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Transfemoral Aortic Valve Replacement With the Edwards SAPIEN and Edwards SAPIEN XT Prosthesis Using Exclusively Local Anesthesia and Fluoroscopic Guidance

Feasibility and 30-Day Outcomes

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Objectives The authors report the feasibility and 30-day outcomes of transfemoral aortic valve replacement (TAVR), using the Edwards SAPIEN (Edwards Lifesciences, Irvine, California) and Edwards SAPIEN XT (Edwards Lifesciences) prosthesis, implanted using exclusively local anesthesia and fluoroscopic guidance.

Background Transfemoral TAVR is often managed with general anesthesia. However, a simplified percutaneous approach using local anesthesia has become more popular because it offers multiple advantages in an elderly and fragile population.

Methods Between May 2006 and January 2011, the authors prospectively evaluated 151 consecutive patients (logistic EuroSCORE: 22.8 ± 11.8%) who underwent TAVR (SAPIEN: n = 78, SAPIEN XT: n = 73) using only local anesthesia and fluoroscopic guidance. The primary endpoint was a combination of all-cause mortality, major stroke, life-threatening bleeding, stage 3 acute kidney injury (AKI), periprocedural myocardial infarction (MI), major vascular complication, and repeat procedure for valve-related dysfunction at 30 days.

Results Transarterial femoral approach was surgical in all SAPIEN procedures and percutaneous in 97.3% of SAPIEN XT, using the ProStar vascular closure device, and was well tolerated in all cases. Conversion to general anesthesia was required in 3.3% (SAPIEN cases) and was related to complications. Vasopressors were required in 5.5%. Procedural success was 95.4%. The combined-safety endpoint was reached in 15.9%, including overall mortality (6.6%), major stroke (2.0%), life-threatening bleeding (7.9%), stage 3 AKI (0.7%), periprocedural MI (1.3%), major vascular complication (7.9%), and repeat procedure for valve-related dysfunction (2.0%) at 30 days. A permanent pacemaker was required in 5.3%.

Conclusions This single-center, prospective registry demonstrated the feasibility and safety of a simplified transfemoral TAVR performed using only local anesthesia and fluoroscopic guidance in high surgical risk patients with severe aortic stenosis. (J Am Coll Cardiol Intv 2012;5:461–7) © 2012 by the American College of Cardiology Foundation

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Since the first-in-man transfemoral aortic valve replacement (TAVR) in 2002, many registries have shown that TAVR can be accomplished in high-risk patients with outcomes that compare favorably with surgical aortic valve replacement (1–8). This has been observed with the 2 devices currently used, the balloon-expandable Edwards SAPIEN (Edwards Lifesciences, Irvine, California) and the self-expandable Medtronic CoreValve (Medtronic CV, Irvine, California) prosthesis. Recently, using the Edwards SAPIEN device, the pivotal randomized PARTNER-US (Placement of Aortic Transcatheter Valve) trial demonstrated the superiority of TAVR over standard care with

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reduction of death at 1 year in nonsurgical candidates and a similar rate of survival at 1 year with TAVR and surgical aortic valve replacement in high surgical risk patients (9,10). As a consequence, the number of TAVR and the number of centers are dramatically increasing worldwide.

Abbreviations and Acronyms

BAV = balloon aortic valvuloplasty
CT = computed tomography
MI = myocardial infarction
RVP = rapid ventricular pacing
TAVR = transfemoral aortic valve replacement
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography
VARC = Valve Academic Research Consortium

Among the current approaches used for TAVR, transfemoral access is generally the first choice for the majority of investigators. The CoreValve is delivered through an 18-F sheath whereas the 23- and 26-mm Edwards SAPIEN valves require a 22- and 24-F sheath, respectively. Since October 2009, the new generation of Edwards valves, the SAPIEN XT valve, has decreased the required sheath size to 18- and 19-F, respectively.

Initially, because of the large caliber of the Edwards sheath, the femoral artery was generally accessed surgically, and the procedure was performed under general anesthesia. With the decrease in sheath sizes, an increasing number of operators have switched to a percutaneous approach performed using local anesthesia. However, with this simplified technique, intraprocedural transesophageal echocardiography (TEE), which has been advised as a helpful adjunct for valve positioning, assessment of the results, and detection of complications, is not used.

Interestingly, since the first-in-man implantation in 2002, our group has performed transfemoral cases using exclusively local anesthesia and fluoroscopic guidance for valve implantation without intraprocedural TEE (1,2). Thus, we sought to report the feasibility and safety of this strategy in our series of patients entered in a prospective registry using Edwards SAPIEN and SAPIEN XT valves.

Methods

Patient selection. Between May 2006 and May 2011, 151 consecutive patients (mean age: 83.3 years, 58.9% female) in whom transfemoral TAVR was performed were included in a prospective, single-center registry. All patients selected by our multidisciplinary team had severe, degenerative aortic stenosis and were included with respect to the inclusion criteria of successive European trials and registries (3,5,6). All patients gave written informed consent.

In our group, the screening process included transthoracic echocardiography (TTE), selective coronary angiography, aortography, and iliofemoral angiography. TEE was limited to rare patients with poor echocardiographic windows. All patients with unstable hemodynamics were stabilized with balloon aortic valvuloplasty (BAV) before TAVR.

An annulus diameter of 18 to 21 mm was considered appropriate for the 23-mm prosthesis and >21 to 24 mm for the 26-mm prosthesis. In cases of borderline sizes (20.5 to 21.5 mm), aortography was performed during balloon pre-dilation with a 23-mm balloon, and the optimal valve size was selected based on the presence or absence of aortic regurgitation at full balloon inflation.

Computed tomographic (CT) was also systematically performed to assess the feasibility of the transfemoral approach. A minimum diameter of 7 and 8 mm was required for the 23- and 26-mm SAPIEN valves, respectively, and 6 and 6.5 mm for the SAPIEN XT valves, respectively. Before percutaneous implantation, we also confirmed the absence of calcified plaque at the area of the femoral puncture site.

Patient preparation and procedure. The procedures were performed using the SAPIEN valve up to October 2009, and the SAPIEN XT valve thereafter. Both of these valves have been described elsewhere (3–6,9–11). Briefly, the SAPIEN valve is made of 3 bovine pericardial leaflets matched for elasticity and thickness, sewn onto a stainless steel stent frame partially covered with a synthetic polyethylene terephthalate fabric sealing cuff. The prosthesis is crimped over the balloon of the RetroFlex delivery system. The SAPIEN XT valve uses 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 after introduction into the abdominal aorta.

Cardiac catheterization and pre-medication. All procedures were performed in a conventional cardiac catheterization laboratory with sterile precautions. For the surgical arterial cut-

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down approach (SAPIEN valve), the team was composed of 2 interventional cardiologists, a cardiac surgeon, and 2 nurses. The cardiac surgeon was not always present for the percutaneous approach (SAPIEN XT valve). All the equipment was present and ready to be used in the catheterization laboratory, and both the anesthesiologist and the echocardiographer were immediately available in case of any complications.

Patients were preloaded with aspirin (160 mg) and clopidogrel (300 mg) and continued to take clopidogrel (75 mg) for 1 month and aspirin (75 to 160 mg) indefinitely. Heparin (5,000 IU) was administered immediately after surgical cutdown or placement of the vascular closure device.

Local anesthesia and sedation. Lidocaine 2% (20 to 30 ml) was used for local anesthesia; it was injected into the skin, into the subcutis, and around the femoral artery for percutaneous and surgical approaches. Additional doses of lidocaine could be administered at any time during the procedure at the discretion of the operator. Conscious sedation consisted of intravenous administration of midazolam (1 mg) and nalbuphine (5 mg) at the start of the procedure. Additional half or full doses of each could be administered at the discretion of the operator.

Procedure. The techniques of SAPIEN and SAPIEN XT valve implantation have been described in detail elsewhere (9–11). Briefly, in our center, supravalvular aortography was performed to select the optimal view aligning all cusps in a single plane. The selected femoral artery was cut down or "pre-closed" with a 10-Fr ProStar XL (Abbott, Chicago, Illinois). After crossing the aortic valve, a 260-cm-long 0.035-inch Amplatz Extra-Stiff J-tip guidewire (COOK, Bjaeverskov, Denmark) was placed in the left ventricle. BAV was performed with rapid ventricular pacing (RVP, 180 to 220 beats/min) using a 20- or 23-mm balloon in accordance with the valve size. Valve positioning was based on fluoroscopy using annular calcification as a landmark, and serial (5 to 10 ml) supra-annular aortography to validate the position of the valve during RVP. The prosthesis was delivered also using RVP. Removal of the sheath was cautiously achieved with serial contralateral angiograms to detect iliofemoral complications. The femoral arteriotomy was then closed surgically or by 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. Patients were monitored in intensive care unit for 24 h after valve implantation.

Data collection. Clinical and TTE parameters were obtained at baseline, discharge, and 1 month, and the data were entered into our institutional database. For the patients from remote institutions (16%), outcomes at 30 days were obtained by telephonic interview of the referring physician and exchange of TTE reports. No patient was lost for follow-up.

Endpoint definitions. The primary safety endpoint was a combination of all-cause mortality, major stroke, life-threatening bleeding, stage 3 acute kidney injury (AKI), periprocedural myocardial infarction (MI), major vascular complication, and repeat procedure for valve-related dysfunction at 30 days. All complications were reported according to the Valve Academic Research Consortium (VARC) classification (12).

Secondary endpoints included: conversion to general anesthesia and need for vasopressors during the procedure, device success according to the VARC definition (defined as successful vascular access, delivery, and deployment of the device, successful retrieval of the delivery system with correct position of the device, post-TAVR aortic valve area >1.2 cm^2, and mean aortic valve gradient <20 mm Hg or peak velocity <3 m/s without moderate or severe prosthetic valve regurgitation), New York Heart Association (NYHA) heart failure functional class, transvalvular mean pressure gradient, effective aortic valve area, presence and severity of aortic valvular regurgitation, and/or mitral valve regurgitation on TTE.

Statistical analysis. Qualitative variables were expressed as percentage, and quantitative variables as mean ± SD or median (25th to 75th interquartile range). Comparison of numerical variables was performed with the Student *t* test or Wilcoxon rank sum test, depending on variable distribution. The chi-square test or Fischer exact test was used to compare qualitative variables. All statistical tests were 2-sided. Differences were considered statistically significant at p values <0.05. All data were analyzed using SPSS software (version 17.0, IBM, Armonk, New York).

Results

The results are presented for the whole population and stratified by valve type (SAPIEN: n = 78, SAPIEN XT: n = 73).

Baseline characteristics. Baseline clinical characteristics are shown in Table 1. All patients were severely symptomatic. The mean logistic EuroSCORE was 22.8%, and significantly lower in the SAPIEN XT group (17.4% vs. 27.8%, $p < 0.0001$). History of MI, coronary artery bypass graft, BAV, and chest irradiation were less frequent in the SAPIEN XT group. All other variables were comparable in the 2 groups.

Baseline TTE data (Table 2) confirmed the severity of aortic stenosis, similar in the 2 groups. Left ventricular ejection fraction was moderately, but significantly, lower in the SAPIEN group due to selection of more severely ill patients per protocol.

Procedural outcomes. The results are shown in Table 3. Transarterial access was well tolerated in all cases and consisted of surgical cutdown in all SAPIEN cases and percutaneous approach in all but 2 patients in the SAPIEN XT group.

The prosthesis was placed in the appropriate position in all cases. A single valve was implanted in all cases, and there was no valve embolization. Procedural device success rate was 95.4% in the overall population. Balloon post-dilation was used to expand the valve and to minimize the leak in case of severe aortic regurgitation (grade ≥3) immediately

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Table 1. Baseline Characteristics

	Overall Population (N = 151)	SAPIEN (n = 78)	SAPIEN XT (n = 73)	p Value
Age, yrs	83.3 ± 6.4	83.9 ± 5.8	82.7 ± 6.9	0.19
Female	89 (58.9)	43 (55.1)	46 (63.0)	0.32
Hypertension	105 (69.5)	52 (66.7)	53 (72.6)	0.43
Diabetes	41 (27.2)	18 (23.1)	23 (31.5)	0.24
Previous MI	37 (24.5)	29 (37.2)	8 (11.0)	<0.0001
Previous PCI	39 (25.8)	22 (28.2)	17 (23.3)	0.49
Previous CABG	26 (17.2)	18 (23.1)	8 (11.0)	0.049
Atrial fibrillation	61 (40.4)	29 (37.2)	32 (43.8)	0.41
Pacemaker	15 (9.9)	10 (12.8)	5 (6.8)	0.22
Previous BAV	72 (47.7)	49 (62.8)	23 (31.5)	<0.0001
PAD	20 (13.2)	8 (10.3)	12 (16.4)	0.26
Porcelain aorta	8 (5.3)	3 (3.8)	5 (6.8)	0.48
Previous stroke	8 (5.3)	4 (5.1)	4 (5.5)	1.00
Creatinine, μmol/l	113 ± 52	118 ± 43	109 ± 60	0.30
COPD	51 (33.8)	29 (37.2)	22 (30.1)	0.36
Chest irradiation	16 (10.6)	12 (15.4)	4 (4.5)	0.048
Neoplasia	34 (22.5)	22 (28.2)	12 (16.4)	0.08
NYHA functional class III or more	115 (76.1)	63 (80.8)	52 (71.2)	0.10
Logistic EuroSCORE, %	22.8 ± 11.8	27.8 ± 11.1	17.4 ± 10.0	<0.0001

Values are mean ± SD or n (%).

BAV = balloon aortic valvuloplasty; CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PAD = peripheral artery disease; PASP = pulmonary artery systolic pressure; PCI = percutaneous coronary intervention.

after TAVR. This strategy was adopted in 12 (7.9%) patients (7 [9.0%] in the SAPIEN group vs. 5 [6.8%] in the SAPIEN XT group, p = 0.629). Procedural failure was related to unsuccessful vascular access in 2% or severe aortic regurgitation (grade ≥3) in 2.6%.

Conversion to emergent cardiovascular surgery was required in only 5 SAPIEN cases (3.3%) (1 aortic dissection, 1 aortic annulus rupture with tamponade, 2 vascular ruptures, and 1 major aortic regurgitation). Conversion to general anesthesia in the cardiac catheterization laboratory before transfer to the operating room occurred in only 1 patient (annulus rupture). Two patients (aortic dissection and annulus rupture) did not survive surgery, whereas the other 3 patients had uneventful outcomes. There was no conversion to general anesthesia or surgery in the SAPIEN XT group. Hemodynamics remained remarkably stable at each step of the procedures. Vasopressors were required in only 7 patients (5.5%), including those just described above and 2 patients who had prolonged hypotension after valve delivery.

Procedural duration was markedly shorter in the SAPIEN XT group, whereas contrast volume was greater in this group, due to additional use of contrast associated with the "pre-close" technique.

30-day safety endpoint. The results are shown in Table 4. In the overall population, the combined 30-day safety endpoint was reached in 15.9% (17.9% vs. 13.7% with SAPIEN and SAPIEN XT, respectively, p = 0.47), including death (6.6%, 60% of cardiovascular origin), major stroke (2.0%), life-threatening bleeding (7.9%), stage 3 AKI (0.7%), periprocedural MI (2.0%), major vascular complication (7.9%), and repeat procedure for valve-related dysfunction (2.0%). According to the VARC definition, bleeding was life threatening in 7.9%, major in 11.3%, and minor in 3.3%. These safety endpoints were similar with the 2 models of valves. Failure of vascular closure devices occurred in 7 patients (9.6%) in the SAPIEN XT group, requiring endovascular stent graft in 4 patients and vascular surgery in 3 patients. Finally, a permanent pacemaker was required in 5.3% of the overall population.

Secondary endpoints. Secondary endpoints are shown in Table 5. NYHA heart failure functional class was dramatically improved at 30 days. Hemodynamic parameters, aortic valve area, and mean valvular gradient were also markedly improved. Moderate-to-important aortic regurgitation was infrequent (grade ≥3 in 2.6%). These results were comparable in the SAPIEN and SAPIEN XT groups.

Discussion

Local anesthesia and conscious sedation have been our choice since the first-in-man case in 2002. The trans-septal antegrade approach used in compassionate cases via the femoral vein in our earliest series did not require general anesthesia (1,2). Several cases of percutaneous retrograde approach were also performed at this early phase with the same strategy. We thus became rapidly convinced of the

Table 2. Baseline Echocardiographic Characteristics

	Overall Population (N = 151)	SAPIEN (n = 78)	SAPIEN XT (n = 73)	p Value
Aortic annulus diameter, mm	21.2 ± 1.5	21.1 ± 1.5	21.3 ± 1.5	0.06
Mean aortic gradient, mm Hg	44.6 ± 17.1	41.4 ± 15.1	48.1 ± 18.5	0.03
Aortic valve area, cm^2	0.67 ± 0.15	0.67 ± 0.16	0.66 ± 0.15	0.81
PASP, mm Hg	42.7 ± 13.2	43.8 ± 12.4	41.7 ± 13.9	0.26
LVEF, %	55.9 ± 15.7	52.7 ± 17.1	59.3 ± 13.3	0.02

Values are mean ± SD.

Abbreviations as in Table 1.

Table 3. Procedural Outcomes

	Overall Population (N = 151)	SAPIEN (n = 78)	SAPIEN XT (n = 73)	p Value
Surgical cutdown	80 (53.0)	78 (100)	2 (2.7)	<0.0001
Conversion to general anesthesia	5 (3.3)	5 (6.5)	0 (0)	0.06
Vasopressors	7 (5.5)	6 (7.8)	1 (1.4)	0.12
Device success	144 (95.4)	73 (93.6)	71 (97.3)	0.28
Successful vascular access	148 (98.0)	76 (97.4)	72 (98.6)	0.32
Successful implantation	148 (100)*	76 (100)*	72 (100)*	1.0
Correct position	148 (100)*	76 (100)*	72 (100)*	1.0
AVA >1.2 cm^2	148 (100)*	76 (100)*	72 (100)*	1.0
MAG <20 mm Hg	148 (100)*	76 (100)*	72 (100)*	1.0
AR grade ≥3	4 (2.6)	3 (3.8)	1 (1.4)	0.31
Only 1 valve implanted	148 (100)*	76 (100)*	72 (100)*	1.0
Procedural duration, min	136.6 ± 47.0	151.7 ± 2.7	105.9 ± 40.3	<0.0001
X-ray time, min	24.4 ± 18.3	25.9 ± 23.1	22.5 ± 9.0	0.18
Contrast volume, ml	185.2 ± 96.4	139.4 ± 53.7	243.5 ± 107.1	0.001

Values are n (%) or mean ± SD. *Events were only evaluated in patients with successful vascular access.
AR = aortic regurgitation; AVA = aortic valve area; MAG = mean aortic gradient.

feasibility, safety, and tolerance of this strategy. We have continued to use this strategy for all cases of transfemoral retrograde approach with or without surgical cutdown. To our knowledge, the feasibility and safety of TAVR using local anesthesia has never been previously prospectively reported in a large series of consecutive patients. The main

Table 4. 30-Day Safety Analysis

	Overall Population (N = 151)	SAPIEN (n = 78)	SAPIEN XT (n = 73)	p Value
Combined-safety endpoint	24 (15.9)	14 (17.9)	10 (13.7)	0.47
30-day death				
All cause	10 (6.6)	6 (7.7)	4 (5.5)	0.74
Cardiovascular cause	6 (4.0)	4 (5.1)	2 (2.7)	0.45
Stroke				
Major stroke	3 (2.0)	1 (1.3)	2 (2.7)	0.61
Minor stroke	2 (1.3)	1 (1.3)	1 (1.4)	1.0
Transient ischemic attack	1 (0.7)	0 (0)	1 (1.4)	0.48
Bleeding				
Life-threatening bleeding	12 (7.9)	6 (7.7)	6 (8.2)	0.90
Major bleeding	18 (11.9)	9 (11.5)	9 (12.3)	0.88
Minor bleeding	5 (3.3)	1 (1.3)	4 (5.5)	0.19
Transfusions	42 (27.8)	26 (33.3)	16 (21.9)	0.12
AKI				
Stage 3 AKI	1 (0.7)	1 (1.3)	0 (0)	1.0
Stage 2 AKI	1 (0.7)	1 (1.3)	0 (0)	1.0
Stage 1 AKI	39 (25.8)	23 (29.5)	16 (21.9)	0.29
Vascular complications				
Major vascular complication	12 (7.9)	6 (7.7)	6 (8.2)	0.90
Minor vascular complication	20 (13.2)	7 (9.0)	13 (17.8)	0.11
Periprocedural MI	3 (2.0)	2 (2.6)	1 (1.4)	1.0
Repeat procedure for valve-related dysfunction	3 (2.0)	3 (3.8)	0 (0)	0.25
Pacemaker	8 (5.3)	5 (6.4)	3 (4.1)	0.72
Days from procedure to CCU discharge	2.0 (1.0–3.0)	1.5 (1.0–2.0)	2.0 (1.0–3.0)	0.66
Days from procedure to discharge	7.0 (5.0–9.0)	8.0 (7.0–9.0)	6.0 (5.0–9.0)	0.003

Values are n (%) or median (25th–75th interquartile range).
AKI = acute kidney injury; CCU = coronary care unit; MI = myocardial infarction.

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Table 5. 30-Day Secondary Endpoints

	Overall Population (N = 151)	SAPIEN (n = 78)	SAPIEN XT (n = 73)	p Value
NYHA functional class III or more	8 (5.3)	5 (6.4)	3 (4.1)	0.72
Mean aortic gradient, mm Hg	9.5 ± 2.9	9.6 ± 2.6	9.5 ± 3.3	0.94
Aortic valve area, cm^2	1.82 ± 0.24	1.80 ± 0.21	1.84 ± 0.27	0.51
LVEF, %	61.4 ± 12.2	58.4 ± 11.8	65.0 ± 11.8	0.33
AR grade ≥3	4 (2.6)	3 (3.8)	1 (1.4)	0.31
MR grade ≥3	5 (3.3)	3 (3.8)	2 (2.7)	1.0
PASP, mm Hg	40.4 ± 13.4	40.7 ± 11.7	40.0 ± 15.2	0.76

Values are n (%) or mean ± SD.
MR = mitral regurgitation; NYHA = New York Heart Association; other abbreviations as in Tables 1 and 3.

goal of the present study was to report the results obtained in our institution with the exclusive use of this simplified strategy. We further sought to compare the results obtained with the SAPIEN and the SAPIEN XT valves.

General versus local anesthesia. Transfemoral TAVR is generally performed with general anesthesia as shown in the FRANCE (FRench Aortic National CoreValve and Edwards) registry reporting 73.7% and 82% rates of general anesthesia with the SAPIEN and CoreValve devices, respectively (6). Other series are reporting exclusive use of general anesthesia for SAPIEN valve implantation (4,9–11,13). Among the arguments favoring general anesthesia are greater patient compliance, complete airway control, better procedural tolerance, and the capability to rapidly initiate cardiac support. However, with the introduction of smaller sheath sizes, local anesthesia with conscious sedation is currently emerging as a valuable alternative. In our experience, lack of pain, patient tolerance of femoral access, and RVP were consistently observed. Endotracheal intubation was not required to improve the patient's comfort and compliance.

Advantages to local anesthesia include more stable hemodynamics, less need for inotropic and/or vasopressor support (with the risk of subsequent vasoconstriction of the arterial access), lack of endotracheal intubation/ventilation/extubation, fewer vascular access sites, and shorter procedural duration and hospital stay. In our series, conversion to general anesthesia before transfer to surgery was required in a single case for major aortic complication. Periprocedural cardiopulmonary support was not required in our series. Conversion to thoracic or vascular surgery was limited to 5 cases (3%).

TEE versus no TEE. General anesthesia is required for adjunct intraprocedural TEE. In the FRANCE registry (6), 66.3% of the transfemoral procedures were performed with intraprocedural TEE up to 100% in other registries as well as in the pivotal PARTNER-US trial (4,9–11,13). Using only fluoroscopic guidance without intraprocedural TEE facilitated the use of conscious sedation in lieu of general anesthesia. With our strategy, procedural success remained very high (95.4%) and comparable to other series. Appropriate valve positioning by fluoroscopy and repeated aortography was achieved without valve migration or malposition. Without TEE, immediate results and complications were adequately assessed using hemodynamics, angiography, and TTE.

Edwards SAPIEN versus SAPIEN XT valves. This is one of the first studies to compare the SAPIEN with the SAPIEN XT valve: The comparison of outcomes with the 2 models of Edwards valves showed no difference in stroke, AKI, periprocedural MI, and vascular complications. Although

Table 6. Comparative Results With Randomized and Observational Studies Using the Edwards Prosthesis

Variables	Rouen TF (n = 151)*	Partner-A TF (n = 244)	Partner-B (n = 179)	SOURCE TF (n = 463)	FRANCE TF-Edwards (n = 95)	Vancouver TF (n = 205)*
30-day or in-hospital death	10 (6.6)	8 (3.3)	9 (5.0)	29 (6.3)	8 (8.4)	14 (6.8)
Major stroke	3 (2.0)	7 (2.9)	9 (5.0)	11 (2.4)	4 (4.2)	5 (2.4)
Significant bleeding	12 (7.9)	23 (9.5)†	30 (16.8)†	NA	NA	29 (14.1)
Transfusions	42 (27.8)	NA	NA	46 (9.9)	8 (8.4)	NA
Stage 3 AKI and/or renal replacement therapy	1 (0.7)	6 (2.5)	2 (1.1)	6 (1.3)	1 (1.0)	1 (0.5)
Major vascular complications	12 (7.9)	34 (14.0)	29 (16.2)	49 (10.6)	6 (6.3)	24 (11.7)
Periprocedural MI	2 (1.3)	0 (0)	0 (0)	3 (0.7)	2 (2.0)	NA
Repeat procedure for valve-related dysfunction	3 (2.0)	3 (3.8)	3 (1.7)*	NA	NA	0 (0)
30-day AR grade ≥3	4 (2.6)	38 (13.1)	23 (15.0)	7 (1.5)	NA†	NA†
Pacemaker	8 (5.3)	5 (6.4)	6 (3.4)	31 (6.7)	5 (5.3)	11 (5.4)

Values are n (%). *Evaluated with Valve Academic Research Consortium definition. †Only available in the global cohort, including CoreValve or transapical approach.
NA = not available; TF = transfemoral; other abbreviations as in Tables 3 and 4.

the 30-day mortality was lower in the SAPIEN XT group (5.5% vs. 7.7%), it was not statistically significant. As expected, the percutaneous approach used in this group was associated with significantly shorter procedural duration and hospital stay. As observed in other European series, patients receiving SAPIEN XT valves were less sick, as shown by the lower logistic EuroSCORE in our SAPIEN XT group. Even if indications of TAVR have been restricted to inoperable and high surgical risk patients (logistic EuroSCORE >20% and/or Society of Thoracic Surgeons (STS) score >10%) in our institution, there is a trend for considering TAVR in lower-risk patients, in particular >85-year-old patients when the transfemoral approach is feasible. An extension of indications to lower risk patients should be evaluated through randomized studies and/or well controlled prospective registries.

Comparison of our results to other reports. Our population was comparable to that of many other series (Table 6). In our overall population, the combined safety endpoint at 30 days was reached in 15.9%. The use of the recent VARC definition for assessing safety at 30 days does not allow for the comparison to previous reports, which did not use standardized definitions (12). To our knowledge, only 1 study reported the results of the Edwards prosthesis using the VARC definitions (13). In this study, in which general anesthesia was used, the combined safety endpoint at 30 days was comparable to ours (18.4%) as well as other individual endpoints (13). Even when compared with studies using non-VARC endpoints, our overall results look similar (Table 6). Thirty-day mortality, incidence of stroke, periprocedural MI, major vascular complications, and bleeding complications were comparable to other series in which most procedures were performed with general anesthesia and adjunct TEE.

Study limitations. This prospective study reflects a single-center experience on a relatively limited number of patients. We excluded our TAVR patients treated before May 2006 with another approach (compassionate procedures; antegrade cases), other delivery systems (RetroFlex 1 and 2), and different screening process (no CT angiography). However, the results are those of an experienced team, with a consistent strategy for patient selection and procedural management. Thus, they may not be reproducible by less experienced teams. Finally, the study was underpowered for a definitive comparison of the SAPIEN versus the SAPIEN XT prosthesis.

Conclusions

The results of this single-center, prospective registry demonstrated the feasibility and safety of transfemoral TAVR performed using exclusively local anesthesia and fluoroscopic guidance. The benefit of this simplified strategy deserves further study in a larger series of patients receiving the SAPIEN XT valve. Such a strategy might facilitate expanded use of TAVR in the future.

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Key Words: anesthesia ■ aortic stenosis ■ TAVR ■ Valve Academic Research Consortium (VARC).