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Research Article

Comparison of the New Generation Edwards Sapien 3 Valve and Sapien XT for Transcatheter Aortic Valve Replacement (TAVR)

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Abstract

Background: The new balloon-expandable valve Edwards Sapien 3 provide a superiority over previous device, in a broader range of patients, with better accuracy in valve positioning and less paravalvular regurgitation. We aimed to evaluate periprocedural and short-term outcomes using the Sapien 3 compared with the earlier generation Sapien XT prosthesis.

Methods: A single center prospective study included 142 consecutive patients who underwent TAVR with SAPIEN device between January 2013 and March 2015 (n = 76 SXT and n = 66 S3). Valve Academic Research Consortium endpoints were used.

Results: Sapien 3 patients had a higher prevalence of peripheral arterial disease and ilio-femoral axis calcifications on CT scan. Device implantation success rate was higher in the Sapien 3.The prevalence of moderate to severe paravalvular leak was lower in Sapien 3 patients (0% vs 9.2%, p = 0.01), as well as, the incidence of life-threatening and major bleeding events (1,5% vs 13,1%, p = 0.02). There was no difference regarding the 30-days rate of MACCE between patients, including death (3% vs. 5%), stroke (3% vs. 2.6%) and major vascular complications (6% vs. 8%).

Conclusion: Sapien 3 valve allows TAVR in patients with more severe peripheral artery disease with lower rate of paravalvular regurgitations and major bleeding compared with Sapien XT.

Keywords: *Edwards Sapien 3; Transcatheter Aortic Valve Replacement (TAVR); Aortic Stenosis*

Background

Transcatheter aortic valve replacement (TAVR) is an established therapy for patients with severe inoperable aortic stenosis or high surgical risk.

Since the first TAVR in humans in 2002 [1], many registries have shown a survival benefit as compared with medical therapy alone in patients unfit for surgery [2,3] and non-inferior to surgery in high-risk population for which both strategies were equally feasible [4]. These results have recently been confirmed up to 2-year follow-up [3,5].

The large sheath diameter required for transfemoral TAVR with the first generation of Edwards-SAPIEN prosthesis was the most important limitation of this technique. Various models of this prosthesis have been developed, with progressive technical improvements and a reduction in the profile of the delivery system to exceed the limits associated with first generation of ES prosthesis [6].

One of the latest generations of Transcatheter Heart Valve (THV) is the Edwards-SAPIEN 3 (S3) (Edwards Lifesciences), a prosthesis designed for easy placement within the valve plane and an improvement outcome of the intervention.

In this study, we sought to assess short-term outcomes in patients who benefited from 3rd generation S3 valve implantation and to compare these results to those obtained with the earlier generation SAPIEN XT (SXT) device.

Materials and Methods

Patient selection and evaluation

Between January 2013 and March 2015, consecutive high-risk patients underwent TAVR using balloon-expandable Edwards prostheses, were included in a prospective, single-center registry. We began with the SXT valve in January 2013 and then switched recently to S3 in October 2014. All patients had severe, degenerative symptomatic aortic stenosis (aortic valve area - AVA < 1 cm^2 and/or transvalvular mean pressure gradient - MPG > 40 mmHg). The indication for TAVR was based on the decision of the Heart team [7]. Patients were considered candidates for TAVR when their logistic EuroSCORE was greater or equal to 20%, in case of frailty, or in case of comorbidities contraindicating surgical aortic valve replacement. All patients provided signed informed consent for subsequent data collection and analysis for research purposes.

The screening process included transthoracic echocardiography (TTE), carotid ultrasound, selective coronary angiography and computed tomography (CT) of the aorta and iliofemoral access. The measurement of the AV annulus was based on CT scan. An annulus diameter of 18 - 21 mm was considered appropriate for the 23-mm prosthesis and 21 - 24 mm for the 26-mm prosthesis. Before implantation, the vascular access suitability was based on the iliofemoral evaluation on multi-slice CT [8-10]. A minimum diameter of 6 and 6.5 mm is required for the 23- and 26-mm S XT valves, while 5.5 and 6 for 23 and 26 mm S3 valves, respectively. We assessed, on CT scan, the arterial tortuosities and calcifications at the area of femoral puncture site, then classified in 4 grades [11].

Devices

The SAPIEN XT

The first generation of SAPIEN prosthesis is made of three bovine pericardial leaflets, sewn onto a stainless steel stent frame partially covered with a synthetic polyethylene terephthalate (PET) fabric sealing cuff. The SXT valve is made of a cobalt chromium frame with thinner struts and a more open cell structure to allow tighter crimping. The valve is crimped over the shaft of the NovaFlex™ delivery system and mounted on the balloon. The NovaFlex™ allows a reduction in sheath size to 18F and 19F for the 23- and 26-mm valve sizes, respectively.

The SAPIEN 3

The S3 incorporates a unique stent and leaflet design that allows for crimping to a further reduced profile as compared to the earlier THV. The inflow of the S3 is covered by an internal PET skirt and additional outer PET sealing cuff intended to reduce paravalvular regurgitation.

The delivery system

The delivery system (Commander; Edwards Lifesciences) is a further development of the NovaFlex delivery catheter (Edwards Lifesciences). The specially designed nose-cone-tipped inner balloon catheter on which the prosthesis is crimped has radiopaque valve alignment markers defining the valve position and the working length of the balloon. A central radiopaque marker aids valve positioning. The outer deflectable flex catheter is attached to the handle, which incorporates a wheel to deflect the flex catheter tip, an indicator which indicates the degree of tip flexion; for fine alignment of the THV during valve positioning.

The expandable sheath

The 26 mm S3 is compatible with a 14 Fr expandable sheath (eSheath; Edwards Lifesciences). The expandable sheath reduces the stress on the access vessel. This may reduce the potential for arterial injury during introduction.

Procedure

All procedures were performed in a "hybrid" catheterization laboratory, with sterile precautions, using local anaesthesia and conscious sedation in all cases.

Patients were preloaded with Aspirin (250 mg) and Clopidogrel (300 mg), Heparin (5000 IU) was administered immediately after placement of the vascular closure device, 11 F Prostar XL™ (Abbott Inc.) in the femoral artery. After discharge, the almost of patients were treated with dual antiplatelet therapy Clopidogrel (75 mg/d, 6 months) and aspirin (75 mg/d, indefinitely).

Valve positioning was based on fluoroscopy, using Pig tail catheter and annular calcification as a landmark. Serial (5 - 10 mL) supravalvular aortography was performed to validate the position of the valve and to confirm the optimal view aligning all cusps in a single plane. The prosthesis was also delivered using rapid ventricular pacing. Supra annular aortography was performed after valve deployment to evaluate a residual aortic regurgitation. The femoral arteriotomy was then closed using the Prostar device. In the absence of a new left bundle branch block or atrioventricular block, the pacing lead was removed at the end of the procedure. After TAVR, patients were transferred to the Intensive Care Unit for close monitoring for 24 hours. A TTE was performed 6h after the procedure and prior to discharge to assess prosthesis performance especially paravalvular aortic regurgitation (PAR) and left ventricular ejection fraction (LVEF).

Objectives and definitions

VARC-2 outcome definitions were endorsed [12]. We considered: procedure success, clinical outcomes, MACCE, complications, and prosthetic valve performance at 30-day follow-up. Prostheses performance was evaluated during hospital stay as well as at 1-month follow-up by measuring AVA, MPG, and evaluation of degree of aortic regurgitation (AR).

Data collection and analysis

All patients undergoing TAVR were prospectively enrolled after duly signing their consent allowing scheduled follow-up and data collection storage for scientific purposes. Data regarding clinical status, emergent and concurrent therapies, preoperative, TTE and CT scan values and findings, procedural features, as well as data pertaining to procedural performances were carefully collected upon admission, as well as during and after hospital stay entered into our institutional database (Clinicom); In patients from remote institutions, outcomes at 30 days were obtained by telephone interviews of the referring physician and exchange of TTE reports. No patients were lost to follow-up.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) or median (interquartile range), according to the distribution. Categorical variables are presented as frequencies and percentages. We used student's *t* test or the Manfred-Whitney test to compare differences between continuous variables, and the Chi-square test to compare differences between categorical variables, as appropriate. Differences were considered statistically significant at P values less than 0.05. All statistical analysis was performed using SPSS Statistics software version 18.0 (SPSS Inc., Chicago, IL, USA).

Results

Baseline characteristics

During the study period (January 2013 to March 2015), 142 patients underwent TAVR with SAPIEN device at our center. The current registry consist of two sequential cohorts comprised: 76 (54.6%) with the SXT (January 2013 - September 2014) and 66 (46.4%) with

the S3 (October 2014 and March 2015). Baseline clinical characteristics are shown in table 1. The mean age of our population was 84,2 ± 7,7 years predominated by female sex.

	Total (n = 142)	SAPIEN XT (n = 76)	SAPIEN 3 (n = 66)	P-Value
Age (y)	84.2 ± 7.7	84.2 ± 8.2	84 ± 7.1	0.81
Female	91 (64.1)	45 (59.2)	46 (69.7)	0.19
Diabetes	38 (26.7)	19 (25)	19 (28 .81)	0.57
BMI (kg/m^2)	22.1 ± 1.2	21.7 ± 1.2	22.4 ± 1.3	0.39
Previous MI < 90d	3 (2.1)	1 (1.3)	2 (3)	0.59
Previous PCI (n, %)	49 (34.5)	28 (36.8)	21 (31.8)	0.53
Previous CABG	12 (8.4)	8 (10.5)	4 (6.1)	0.35
Atrial fibrillation	40 (28,1)	23 (30,3)	17 (25.8)	0.59
Pacemaker	24 (16.9)	12 (15.8)	12 (18.2)	0.67
Peripheral artery disease	71 (50)	28 (36.8)	43 (65.2)	0.001
Previous stroke	6 (4.2)	4 (5.3)	2 (3)	0.69
Creatinine (µmol/L)	99.3 ± 43.8	103.4 ± 43.3	95.4 ± 44.5	0.85
Aortic bioprothesis	2 (1.4)	1 (1.3)	1 (1.5)	0.92
Previous cardiac surgery (n)	5 (3.6)	4 (5.3)	1 (1.5)	0.37
CKD stage ≥ III	4 (2.9)	3 (3.9)	1 (1.5)	0.38
CKD stage II	48 (33.8)	26 (34.2)	22 (33.3)	0.91
Coronary artery disease	35 (24.6)	20 (26.3)	15 (22.7)	0.55
COPD (n)	36 (25.3)	24 (31.6)	12 (18.2)	0.07
Log euroSCORE, %	16.71 ± 10.03	17.8 ± 10.8	15.8 ± 10.8	0.3
Approach				
Ilio femoral	136 (95.7)	73 (96)	63 (95.5)	0.86
Trans-aortic	1 (0.7)	1 (1.3)	0	0.34
Trans Carotid	5 (3.5)	2 (2.6)	3 (4.5)	0.53

Table 1: *Baseline clinical characteristics.*

Data are mean ± SD or count (%). BMI: Body-Mass Index; MI: Myocardial Infarction; PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Graft; CKD: Chronic Kidney Disease; COPD: Chronic Obstructive Pulmonary Disease.

Most of patients had severe degenerative symptomatic aortic stenosis, except two patients (one in each group) who had a degenerated stenotic aortic bioprosthesis. There was no difference between groups regarding age, Euroscore, gender, previous medical history and left ventricle ejection fraction. However, S3 patients had a higher prevalence of peripheral arterial disease (65.2 vs. 36.8%, p = 0.001). TAVR was performed through transfemoral access in about 96% in both groups.

Baseline TTE data (Table 2) confirmed the severity of aortic stenosis in both groups. S3 patients had a smaller aortic valve area than SXT subjects (0.67 ± 0,9 vs 0.76 ± 0.14 cm^2/m^2, p = 0.007).

S3 patients had higher prevalence of iliofemoral axis calcifications on CT scan (47.9 vs 26.5%, p = 0.008). Whereas there was no significant difference in aortic annulus diameter between the two groups (25 ± 4.5 vs 23.8 ± 2 mm, p = ns) (Table 2).

	Total (%)	SAPIEN XT	SAPIEN 3	p-Value
Echocardiography				
AV MPG (mmHg)	47.96 ± 14.28	49.55 ± 14.8	46.0 ± 12.33	0.17
AVA (cm^2)	0.71 ± 0.02	0.76 ± 0.14	0.67 ± 0.19	0.007
PASP (mmHg)	47.40 ± 10.9	46.88 ± 11.4	52.8 ± 8.1	0.96
LVEF (%)	54.78 ± 10.65	55.68 ± 11	54.5 ± 10.13	0.53
Computed Tomography Scan				
AV Annulus Effective Diam (mm)	24.24 ± 3.2	23.8 ± 2	25.07 ± 4.5	0.91
MLD of access site vessel on therapeutic side (mm)	7.7 ± 0.96	8.0 ± 0.9	7.5 ± 1.0	0.21
Iliofemoral evaluation				
Calcifications %				
Grade 0	18.20%	23.50%	14.60%	0.26
Grade 1	42.70%	50.00%	37.70%	
Grade 2	29.20%	20.50%	35.40%	
Grade 3	10%	6.00%	12.50%	
≥ Grade 2		26.5%	47.9%	0.008
Tortuosities %				
Grade 0	16%	20.50%	12.50%	0.54
Grade 1	31.70%	35.30%	29.10%	
Grade 2	31.70%	29.40%	33.30%	
Grade 3	20.70%	14.70%	25%	
≥ Grade 2		44.1%	58.3%	0.059

Table 2: *Baseline imaging findings.*

AV: Aortic Valve; PG: Pressure Gradient; AVA: Aortic Valve Area; PASP: Pulmonary Arterial Systolic Pressure; LVEF: Left Ventricular Ejection Fraction; MLD: Minimum Lumen Diameter.

Procedural outcome

Device implantation success rate was significantly higher in S3 group (100% vs 90%; p = 0,02) (Table 3). Procedural failure in SXT patients was related to: per procedure death in three cases (two in SXT and one in S3), unsuccessful implantation in four cases (SXT); a second valve implantation (SXT); and severe aortic regurgitation (≥ grade 3) in one case (S XT).

In S3 cohort patients, the prosthesis was positioned correctly in all cases with successful vascular access. Post-dilation was almost not necessary. No case of severe aortic regurgitation, valve migration or embolization was observed and no patient required implantation of a second THV (Table 3).

	Total (n = 142)	SAPIEN XT (n = 76)	SAPIEN 3 (n = 66)	P-Value
Valve diameter (n, %)				
23 mm	39 (27.4)	15 (19.7)	24 (36.4)	0.08
26 mm	73 (51.4)	45 (59.2)	28 (42.4)	
29 mm	30 (21.1)	16 (21)	14 (21.2)	
Device success (n, %)	**136 (95)**	**68 (90)**	**66 (100)**	**0.002**
Successful vascular access	140 (98.5)	74 (97.3)	66 (100)	0.18
Successful implantation	138 (97.1)	72 (94.7)	66 (100)	0.06
Correct position	140 (98.5)	74 (97.3)	66 (100)	0.18
Two valves implantation	1 (0.7)	1 (1.3%)	0	0.34
Valve migration	1 (0 .7)	1 (1.3)	0	
Aortic annulus rupture	1 (0.7)	1 (1.3)	0	

Switch to conventional AVR surgery	4 (2.8)	3 (3.9)	1	0.38
Switch to conventional vascular surgery	3 (2.1)	3 (3.9)	0	0.1
TTE control				
AR = 0	69 (49)	26 (34)	43 (66)	0.001
AR = I	66 (46)	43 (56)	23 (34)	
AR ≥ grade 2	7 (5)	7 (9.2)	0	0.01
AR ≥ grade 3	1 (0.7)	1 (1.3%)	0	
AV Mean PG (mmHg)	8.48 ± 5.35	8.91 ± 6.2	8.2 ± 3.37	0.59
Procedure to discharge (days)	7.7 ± 4.8	7.9 ± 5.5	7.32 ± 3.1	0.51
Aspirine (n, %)	136 (95.8)	73 (96)	63 (95.4)	0.86
Clopidogrel	63 (44.3)	23 (30)	40 (60)	0.0002

Table 3: *Procedural outcomes.*

AVR: Aortic Valve Replacement; TTE: Transthoracic Echocardiography.

Conversion to cardiac surgery was required in four patients (2,8%). Three in the SXT group (one patient with aortic dissection that did not survive surgery, one patient with aortic annulus rupture complicated by tamponade but died later in multi organ failure, and the last with major aortic regurgitation), whereas in S3 group one patient has undergone cardiac surgery related to iatrogenic left ventricle injury by Extra stiff wire. Urgent vascular surgery was required in three cases (2,1%) all in SXT group due to lower limb ischemia related to complicated vascular closure systems.

After TAVR, TTE documented a significant mean transaortic gradient reduction from 47, 96 mmHg ± 14,28 to 8,48 mmHg ± 5,35 (P < 0,001). There were significantly lower rate of moderate to severe PAR in S3 group compared with SXT group (100% vs 9, 2%; p = 0,01), mild (34% vs 56%; p = 0,001) and trace for the reminder. One patient has developed later severe PAR (valve in valve procedure) related to low deployment of THV resulting left ventricular failure yields finally a second redo aortic valve replacement 20 days after.

Thirty-day safety outcomes and complications (Table 4)

	Total (n = 142)	SAPIEN XT (n = 76)	SAPIEN 3 (n = 66)	P-Value
MACCE				
Death (n, %)	6 (4.2)	4 (5.1)	2 (3)	0.51
Stroke	4 (2.8)	2 (2.6)	2 (3)	0.88
Myocardial infraction	2 (1.4)	2 (2.6)	0	0.18
Vascular Complications	19 (13.4)	13 (17.1)	6 (9)	
Major	10 (7)	6 (8)	4 (6)	0.27
Minor	9 (6.3)	7 (9.2)	2 (3)	0.058
Bleeding	18 (12.7)	13 (17.1)	5 (7.5)	
Life-threatening	7 (5)	6 (8)	1 (1.5)	
Major	4 (2.8)	4 (5.1)	0	0.02
Minor	7 (5)	3 (3.9)	4 (6.1)	
Transfusions	14 (9.8)	10 (13.1)	4 (6.1)	0.15
Pacemaker	18 (12.7)	11 (14.5)	7 (10.6)	0.49
Tamponade	5 (3.5)	3 (3.9)	2(3)	0.76
Acute kidney injury ≥ stage III	2 (1.4)	2 (2.6)	0	0.18
Infectious Complications	6 (4.2)	2 (2.6)	4 (6.1)	0.42

Table 4: *Thirty-day safety outcomes.*

Data are median (interquartile range) or count (%). MACCE: Major Adverse Cardiovascular and Cerebrovascular Events.

In our study, there was no difference regarding thirty-days rate of MACCE between patients, including no difference in terms of death (3% vs. 5%), stroke (3% vs. 2,6%) and myocardial infarction (0% vs. 2,6%). It seems that the use of S3 versus SXT have no significant impact on death occurrence. The causes of death in the S3 group were: 1) post-operative multi organ failure due to left ventricle injury (tamponade) and vascular access complications, 2) Intrahospital death after hemorrhagic cerebro-vascular accident. Whereas in the SXT, there were four cases of death: 1) left main artery obstruction complicated by refractory cardiogenic choc, 2) post-operative multi organ failure after TAVR due to aortic annulus rupture and vascular access complication, 3) two cases related to tamponade with one case of iatrogenic right ventricle injury caused by transvenous pacemaker led.

Life-threatening and major bleedings were significantly fewer in the S3 group (1, 5% vs 13,1%; p = 0,02). Moreover, the need for blood transfusion was slightly lower in the S3 group (6,1% vs 13,1%; P = 0.15).

Major vascular complication occurred in ten patients with no significant difference between the two group 6% vs 8%; P = 0,27), including six patients in SXT (four cases required urgent vascular surgery related to: vascular rupture in one case, closure system failure in one case and arterial occlusion in the others, whereas two cases required percutaneous angioplasty), and four patients in S3 (one case of femoral occlusion and three cases of arterial dissection treated by transluminal angioplasty).

A permanent pacemaker was required in 12,7% in our population, without significant difference between the two groups (10,6% versus 14,5%, p = 0,49).

Overall, 5 patients (3,5%) have had pericardial effusion complicated by tamponade without difference between the two groups.

Finally, median hospital stay was comparable between the two groups.

Discussion

The main findings of this study are:

1. The introduction of the third generation of Edwards SAPIEN 3 and his delivery system improved the performance of TAVR via transfemoral approach in the majority of patients especially in those with severe peripheral artery disease and small iliofemoral diameter.

2. The use of S3 versus SXT allows TAVR with higher device success rate and lower complications.

3. The S3 has better short-term outcomes with fewer occurrences of paravalvular regurgitations and major bleeding compared with SXT.

Device success

In our study, the procedure success rate was statistically higher in the S3 (100% vs 90%; p = 0.02). No patient required a second valve; similarly, no cases of aortic rupture or valve embolization were noted in the S3.

Despite the higher prevalence of peripheral artery disease with more calcific iliofemoral axis, the introduction of S3 prosthesis has increased greatly the possibility of transfemoral TAVR with good results. The new expandable sheaths of small size and low profile seems to play an important role in the transfemoral success, with less bleeding and major vascular complications noted in our study.

Performance of the THV

In the group S3, the valve was deployed correctly in 100% of cases. No patient had presented a significant paravalvular aortic regurgitation (PAR) (≥ grade 2) against 9.2% in the SXT group (p = 0.01).

It is important to know that the expanded length of the S3 is slightly greater than the currently available SXT. Although differences are small, this increase seems to greatly facilitate optimal positioning within the native aortic valve and annulus. The stent frame gives a high resistance to compression, to maintain a perfectly circular opening condition with good coaptation of the leaflets. In addition, increased flexion capabilities facilitate supporting the catheter within the transverse aorta while engaging the native valve in a coaxial manner [13].

It is currently established by various registers [2,14-16], that the occurrence of PAR after TAVR, are associated with high morbidity and mortality, as soon as they exceed the moderate state. In the PARTNER 1A and 1B trials [2,16], moderate or severe PAR at 30 days were reported in 12.2% and 11.8%, respectively [1,3]. In late trials using S3, an important decline of severe PAR rate was noted [17,18]. In the present study no patient had moderate or severe PAR in S3 vs 9.2% in SXT (p = 0.01). PAR was mild in 34% vs 56% in SXT. Possible reasons for this low PAR rate include: 1) the outer PET sealing cuff, which enhances paravalvular sealing; 2) more accurate positioning by length and stent frame, and 3) improved sizing with adjunctive CT scan. In our center, PAR rates decline steadily, especially with the newest TH, due to a good assessment of the aortic annulus, a wider range of valve diameters and training of our team which has now greatly exceeded the learning curve.

Thirty-day results

MACCE

In our study, there was no difference regarding thirty-day rate of MACCE between the two groups.

The rate of mortality all-causes was 4.2% of patients with no significant difference between the two groups. The causes of death in our population were dominated by the occurrence of tamponade in almost half of cases.

No procedure has complicated by myocardial infarction in S3 against two patients in the SXT. Our result is similar to that found in other registries FRANCE 2 [14] and SOURCE [19] (1.1% and 2.5%, respectively, against 1.4% in our study). The struts of the stent have been expanded from previous generations to prevent occlusion of coronaries ostia, even if the valve is longer.

Concerning the occurrence of stroke, four patients (2.8%) had a stroke at 30 days without difference between the two groups. Current thoughts considered that mainly to the valve itself that stroke and mortality can be attributed. The emboli causing stroke during TAVR are likely not linked to the crossing of the aortic arch, when looking at the doppler studies, but released during deployment of the valve [20]. With the new generation THV, less traumatic, combined with cerebral protection devices and improvement in the learning curve, we can expect a reduction in the rate of stroke.

Complications

Vascular complications, one of the most frequent and early complications are a major cause of morbidity and mortality after TAVR [2,21]. In the PARTNER II, S3 trial, major vascular complications were observed in 16.2% of patients undergoing TAVR with the SAPIEN THV. The strongest predictor for vascular complications is the ratio of the outer diameter of the sheath to the minimal lumen diameter of the access artery [22]. Downsizing delivery systems reduces the risk of vascular complications and translates into better outcomes [17,18]. The ability to introduce the S3 through a 14-F expandable sheath is likely to translate into better outcomes and facilitate transfemoral TAVR in patients previously considered unsuitable for femoral access [17]. In our experience, major vascular complications rates

down with S3 (6% vs. 8%, p = 0.27), despite the high prevalence of peripheral artery disease and the excessive calcification of iliofemoral axis in this group. Indeed, all the events in our study were effectively related to failure of vascular closure devices without aortic dissection or iliofemoral rupture. This could be explained both by the improvement of learning curve, and lower profiles of sheaths.

Concerning the bleedings, in S3 vs SXT, we noticed a significant reduction in major and life-threatening bleedings rates (1.5% vx 13.1%, p = 0.02).

The causes of bleeding are mainly due to complications at the vascular access favored by the large size of sheath used for implantation of SXT.

The occurrence of atrioventricular block requiring the implantation of a permanent pacemaker is a concern after TAVR. In our study, the implantation of a new pacemaker was necessary in 18 patients (12.7%) without difference between the two groups (10.6% against 14.5% in the group SXT). On this point, therefore, the S3 does not seem to bring significant improvement. This can be explained by the fact that the risk of occurrence of an AV block in S3 is slightly increased due to the length of the S3 valve (potential extension of the contact with the septum area) despite the possibility of accurate positioning with the new valve.

Though the good immediate results recorded by S3, the hospital stay of patients remains unchanged (mean 7.7 ± 4.8) whatever the implanted valve. This can be attributed to the frailty state of our elderly population with more associated comorbidities.

Finally, in light of these outcomes, we believe that THV and teams improve, take into account the best selection of patients, best imaging to choose adequately the valve, and the improved implantation techniques.

The requirement for a smaller iliofemoral diameter, the low risk of major adverse events, and the favorable performance of the S3 prosthesis have dramatically extended the clinical application for transfemoral access, which can now be performed safely using pre-closing vascular devices.

Conclusion

The use SAPIEN 3 allows TAVR in patients with more severe peripheral artery disease. Moreover, this device provides excellent short-term outcome and lower rates of paravalvular regurgitations compared to the previous generation SAPIEN-XT valve.

Bibliography

1. Cribier A., *et al.* "Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description". *Circulation* 106 (2002): 3006-3008.

2. Leon MB., *et al.* "Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery". *The New England Journal of Medicine* 363 (2010): 1597-1607.

3. Kodali SK., *et al.* "Two-year outcomes after transcatheter or surgical aortic-valve replacement". *The New England Journal of Medicine* 366 (2012): 1686-1695.

4. Smith CR., *et al.* "Transcatheter versus surgical aortic-valve replacement in high-risk patients". *The New England Journal of Medicine* 364 (2011): 2187-2198.

5. Makkar RR., *et al.* "Transcatheter aortic-valve replacement for inoperable severe aortic stenosis". *The New England Journal of Medicine* 366 (2012): 1696-1704.

6. Nietlispach F., *et al.* "Current balloon-expandable transcatheter heart valve and delivery systems". *Catheterization and Cardiovascular Interventions* 75 (2010): 295-300.

7. Amabile N., *et al.* "Early and mid-term cardiovascular outcomes following TAVI: impact of pre-procedural transvalvular gradient". *International Journal of Cardiology* 167 (2013): 687-692.

8. Tops LF., *et al.* "Non-invasive Evaluation of the Aortic Root with Multislice Computed Tomography: Implications for Transcatheter Aortic Valve Replacement". *Journal of the American College of Cardiology* 1 (2008): 321-330.

9. Kurra V., *et al.* "Prevalence of significant peripheral artery disease in patients evaluated for percutaneous aortic valve insertion: pre-procedural assessment with multidetector computed tomography". *The Journal of Thoracic and Cardiovascular Surgery* 137 (2009): 1258-1264.

10. Leipsic J., *et al.* "Multidetector computed tomography in transcatheter aortic valve implantation". *JACC: Cardiovascular Imaging* 4 (2011): 416-429.

11. Eltchaninoff H., *et al.* "Aorto-iliac angiography as a screening tool in selecting patients for transfemoral aortic valve implantation with the Edwards SAPIEN bioprosthesis". *EuroIntervention* 5 (2009): 438-442.

12. Leon MB., *et al.* "Standardized endpoint definitions for Transcatheter Aortic Valve Implantation clinical trials: a consensus report from the Valve Academic Research Consortium". *Journal of the American College of Cardiology* 57 (2011): 253-269.

13. Binder RK., *et al.* "Transcatheter Aortic Valve Replacement With the SAPIEN 3. A New Balloon-Expandable Transcatheter Heart Valve". *Journal of the American College of Cardiology Interventions* 6 (2013): 293-300.

14. Gilard M., *et al.* "Registry of transcatheter aortic-valve implantation in high-risk patients". *The New England Journal of Medicine* 366 (2012): 1705-1715.

15. Abdel-Wahab M., *et al.* "Aortic regurgitation after transcatheter aortic valve implantation: incidence and early outcome. Results from the German transcatheter aortic valve interventions registry". *Heart* 97 (2011): 899-906.

16. Webb J., *et al.* "Multicenter Evaluation of a Next-Generation Balloon-Expandable Transcatheter Aortic Valve". *Journal of the American College of Cardiology* 64 (2014): 2235-2243.

17. Thomas M., *et al.* "Thirty-day results of the SAPIEN aortic bioprosthesis European outcome (SOURCE) registry: a European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve". *Circulation* 122 (2010): 62-69.

18. Van Mieghem NM., *et al.* "Histopathology of Embolic Debris Captured During Transcatheter Aortic Valve Replacement". *Circulation* 127 (2013): 2194-2201.

19. Van Mieghem NM., *et al.* "Vascular complications with transcatheter aortic valve implantation using the 18 Fr Medtronic CoreValve system: the Rotterdam experience". *EuroIntervention* 5 (2010): 673-679.

20. Toggweiler S., *et al.* "Percutaneous aortic valve replacement: vascular outcomes with a fully percutaneous procedure". *Journal of the American College of Cardiology* 59 (2012): 113-118.

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