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CLINICAL RESEARCH

Performing optimal transcatheter aortic valve implantation: The need for tailored use of transcatheter valves

Pour un TAVI optimal : nécessité d'une utilisation individualisée des prothèses percutanées

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Aortic stenosis;
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Summary
Background. — Despite the worldwide development of transcatheter aortic valve implantation (TAVI) over the last decade, strategies that take patient characteristics into account to guide the choice of transcatheter heart valve have not been evaluated.
Aim. — To evaluate the immediate results of TAVI using a tailored choice of balloon-expandable or self-expanding transcatheter heart valve, according to each patient's clinical and anatomical characteristics.
Methods. — This single-centre observational study included all patients treated with TAVI from 2012 to 2017. The 30-day results were reported according to Valve Academic Research Consortium-2 criteria. A total of 502 patients were included (mean age, 81 ± 9 years; 52% men; mean EuroSCORE II, 7.0 ± 6.5%). Three main variables guided the choice of transcatheter heart valve: the anatomy of the iliofemoral arteries and of the aortic root, and the general condition of the patient.

Abbreviations: CER, CoreValve Evolut R; CS, CoreValve System; PVL, paravalvular leakage; S3, SAPIEN 3; SXT, SAPIEN XT; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve; TTE, transthoracic echocardiography; VARC-2, Valve Academic Research Consortium-2.

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Results. — A SAPIEN™ balloon-expandable transcatheter heart valve was used in 275 patients (55%) and a CoreValve™ self-expanding transcatheter heart valve in 227 patients (45%). The approach was transfemoral in 427 patients (85%), and only 29 patients (6%) required transthoracic access. At 30-day follow-up, the rates of adverse events were as follows: mortality, 3.2%; stroke, 3.0%; major bleeding, 5.9%; and major vascular complications, 6.0%. Rates of complications at 30 days were similar in the SAPIEN™ and CoreValve™ groups, except for a higher rate of pacemaker implantation in the latter group (29.5% vs. 14.5%; $P < 0.001$).
Conclusion. — The choice of balloon-expandable or self-expanding transcatheter heart valve tailored to the patient's clinical and anatomical characteristics allows for maximal use of the transfemoral approach, and is associated with low 30-day rates of major complications and mortality.

MOTS CLÉS
Rétrécissement aortique ;
Implantation valvulaire aortique par cathéter ;
Valve déployée par ballon ;
Valve auto-déployée

Résumé
Contexte. — Malgré le développement de l'implantation valvulaire aortique par cathéter (TAVI) au cours de la dernière décennie, l'intérêt d'une stratégie intégrant les caractéristiques des patients pour guider le choix du modèle prothétique n'a jamais été évalué.
Objectif. — L'objectif de notre étude était d'évaluer les résultats immédiats du TAVI utilisant de façon individualisée une prothèse auto-déployée ou déployée par ballon selon les caractéristiques cliniques et anatomiques du patient.
Méthodes. — Cette étude observationnelle monocentrique a inclus tous les patients traités par TAVI de 2012 à 2017. Les résultats à 30 jours ont été rapportés selon les critères VARC-2. Au total, 502 patients ont été inclus (81 ± 9 ans ; 52 % hommes; EuroSCORE II 7,0 ± 6,6 %). Trois paramètres principaux ont guidé le choix du modèle prothétique: l'anatomie des artères ilio-fémorales, de la racine aortique et l'état général du patient.
Résultats. — Une valve SAPIEN™ a été utilisée chez 275 patients (55 %) et une CoreValve™ chez 227 (45 %). L'approche a été transfémorale chez 427 patients (85 %) et seuls 29 patients (6 %) ont nécessité un abord transthoracique. À 30 jours, les taux d'événements indésirables étaient les suivants : mortalité, 3,2 %; accident vasculaire cérébral, 3,0 %; saignement majeur, 5,9 % ; complication vasculaire majeure, 6,0%. Les taux de complications à 30 jours étaient identiques dans les groupes SAPIEN™ et CoreValve™, à l'exception d'un taux d'implantation de pacemaker plus élevé dans le groupe CoreValve (29,5 % contre 14,5 %; $p < 0,001$).
Conclusion. — Le choix entre une prothèse déployée par ballon ou auto-déployée adapté aux caractéristiques cliniques et anatomiques des patients permet une utilisation maximale de la voie transfémorale et est associé à de faibles taux de complications majeures et de mortalité à 30 jours.

Background

Over the last decade, transcatheter aortic valve implantation (TAVI) has expanded considerably to treat severe aortic stenosis in high-risk and inoperable patients, and its indications are now extending to lower-risk populations [1—4]. Hundreds of thousands of patients have already been treated using several types of transcatheter heart valves (THVs). However, since the beginning of the TAVI era, two THV families have shared the vast majority of the market worldwide, i.e. successive generations of SAPIEN™ balloon-expandable valves (Edwards Lifesciences, Irvine, CA, USA) and CoreValve™ self-expanding valves (Medtronic Inc., Minneapolis, MN, USA). No clinical superiority of one THV over the other has been demonstrated so far [5—7]. Thus, the choice between balloon-expandable and self-expanding THVs has been, and is still mostly driven by various considerations that may differ from one centre to another (historical reasons, local preferences and experience, economic constraints, national politics, etc.). However, because of their specific characteristics, properties and modalities of implantation, there is a strong rationale for taking into account the main clinical and anatomical characteristics of the patients to orient the choice towards the most adequate THV in each particular case [8,9]. So far, no data regarding this question have been reported.

The aim of this study was to present the immediate results of a TAVI programme characterized by the use of either balloon-expandable or self-expanding THVs, tailored

to the main clinical and anatomical characteristics of each specific patient.

Methods

Population

Between January 2012 and January 2017, a total of 502 patients with symptomatic severe aortic stenosis at very high or prohibitive surgical risk were treated with TAVI, and were included in the analysis. The indication for TAVI and the selection of the route were based on the judgment of a multidisciplinary team, including cardiologists, cardiovascular surgeons and anaesthesiologists [10]. All patients provided written informed consent before the procedure. Data were gathered prospectively in a local database. Outcomes were defined according to the Valve Academic Research Consortium-2 (VARC-2) procedural criteria [11].

Choice of THV

During the study period, the most recent two generations of balloon-expandable and self-expanding THV families were used: Edwards SAPIEN XT™ (SXT) and SAPIEN 3™ (S3) on the one hand, and Medtronic CoreValve™ System (CS) and CoreValve™ Evolut R™ (CER) on the other. The characteristics and properties of these THVs have been described previously [12]. As a general principle, three main variables were considered to guide the choice for each particular patient, with balloon-expandable THV via the transfemoral route being chosen as a default.

The access route

The suitability of the transfemoral approach was the main decision variable. If SXT/S3 THVs could not be used transfemorally, the lower-profile CS/CER THVs were considered as the second option. If the latter was still not possible, the use of the left subclavian approach with CS/CER THVs was considered as the third option. If still not possible, the other arterial routes (brachiocephalic or carotid arteries) were evaluated, with either SXT/S3 or CS/CER THVs as the fourth option. The transthoracic routes (mainly transapical with SXT/S3 THVs, exceptionally transaortic) were the last options, only if none of the previous transarterial routes was suitable. The transcaval access was not used in this series.

The anatomy of the aortic root

The anatomy of the aortic root also played a crucial role in the choice of THV, depending on the five variables detailed below.

The size of the aortic annulus

The measurements (minimal, maximal and mean diameters, perimeter and area) were calculated using gated computed tomography at the level of the basal ring. As a general principle, CS/CER THVs were preferred in patients with the smallest annuli, to take advantage of the supra-annular function of the self-expanding THVs, and achieve optimal haemodynamic performances. By comparison, SXT/S3 THVs were preferred in patients with large annuli, to avoid the risk of paravalvular leakages (PVLs). The choice was also dependent on the ratio between the THV and the annulus sizes. When this ratio was in the ''grey zone'' (i.e. dimensions of the aortic annulus borderline between two sizes of one THV) it was advisable to choose the other THV family to avoid under/oversizing. Otherwise, the smaller size of the SXT/S3 THVs (with the possible option of postdilatation) was preferred to reduce the risk of annulus rupture, whereas the upper dimension of the CS/CER THVs was chosen to reduce the risk of periprosthetic leakage, without significantly increasing the risk of annular rupture.

The risk of annular rupture

When the risk of annular rupture was deemed high because of the presence of severe asymmetrical or bulky calcifications of the annulus or left ventricular outflow tract, self-expanding THVs were preferred over balloon-expandable THVs [13].

The risk of coronary obstruction

Besides potential protectives measures, CS/CER THVs were generally preferred in patients deemed at high risk of coronary obstruction, to take advantage of their recapturability and retrievability.

Valve-in-valve

As a general principle, CS/CER THVs were implanted in failing surgical bioprostheses, to take advantage of their supra-annular function, optimize haemodynamic performance [14] and decrease the risk of coronary obstruction in stentless and stented prostheses with externally mounted leaflets.

Bicuspid aortic valve

Patients with bicuspid aortic valve represented a very specific and difficult subset, in which preferences changed over time. With the previous THV generations, the CS was generally preferred over the SXT to take advantage of its conformability to the annular anatomy, while maintaining a quite circular shape at the level of the supra-annular leaflets, and to decrease the risk of annular rupture [15]. However, there has been a recent trend towards the preferential use of the S3 over the CER, as a result of its demonstrated safety and effectiveness [16]. Nevertheless, all decisions were taken after a thorough case-by-case analysis in this heterogeneous population.

General patient characteristics

As a general principle, frailty and small body surface area oriented the choice towards self-expanding THVs. This empirical strategy was motivated by the lower profile of this THV family, more adapted to the iliofemoral and aortic annulus diameters. Other variables, such as the presence of coronary artery disease or left ventricular dysfunction were more rarely taken into account.

The assessment of frailty was achieved using four variables, as proposed by Fried et al. [17]. The eyeball test was used as a subjective physician's estimation of the patient's resiliency for recovery, which incorporates patient history, physical examination and co-morbidities [18,19]. Weakness was assessed by dominant hand grip strength, measured using the average of three trials of maximal isometric grip measured in kilograms with a Jamar dynamometer (Sammons Preston, Chicago, IL, USA). Slowness was assessed

using a 6-minute walk test, conducted according to a standardized protocol, using an internal hallway with the 50-foot distance marked [20]. Finally, self-reported physical activity in daily life was assessed by the revised 9-point Clinical Frailty Scale [21].

The procedure

Procedures were performed in the catheterization laboratory by a team composed of two interventional cardiologists, an echocardiographer and an anaesthesiologist. A cardiovascular surgeon was also present in most cases, and always in non-transfemoral cases [22]. The default option was full percutaneous transfemoral access with locoregional anaesthesia, conscious sedation and transthoracic echocardiography (TTE) assessment. Femoral haemostasis was obtained using the Prostar® closure system (Abbott Vascular, Chicago, IL, USA). Non-transfemoral procedures were performed using surgical access, under general anaesthesia and transoesophageal echocardiography guidance. Aspirin (75 mg) was administered at least 1 day before the procedure. All patients received a weight-adjusted heparin bolus injection (70 IU/kg). Thereafter, patients were monitored for 24—48 hours in the coronary care unit before being moved to the ward. The anticoagulation regimen comprised double antiplatelet therapy for at least 3 months in patients with no indication for long-term oral anticoagulation therapy, and a combination of one antiplatelet agent and oral anticoagulation in the other patients.

Follow-up

The follow-up was conducted through clinical visits or phone contact with patients and their cardiologists at 1 month. All data were gathered prospectively in a local database from the start of patient recruitment.

Statistical analysis

Means and standard deviations were calculated for all continuous variables, and were compared using Student's *t* test for normal distribution variables and the Wilcoxon test for the other variables. Categorical variables are represented in absolute numbers with a percentage, and were compared by the χ^2 test or Fisher's exact test, depending on the size of the sample. Results are reported as hazard ratios with 95% confidence intervals. The degree of statistical significance was defined as $P < 0.05$. All statistical analyses were performed with the SPSS software, version 22.0 (SPSS Inc., Chicago, IL, USA).

Results

Patients

The main baseline characteristics of the whole population and of both THV groups are summarized in Table 1. The study population consisted of 502 consecutive patients with a mean age of 81 ± 9 years; 238 (48%) were women. Patients in the self-expanding THV group had a higher expected risk than those in the balloon-expandable THV group: logistic EuroSCORE, 19.2% vs. 16.3% ($P = 0.016$); and EuroSCORE II, 7.8% vs. 6.4% ($P = 0.047$). Moreover, patients in the self-expanding THV group were also frailer according to the grip strength test (21.1 ± 6.9 vs. 24.0 ± 8.5 kg; $P = 0.013$) and the 6-minute walk test (164.9 ± 84.6 vs. 241.3 ± 127.7 m; $P = 0.003$), and had worse baseline quality of life scores according to the EuroQoL-5D-3L (7.9 ± 2.2 vs. 7.1 ± 2.0 points; $P = 0.003$) and the EuroQoL visual analogue scale (55.5 ± 15.4% vs. 60.1 ± 14.6%; $P = 0.016$).

Table 2 presents the main biological, echocardiographic and computed tomography findings of the preprocedural screening. Biological and echocardiographic findings were similar in both groups; however, as expected given our decision process, computed tomography showed that patients in the self-expanding THV group had smaller aortic annuli (23.3 ± 2.9 vs. 24.8 ± 2.4 mm; $P < 0.001$) and smaller iliofemoral diameters (6.7 ± 1.7 vs. 7.0 ± 1.4 mm; $P = 0.046$) than those in the balloon-expandable THV group.

Procedural technique

Fig. 1 shows the flow chart of the procedures performed in the study population. The use of THVs was well balanced between both families, with 227 patients (45.2%) receiving a self-expanding THV (CS, 131 [26.1%]; CER, 96 [19.1%]) and 275 patients (54.8%) receiving a balloon-expandable THV (SXT, 63 [12.5%]; S3, 212 [42.2%]). A total of 427 procedures (85.1%) were performed via the transfemoral approach, while only 29 (5.8%) required transthoracic access (Table 3). Anaesthesia was mainly performed using a locoregional ilioinguinal-iliohypogastric block (80%), and few patients needed postdilatation after valve implantation (about 10%).

Immediate procedural complications

The main results are presented in Table 4. The rate of implantation failure according to VARC-2 criteria was low (3.4%). There were seven procedural deaths (1.4%), eight non-fatal strokes (1.6%), two non-fatal annulus ruptures (0.4%), one non-fatal coronary obstruction (0.2%), eight life-threatening or major bleeding complications (1.6%) and 14 moderate-to-severe PVLs (5.1%). The only difference observed between the THV groups was a higher incidence of acute atrioventricular blocks in the self-expanding THV group (17.2% vs. 10.9%; $P = 0.038$).

Among the 24 patients (4.8%) with a bicuspid aortic valve, nine (37.5%) received a self-expanding THV, and 15 (62.5%) received a balloon-expandable THV. The rate of moderate-to-severe PVL and annulus rupture was similar to that for the whole population (0% vs. 0.8%; $P = 0.653$).

Valve-in-valve TAVIs were performed in 39 patients (7.8%) with degenerated aortic bioprostheses. In this subset, only one patient (2.5%) had a transprosthetic mean gradient ≥ 20 mmHg on predischarge TTE.

Thirty-day outcomes

Thirty-day outcomes are summarized in Table 5. Overall, 16 patients (3.2%) died, mostly from cardiovascular causes (14.9%). Stroke occurred in 15 patients (3.0%), myocardial infarction in four patients (0.8%), acute heart failure in 50 patients (6.9%), life-threatening/major bleeding in

Table 1 Baseline clinical characteristics.

Variables	All patients	SE group	BE group	*P*
	(*n* = 502)	(*n* = 227)	(*n* = 275)	
Age (years)	81.4 ± 9.0	81.2 ± 9.9	81.5 ± 8.3	0.70
Female sex	238 (47.6)	129 (57.3)	109 (39.6)	< 0.001
Body mass index (kg/m^2)	26.0 ± 5.3	25.5 ± 5.7	26.3 ± 4.9	0.10
Body surface area (m^2)	1.8 ± 0.2	1.76 ± 0.2	1.83 ± 0.2	0.001
Previous cardiac surgery	97 (19.4)	47 (20.9)	50 (18.2)	0.55
Coronary artery disease	166 (33.2)	68 (30.2)	98 (35.6)	0.12
Atrial fibrillation	184 (36.8)	80 (35.6)	104 (37.8)	0.55
Previous pacemaker implantation	68 (13.6)	31 (13.8)	37 (13.5)	0.98
Peripheral artery disease	88 (17.6)	44 (19.6)	44 (16.0)	0.35
Cerebrovascular disease	53 (10.6)	25 (11.1)	28 (10.2)	0.84
Any symptomatic pulmonary disease (restrictive or obstructive)	79 (15.7)	29 (12.8)	50 (18.2)	0.08
Dialysis	21 (4.2)	12 (5.3)	9 (3.3)	0.28
Cancer	102 (20.4)	41 (18.3)	61 (22.2)	0.39
Diabetes mellitus	126 (25.2)	49 (21.8)	77 (28.0)	0.06
Dyspnoea				0.52
NYHA III	321 (64.2)	142 (63.1)	179 (65.1)	
NYHA IV	49 (9.8)	26 (11.6)	23 (8.4)	
Angina CCS ≥ 2	46 (9.2)	22 (9.8)	24 (8.7)	0.79
Syncope	20 (4.0)	7 (3.1)	13 (4.7)	0.36
Congestive heart failure	234 (46.8)	111 (49.3)	123 (44.7)	0.46
≥ 2 episodes during last year	39 (7.8)	15 (6.7)	24 (8.7)	0.33
Cognitive impairment	18 (3.6)	7 (3.1)	11 (4.0)	0.38
Poor mobility	21 (4.2)	16 (7.1)	5 (1.8)	0.004
EuroQoL-5D-3L (out of 15)	7.5 ± 2.1	7.9 ± 2.2	7.1 ± 2.0	0.003
EuroQoL visual analogue scale (%)	58.2 ± 15.0	55.5 ± 15.4	60.1 ± 14.6	0.016
Frail (eyeball test)	122 (24.4)	58 (25.8)	64 (23.3)	0.77
Clinical frailty scale ≥ 3	71 (14.2)	33 (14.7)	38 (13.8)	0.39
Grip strength (kg)	22.7 ± 7.9	21.1 ± 6.9	24.0 ± 8.5	0.013
6-minute walk test (m)	209.8 ± 117.7	164.9 ± 84.6	241.3 ± 127.7	0.003
Logistic EuroSCORE I	17.6 ± 12.5	19.2 ± 13.3	16.3 ± 11.7	0.016
EuroSCORE II	7.0 ± 6.5	7.8 ± 6.6	6.4 ± 6.3	0.047
Charlson Comorbidity Index	1.9 ± 1.5	1.8 ± 1.5	2.0 ± 1.5	0.41

Data are expressed as mean ± standard deviation or number (%). BE: balloon-expandable transcatheter heart valve; CCS: Canadian Cardiovascular Society; NYHA: New York Heart Association; SE: self-expanding transcatheter heart valve.

51 patients (7.0%) and major vascular complications in 30 patients (6.0%).

There was a higher rate of pacemaker implantation in the self-expanding THV group than in the balloon-expandable THV group (29.5% vs. 14.5%; $P < 0.001$). Self-expanding THVs had a better haemodynamic profile, with a lower mean transaortic gradient after the procedure compared with balloon-expandable THVs (respectively, 10 ± 7 vs. 11 ± 4 mmHg; $P = 0.05$). Otherwise, the comparison between groups showed only non-significant trends towards an increase in the incidence of death and a decrease in vascular complications in the self-expanding THV group compared with the balloon-expandable THV group.

Discussion

To our knowledge, the present study is the first to evaluate the results of a tailored approach to TAVI, using two different types of THVs, chosen according to the main clinical and anatomical characteristics of each particular patient. The findings suggest that complementary use of balloon-expandable SXT/S3 THVs and self-expanding CS/CER THVs allows a high rate of full percutaneous transfemoral approach and locoregional anaesthesia, with very low procedural and 1-month complication and mortality rates in a consecutive high-risk TAVI population.

Transfemoral approach

During our whole TAVI programme, one crucial objective was to allow a maximal number of patients to be treated via the transfemoral approach. Indeed, it has been demonstrated that this approach is associated with the lowest mortality compared with other approaches, while avoiding general anaesthesia and allowing rapid functional patient recovery [23]. Data from the FRANCE-2 registry showed that all non-transfemoral approaches were independent predictors

Table 2 Preoperative assessment.

Variables	All patients	SE group	BE group	*P*
	(*n* = 502)	(*n* = 227)	(*n* = 275)	
Biology				
Haemoglobin (g/dL)	12.3 ± 1.9	12.3 ± 1.6	12.3 ± 2.1	0.98
Creatinine (μmoL)	121 ± 98	120.6 ± 95.5	121.4 ± 100.8	0.93
Echocardiography data				
LVEF Simpson (%)	54.7 ± 12.5	55.2 ± 12.4	54.3 ± 12.6	0.47
Mean transaortic gradient (mmHg)	46.7 ± 16.5	45.5 ± 16.7	47.7 ± 16.3	0.15
Maximal transaortic velocity (cm/s)	423.7 ± 83.7	419.8 ± 82.1	426.7 ± 84.9	0.45
Aortic area (cm^2)	0.76 ± 0.3	0.76 ± 0.2	0.77 ± 0.3	0.64
Aortic regurgitation ≥ 3/4	32 (6.4)	19 (8.4)	13 (4.7)	0.15
Mitral regurgitation ≥ 3/4	28 (5.6)	13 (5.8)	15 (5.5)	0.93
PASP (mmHg)	46.9 ± 13.4	46.6 ± 13.9	47.1 ± 12.9	0.68
Computed tomography data				
Calcium score	2781 ± 1495	2666 ± 1559	2891 ± 1432	0.35
Bicuspid valve	24 (4.8)	9 (4.0)	15 (5.5)	0.35
Previous aortic bioprosthesis	39 (7.8)	33 (14.5)	6 (2.2)	< 0.001
Mean aortic annulus Ø (mm)	24.1 ± 2.7	23.3 ± 2.9	24.8 ± 2.4	< 0.001
Mean aortic annulus Ø < 21 mm	31 (6.2)	26 (11.6)	5 (1.8)	< 0.001
Aortic annulus area (mm^2)	463 ± 104.8	409.5 ± 96.0	504.3 ± 92.0	< 0.001
Femoral artery minimal Ø (mm)	6.8 ± 1.6	6.7 ± 1.7	7.0 ± 1.4	0.046
Femoral artery minimal Ø < 5.5 mm	36 (7.2)	25 (11.1)	11 (4.0)	0.012

Data are expressed as mean ± standard deviation or number (%). Ø: diameter; BE: balloon-expandable transcatheter heart valve; LVEF: left ventricular ejection fraction; PASP: pulmonary arterial systolic pressure; SE: self-expanding transcatheter heart valve.

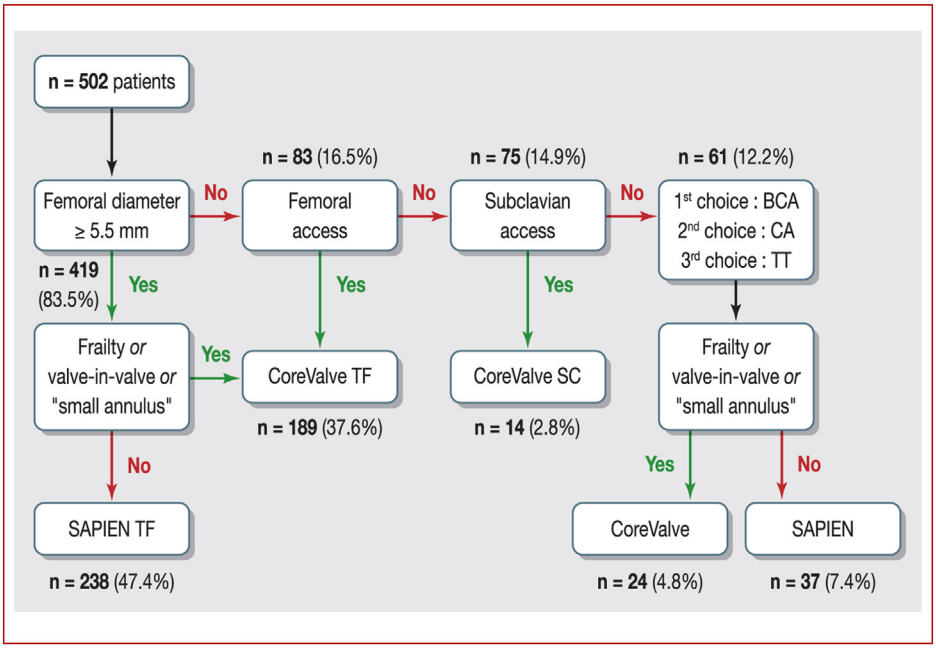

Figure 1. Flowchart of the study population. BCA: brachiocephalic artery; CA: carotid artery; SC: subclavian; TF: transfemoral; TT: transthoracic (transaortic or transapical).

of higher early mortality rate [24,25]. The UK TAVI registry also showed an increased mid-term mortality rate with the transapical compared with the transfemoral approach [5]. The complications induced by thoracotomy and direct ventricular access probably explain this excess mortality. However, a selection bias might also be partly responsible for this finding, as patients treated via the transapical approach have a higher risk profile than patients treated via the transfemoral approach [26]. Nevertheless, all data currently available consistently suggest that the transfemoral

Table 3 Procedural technique.

Variables	All patients	SE group	BE group	*P*
	(*n* = 502)	(*n* = 227)	(*n* = 275)	
Anaesthesia				0.52
Locoregional block	400 (79.7)	176 (77.5)	224 (81.5)	
General	102 (20.3)	51 (22.5)	51 (18.5)	
Primary access				< 0.001
Transfemoral access	427 (85.1)	189 (83.3)	238 (86.5)	0.30
Other transarterial access	46 (9.2)	37 (16.3)	9 (3.3)	< 0.001
Subclavian artery	14 (2.8)	14 (6.2)	0 (0)	
Brachiocephalic artery	24 (4.8)	19 (8.4)	5 (1.8)	
Carotid artery	8 (1.6)	4 (1.8)	4 (1.5)	
Transthoracic access	29 (5.8)	1 (0.4)	28 (10.2)	< 0.001
Transapical	26 (5.2)	0 (0)	26 (9.5)	
Transaortic	3 (0.6)	1 (0.4)	2 (0.7)	
THV type				
Self-expanding				
CoreValve™ System	131 (26.1)	131 (57.7)	0	
CoreValve™ Evolut R™	96 (19.1)	96 (42.3)	0	
Balloon-expandable				
SAPIEN XT™	63 (12.5)	0	63 (22.9)	
SAPIEN 3™	212 (42.2)	0	212 (77.1)	
Valve-in-valve	39 (7.8)	33 (14.5)	6 (2.2)	< 0.001
Implantation failure (VARC-2)	13 (3.4)	8 (3.5)	5 (1.8)	0.21
Optimal position	430 (85.7)	184 (81.1)	246 (89.5)	0.005
Need for a second valve	11 (2.2)	7 (3.1)	4 (1.5)	0.20
Suboptimal initial position	5 (1.0)	2 (0.9)	3 (1.2)	
Migration	3 (0.6)	3 (1.3)	0 (0)	
Aortic regurgitation > 2	4 (0.8)	2 (0.9)	2 (0.8)	
Postdilatation	49 (9.8)	35 (15.4)	14 (5.1)	< 0.001

Data are expressed as number (%). BE: balloon-expandable transcatheter heart valve; SE: self-expanding transcatheter heart valve; THV: transcatheter heart valve; VARC-2: Valve Academic Research Consortium-2.

approach should be used as a default, and this recommendation is now followed universally. This finding was confirmed in the PARTNER 2 trial, with a lower rate of death or disabling stroke after transfemoral TAVI than after surgery in intermediate-risk patients (hazard ratio 0.79, 95% confidence interval 0.62—1.00; *P* = 0.05) [2].

The present study showed that the combined use of balloon-expandable and self-expanding THVs allowed nearly 90% of patients to be treated via the transfemoral approach during the period 2012—2017. This is much more than in all other large contemporary registries including consecutive TAVI patients (73.4% in FRANCE-2 [26], 70.7% in GARY [27] and 71.2% in UK TAVI [5]) and even in the more recent FRANCE-TAVI registry (82.8%) [28]. In the randomized PARTNER 2 study, only 76.3% of the patients were treated via the transfemoral approach with the SXT THV [2]. The direct consequence of the large use of the transfemoral approach was the 5.2% rate of use of transapical access in the present series, compared with 17.8% in FRANCE-2 [26], 27.0% in GARY [27], 19.0% in the Belgian registry [7] and 19.1% in UK TAVI [5].

This high rate of use of the transfemoral route required the combined use of both THV families. Indeed, the use of only SXT/S3 THVs would have excluded all patients with minimal iliofemoral diameters < 6.0/5.5 mm, representing 83 patients (16.5%). The complementary use of CS/CER THVs allowed the transfemoral approach to be used in patients with diameters as small as 5.5/5.0 mm. It is important to point out that this maximal use of the transfemoral approach was not associated with an increased risk of vascular complications or bleedings. Indeed, the rate of major vascular complications after the procedure was 6.0% in our population—similar to the rates in the PARTNER 2 and SURTAVI trials [2,3].

Finally, the 3.2% 30-day mortality rate was lower than in other concomitant registries: 8.1% in FRANCE-2 [26] and 6.3% in UK TAVI [5]. This rate was similar to that observed in FRANCE-TAVI (4.4%) [28] and the PARTNER 2 study (3.9%), although it was a randomized study addressing intermediate-risk patients [2].

Anatomy of the aortic root

Careful analysis of the aortic root is mandatory to avoid life-threatening complications, such as annulus rupture and coronary obstruction, but also PVL, and to obtain an optimal haemodynamic result. All these outcomes are influenced by

Table 4 Procedural complications.

Variables	All patients	SE group	BE group	*P*
	(*n* = 502)	(*n* = 227)	(*n* = 275)	
Procedural death	7 (1.4)	5 (2.2)	2 (0.7)	0.16
Annulus rupture	2 (0.4)	1 (0.4)	1 (0.4)	
Left ventricle perforation	2 (0.4)	2 (0.9)	0 (0)	
Coronary obstruction	1 (0.2)	1 (0.4)	0 (0)	
Tamponade	1 (0.2)	0 (0)	1 (0.4)	
Unexplained cardiac arrest	1 (0.2)	1 (0.4)	0 (0)	
Conversion to surgery	2 (0.4)	1 (0.4)	1 (0.4)	0.90
Cardiac arrest	12 (2.4)	8 (3.5)	4 (1.5)	0.13
Stroke	8 (1.6)	3 (1.3)	5 (1.8)	0.66
Non-fatal coronary obstruction	1 (0.2)	0 (0)	1 (0.4)	0.36
Non-fatal annulus rupture	2 (0.4)	0 (0)	2 (0.7)	0.20
Non-fatal tamponade	10 (2.0)	5 (2.2)	5(1.8)	0.76
Non-fatal left ventricle perforation	2 (0.4)	0 (0)	2 (0.7)	0.20
Right ventricle perforation	1 (0.2)	0 (0)	1 (0.4)	0.36
Mitral valve damage	1 (0.2)	0 (0)	1 (0.4)	0.36
Paravalvular leak > 2/4	14 (5.1)	11 (8.0)	3 (2.2)	0.06
Mean transaortic gradient (mmHg)	10.9 ± 5.9	10.3 ± 7.4	11.5 ± 4.1	0.05
Prosthesis migration	3 (0.6)	3 (1.3)	0 (0)	0.05
Vascular complication	43 (8.6)	16 (7.0)	27 (9.8)	0.27
Dissection	8 (1.6)	4 (1.8)	4 (1.5)	
Thrombosis	4 (0.8)	1 (0.4)	3 (1.1)	
Perforation	5 (1.0)	3 (1.3)	2 (0.7)	
Persistent leak	18 (3.6)	6 (2.6)	12 (4.4)	
Bleeding during procedure	16(3.2)	8 (3.5)	8 (2.9)	0.63
Minor	8 (1.6)	3 (1.3)	5 (1.8)	
Major	6 (1.2)	5 (2.2)	1 (0.4)	
Life-threatening	2 (0.4)	0 (0)	2 (0.7)	
Atrioventricular block	69 (13.7)	39 (17.2)	30 (10.9)	0.038

Data are expressed as number (%) or mean ± standard deviation. BE: balloon-expandable transcatheter heart valve; SE: self-expanding transcatheter heart valve.

the choice of THV. Annulus rupture is a rare complication of TAVI (~1%), although possibly underdetected and underreported [29,30], and it is associated with a high mortality rate [31–33]. Because of their mechanism of deployment, it is mostly observed with balloon-expandable THVs [13]. Our strategy was to favour the use self-expanding THVs in patients deemed at high risk of annular rupture. In the present series, two patients (0.4%) died from annular rupture, one in each THV group. However, the annulus rupture observed in the self-expanding THV group occurred during balloon predilatation. No rupture was caused by the self-expanding THV itself. Whenever possible, balloon predilatation should probably be avoided in such high-risk patients [34].

The prevention of PVL has been a constant challenge since the beginning of TAVI. Indeed, it has been demonstrated that residual moderate/severe PVL represents an adverse prognostic factor, and is associated with an increased risk of all-cause mortality [35]. A meta-analysis published in 2013, including nearly 13,000 patients, reported a pooled estimated incidence of moderate/severe PVL of 12% [36]. However, since then, the new THV generations, especially the S3 THV, have considerably improved prevention of PVL. Overall, because of their higher radial force and better sealing to the annulus, we favoured SXT/S3 over CS/CER THVs in patients at high risk of PVL, and in those with large annuli. As estimated on predischarge TTE, the low rate of moderate-to-severe PVLs (5.1%) observed in our series compares favourably with other contemporary registries (16.5% in FRANCE2 [26], 10.2% in FRANCE-TAVI [28] and 13.6% in UK TAVI [5]).

Patients requiring valve-in-valve TAVI presented two main challenges: avoiding coronary obstruction and achieving the best haemodynamic result with the lowest possible gradient. Both issues led us to mostly use the self-expanding CS/CER THVs in this setting. This strategy was effective, as only one patient (2.5%) requiring valve-in-valve TAVI had a transprosthetic gradient ≥ 20 mmHg in our series. This finding compares favourably with those from the Valve-in-Valve Registry, where high postprocedural gradients (mean gradients ≥ 20 mm Hg) were recorded in 28.4% of the patients [14].

Patients with bicuspid aortic valve illustrated the close impact of THV properties on device preference in specific cases, and the changes over time, concomitant with technological improvements. Indeed, our strategy moved from

Table 5 Thirty-day outcomes.

Variables	All patients	SE group	BE group	*P*
	(*n* = 502)	(*n* = 227)	(*n* = 275)	
Death	16 (3.2)	11 (4.8)	5 (1.8)	0.07
MACCE	30 (6.0)	18 (7.9)	12 (4.4)	0.13
Cardiovascular death	14 (2.8)	10 (4.4)	4 (1.5)	
Stroke	15 (3.0)	8 (3.5)	7 (2.5)	
Myocardial infarction	4 (0.8)	3 (1.3)	1 (0.4)	
Rehospitalizations	38 (7.6)	19 (5.4)	19 (6.9)	0.79
Acute heart failure	50 (6.9)	19 (5.4)	31 (8.2)	0.33
Bleeding	117 (16.0)	60 (17.1)	57 (15.0)	0.61
Minor	66 (9.1)	34 (9.7)	32 (8.4)	
Major	43 (5.9)	23 (6.6)	20 (5.3)	
Life-threatening	8 (1.1)	3 (0.9)	5 (1.3)	
Acute kidney injury	35 (7.0)	21 (9.3)	14 (5.1)	0.19
Vascular complications	106 (21.1)	44 (19.3)	62 (22.5)	0.39
Minor	76 (15.1)	29 (12.8)	47 (17.1)	0.18
Major	30 (6.0)	15 (6.6)	15 (5.5)	0.59
Pacemaker implantation	107 (21.3)	67 (29.5)	40 (14.5)	< 0.001

Data are expressed as number (%). BE: balloon-expandable transcatheter heart valve; MACCE: major adverse cardiac and cerebrovascular events including cardiovascular death, stroke and myocardial infarction; SE: self-expanding transcatheter heart valve.

preferential use of the CS THV at the beginning of the programme, because of its conformability and supra-annular valve function, towards the use of the S3 THV more recently, because of the lower risk of annulus rupture compared with the SXT THV, and the best PVL prevention.

Finally, the availability of two different TVH families was very useful in some patients with annular dimensions in the ''grey zone'', borderline between two THV sizes. In these cases, using the alternative THV family was frequently a simple way to avoid the risks of annular rupture or PVL.

General characteristics

Frailty is important to consider in TAVI candidates because, although difficult to quantify, it has been associated with increased postprocedural mortality [35,37]. Although there is no scientific evidence to support this strategy, we felt that the use of the self-expandable THVs allowed the procedures to be as safe as possible in this high-risk population, as a result of their low profile, their progressive step-by-step deployment and the possibility of recapture and retrieval, should any problem occur. Of note, despite these risky situations, self-expanding THVs did as well as balloon-expandable THVs (except for the incidence of pacemaker implantation), which tended to validate our strategy *a posteriori*.

Study limitations

This was an observational single-centre study aimed at assessing the results of a systematic prospective TAVI strategy, with all inherent potential biases. To avoid too long a study period, with the potential impact of a learning curve and the use of too many device generations, we restricted the analysis to a 5-year period, with only two devices from each THV family, which limited the number of the patients. However, the nature of the study guaranteed homogeneous patient selection, procedural strategy and technique, post-procedural care and data collection.

Conclusion

Our study suggests that the complementary tailored use of balloon-expandable and self-expanding THVs allows a large majority of patients requiring TAVI to undergo transfemoral procedures with locoregional anaesthesia, avoiding the drawbacks of surgical transthoracic routes and general anaesthesia in a high-risk population. This strategy is associated with low procedural and 1-month complication and mortality rates. With the commercialization and reimbursement of other THVs in the near future, the most important task will not be to perform head-to-head comparisons between devices, but to determine which THV types will be safest and most effective in which subsets of patients, according to their clinical and anatomical characteristics.

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The other authors declare that they have no competing interest.

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