, which explains the relatively low rate of pacemaker implantation (7%) and the absence of significant differences between the S3 and SXT.

The present study revealed that 2-month survival tended to be better in the S3 group compared to SXT group. The lower rate of PVL and vascular complication in the S3 group seems to lead to the better outcome. Recently, Del Trigo et al. reported that smaller size of SXT was related to valve hemodynamic deterioration according to the follow-up echocardiographic data [24]. The present study revealed that smaller valve tended to be selected in S3 group. Further studies are required to clarify longer outcomes including survival and hemodynamic change of S3.

Finally, these preliminary data are promising. Indeed, should the 30-day and longer-term results be confirmed, the S3 valve could pave the way for percutaneous treatment of patients at intermediate risk.

Study limitations

The present study has several limitations that should be addressed. Firstly, this was a single-center retrospective observational study conducted in a limited cohort. Further studies with larger cohorts and multi-center analysis are required to confirm our results. Secondly, the mean follow-up period was 82 days and long-term follow-up is needed to confirm the S3 safety.

Conclusions

Although TAVI using the S3 tended to be carried out with a less oversized valve compared to TAVI using the SXT, the frequency of post-procedural PVL ≥2 tended to be lower in the S3 group. The outcomes including vascular complications and 30-day mortality showed a trend in favor of the S3 group.

Conflict of interest statement

Thierry Lefèvre is a proctor for transfemoral-TAVI for Edwards Lifesciences, and is a consultant for Symetis, Direct Flow Medical, Boston Scientific, and Medtronic. Kentaro Hayahida is a proctor for

proctor for transfemoral-TAVI for Edwards Lifesciences. Bernard Chevalier is a consultant and proctor for Medtronic.

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References

[1] Zahn R, Gerckens U, Grube E, Linke A, Sievert H, Eggebrecht H, Hambrecht R, Sack S, Hauptmann KE, Richardt G, Figulla HR, Senges J, German Transcatheter Aortic Valve Interventions-Registry Investigators. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. Eur Heart J 2011;32:198–204.
[2] Moat NE, Ludman P, de Belder MA, Bridgewater B, Cunningham AD, Young CP, Thomas M, Kovac J, Spyt T, MacCarthy PA, Wendler O, Hildick-Smith D, Davies SW, Trivedi U, Blackman DJ, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis: the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry. J Am Coll Cardiol 2011;58:2130–8.
[3] Webb J, Cribier A. Percutaneous transarterial aortic valve implantation: what do we know? Eur Heart J 2011;32:140–7.
[4] Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Brown DL, Block PC, Guyton RA, Pichard AD, Bavaria JE, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010;363:1597–607.
[5] Lefevre T, Kappetein AP, Wolner E, Nataf P, Thomas M, Schachinger V, De Bruyne B, Eltchaninoff H, Thielmann M, Himbert D, Romano M, Serruys P, Wimmer-Greinecker G, PARTNER EU Investigator Group. One year follow-up of the multi-centre European PARTNER transcatheter heart valve study. Eur Heart J 2011;32:148–57.
[6] Arai T, Lefevre T. Who is the right patient for TAVI? J Cardiol 2014;63:178–81.
[7] Wendt D, Al-Rashid F, Kahlert P, El-Chilali K, Demircioglu E, Neuhauser M, Liakopoulos O, Sebastian Dohle D, Erbel R, Jakob H, Thielmann M. Conventional aortic valve replacement or transcatheter aortic valve implantation in patients with previous cardiac surgery. J Cardiol 2015;66:292–7.
[8] Abdel-Wahab M, Zahn R, Horack M, Gerckens U, Schuler G, Sievert H, Eggebrecht H, Senges J, Richardt G, German Transcatheter Aortic Valve Interventions Registry Investigators. Aortic regurgitation after transcatheter aortic valve implantation: incidence and early outcome. Results from the German transcatheter aortic valve interventions registry. Heart 2011;97:899–906.
[9] Van Belle E, Juthier F, Susen S, Vincentelli A, Iung B, Dallongeville J, Eltchaninoff H, Laskar M, Leprince P, Lievre M, Banfi C, Auffray JL, Delhaye C, Donzeau-Gouge P, Chevreul K, et al. Postprocedural aortic regurgitation in balloon-expandable and self-expandable transcatheter aortic valve replacement procedures: analysis of predictors and impact on long-term mortality: insights from the FRANCE2 Registry. Circulation 2014;129:1415–27.
[10] Toggweiler S, Leipsic J, Binder RK, Freeman M, Barbanti M, Heijmen RH, Wood DA, Webb JG. Management of vascular access in transcatheter aortic valve replacement: Part 2: Vascular complications. JACC Cardiovasc Interv 2013;6:767–76.
[11] Binder RK, Rodes-Cabau J, Wood DA, Mok M, Leipsic J, De Larochelliere R, Toggweiler S, Dumont E, Freeman M, Willson AB, Webb JG. Transcatheter aortic valve replacement with the SAPIEN 3: a new balloon-expandable transcatheter heart valve. JACC Cardiovasc Interv 2013;6:293–300.
[12] Yang TH, Webb JG, Blanke P, Dvir D, Hansson NC, Norgaard BL, Thompson CR, Thomas M, Wendler O, Vahanian A, Himbert D, Kodali SK, Hahn RT, Thourani VH, Schymik G, et al. Incidence and severity of paravalvular aortic regurgitation with multidetector computed tomography nominal area oversizing or undersizing after transcatheter heart valve replacement with the Sapien 3: a comparison with the Sapien XT. JACC Cardiovasc Interv 2015;8:462–71.
[13] Hayashida K, Lefevre T, Chevalier B, Hovasse T, Romano M, Garot P, Mylotte D, Uribe J, Farge A, Donzeau-Gouge P, Bouvier E, Cormier B, Morice MC. Transfemoral aortic valve implantation new criteria to predict vascular complications. JACC Cardiovasc Interv 2011;4:851–8.
[14] Zamorano JL, Badano LP, Bruce C, Chan KL, Goncalves A, Hahn RT, Keane MG, La Canna G, Monaghan MJ, Nihoyannopoulos P, Silvestry FE, Vanoverschelde JL, Gillam LD. EAE/ASE recommendations for the use of echocardiography in new transcatheter interventions for valvular heart disease. Eur Heart J 2011;32:2189–214.
[15] Kappetein AP, Head SJ, Genereux P, Piazza N, van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, van Es GA, Hahn RT, Kirtane AJ, Krucoff MW, Kodali S, Mack MJ, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. Eur Heart J 2012;33:2403–18.
[16] Amat-Santos IJ, Dahou A, Webb J, Dvir D, Dumesnil JG, Allende R, Ribeiro HB, Urena M, Paradis JM, DeLarochelliere R, Dumont E, Bergeron S, Thompson CR, Pasian S, Bilodeau S, et al. Comparison of hemodynamic performance of the balloon-expandable SAPIEN 3 versus SAPIEN XT transcatheter valve. Am J Cardiol 2014;114:1075–82.
[17] Athappan G, Patvardhan E, Tuzcu EM, Svensson LG, Lemos PA, Fraccaro C, Tarantini G, Sinning JM, Nickenig G, Capodanno D, Tamburino C, Latib A, Colombo A, Kapadia SR. Incidence, predictors, and outcomes of aortic regurgitation after transcatheter aortic valve replacement: meta-analysis and systematic review of literature. J Am Coll Cardiol 2013;61:1585–95.
[18] Kodali SK, Williams MR, Smith CR, Svensson LG, Webb JG, Makkar RR, Fontana GP, Dewey TM, Thourani VH, Pichard AD, Fischbein M, Szeto WY, Lim S, Greason KL, Teirstein PS, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med 2012;366:1686–95.
[19] Hayashida K, Lefevre T, Chevalier B, Hovasse T, Romano M, Garot P, Bouvier E, Farge A, Donzeau-Gouge P, Cormier B, Morice MC. Impact of post-procedural aortic regurgitation on mortality after transcatheter aortic valve implantation. JACC Cardiovasc Interv 2012;5:1247–56.
[20] Watanabe Y, Lefevre T, Arai T, Hayashida K, Bouvier E, Hovasse T, Romano M, Chevalier B, Garot P, Donzeau-Gouge P, Farge A, Cormier B, Morice MC. Can we predict post-procedural paravalvular leak after Edwards Sapien transcatheter aortic valve implantation? Catheter Cardiovasc Interv 2015;86:144–5.
[21] Ducrocq G, Francis F, Serfaty JM, Himbert D, Maury JM, Pasi N, Marouene S, Provenchere S, Iung B, Castier Y, Leseche G, Vahanian A. Vascular complications of transfemoral aortic valve implantation with the Edwards SAPIEN prosthesis: incidence and impact on outcome. EuroIntervention 2010;5:666–72.
[22] Eltchaninoff H, Prat A, Gilard M, Leguerrier A, Blanchard D, Fournial G, Iung B, Donzeau-Gouge P, Tribouilloy C, Debrux JL, Pavie A, Gueret P, FRANCE Registry Investigators. Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) registry. Eur Heart J 2011;32:191–7.
[23] Tarantini G, Mojoli M, Purita P, Napodano M, D'Onofrio A, Frigo A, Covolo E, Facchin M, Isabella G, Gerosa G, Iliceto S. Unravelling the (arte)fact of increased pacemaker rate with the Edwards SAPIEN 3 valve. EuroIntervention 2015;11:343–50.
[24] Del Trigo M, Munoz-Garcia AJ, Wijeysundera HC, Nombela-Franco L, Cheema AN, Gutierrez E, Serra V, Kefer J, Amat-Santos IJ, Benitez LM, Mewa J, Jimenez-Quevedo P, Alnasser S, Garcia Del Blanco B, Dager A, et al. Incidence, timing, and predictors of valve hemodynamic deterioration after transcatheter aortic valve replacement: multicenter registry. J Am Coll Cardiol 2016;67:644–55.