Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) registry

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Aims
Transcatheter aortic valve implantation is a therapeutic alternative for high-surgical-risk patients with severe symptomatic aortic stenosis. Two models of prosthesis are currently commercialized in France, which can be implanted either via a transarterial or a transapical approach. The aim of the study was to evaluate in a national French registry the early safety and efficacy of transcatheter aortic valve replacement (AVR) using either the Edwards SAPIEN™ or CoreValve™ in high-surgical-risk patients with severe aortic stenosis.

Methods and results
The multicentre national registry was conducted in 16 centres between February 2009 and June 2009, under the authority of the French Societies of Cardiology and Thoracic and Cardio-Vascular Surgery. The primary endpoint was mortality at 1 month. Two hundred and forty-four high-surgical-risk patients (logistic EuroSCORE ≥ 20%, STS ≥ 10%, or contra-indication to AVR) were enrolled. Mean age was 82 ± 7 years and 43.9% were female. Edwards SAPIEN and CoreValve were implanted in 68 and 32% of patients, respectively. The approaches used were transarterial (transfemoral: 66%; subclavian: 5%) or transapical in 29%. Device success rate was 98.3% and 30-day mortality was 12.7%. Severe complications included stroke (3.6%), tamponade (2%), acute coronary occlusion (1.2%), and vascular complications (7.3%). Pacemaker was required in 11.8%. At 1 month, 88% of patients were in NYHA class II or less.

Conclusion
This prospective registry reflects the real-life experience of transcatheter aortic valve implantation in high-risk elderly patients in France. The early results are satisfactory in terms of feasibility, short-term haemodynamic and functional improvement, and safety. Longer term follow-up will be further assessed.

Keywords
Aortic stenosis • Transcatheter aortic valve implantation

Introduction
In 2002, the first transcatheter aortic valve implantation (TAVI) was performed by Cribier et al.¹ in a patient with severe aortic stenosis (AS) and cardiogenic shock. Seven years later, more than 8000 patients have been treated by TAVI worldwide using one of the two models of prosthesis now commercially available: the balloon expandable Edwards SAPIEN™ prosthesis (Edwards Lifesciences LLC, Irvine, CA, USA) and the self-expandable CoreValve™ (Medtronic CV, Irvine, CA, USA). Both of these were approved by the
European Standards authorities in 2007, allowing their commercialization in Europe for the recommended indications.

Since the initial description of the transvenous,\textsuperscript{2,3} transarterial\textsuperscript{4–7}, and transapical (TA)\textsuperscript{8–10} TAVI, the feasibility and safety of the TAVI technique have been confirmed and are rapidly gaining credibility as a viable alternative to open heart aortic valve replacement (AVR) in high-risk patients with severe AS. Dissemination from highly experienced centres to less experienced ones while maintaining similar results requires additional demonstration.

The aim of our study was to evaluate TAVI in France in a large population of patients with severe degenerative symptomatic AS considered at too high risk or contra-indicated for conventional AVR, included in a multicentre prospective registry. This registry which reflects the real-life experience of selected centres in the country included patients treated with the two commercially available models utilizing both transarterial and TA approaches.

Methods

Study design and patient population

Between February and July 2009, a total of 244 consecutive patients were included in a prospective multicentre registry. This registry involved symptomatic adults requiring TAVI due to severe, degenerative, valvular AS, and who were very high-risk candidates for AVR surgery at the time of enrolment. The 16 centres which participated in the registry were selected by the French Ministry of Health based on: the presence of a multidisciplinary on-site team (interventional cardiologist, cardio-thoracic surgeon, anaesthetist, imaging specialist), annual volume of AVR (>200 patients/year), preliminary experience in balloon aortic valvuloplasty and/or TAVI and, finally, a homogeneous geographic distribution throughout the country. Ten centres were in their learning phase and the first procedures were supervised by a proctor. Three other centres had participated previously in the Edwards initial feasibility studies and three had started the TAVI program in 2008 with more than 10 cases performed. The two commercially available valves were used and the choice was left at the discretion of the medico-surgical team. Six centres implanted both devices. All operators received preliminary training (organized by the two companies) and were supervised on site for the first procedures (2–6 for the Edwards; 10–15 for the CoreValve). Inclusion criteria were: aortic valve area (AVA) ≤1 cm\textsuperscript{2} or 0.6 cm\textsuperscript{2}/m\textsuperscript{2}; severe symptoms (NYHA functional class II or more); logistic EuroSCORE ≥20% and/or STS risk score ≥10% and/or contraindication to AVR (porcelain aorta, chest deformation, chest radiation). Native aortic annulus diameter had to be measured 18–24 mm for the Edwards SAPIEN and 20–27 mm for the CoreValve. Major exclusion criteria were: life expectancy <12 months due to comorbid conditions; pre-existing aortic bioprosthesis; myocardial infarction <14 days; unprotected >70% left main coronary artery disease; haemodynamic instability or cardiogenic shock; history of, or active, endocarditis; active peptic ulcer or upper gastro-intestinal bleeding within the prior 6 months; active infections requiring current antibiotic therapy or clinical suspicion of active infection; hypersensitivity or contraindication to aspirin, heparin, ticlopidine, or clopidogrel, or sensitivity to contrast media. All patients gave written informed consent.

Aim of the study

The purpose of this multicentre study is to evaluate the feasibility, safety, and efficacy of TAVI using the two available devices. The primary endpoint is mortality rate at 1 month, 6 months, 1, 2, and 3 years. The secondary endpoints are: (i) safety (major adverse cardiovascular and cerebrovascular events): myocardial infarction, cardiac or vascular surgery, and stroke, during the follow-up period; (ii) Efficacy with periodic assessment of aortic valve function by echocardiography: transvalvular mean pressure gradient, effective AVA, presence and severity of aortic valvular regurgitation, and/or mitral valve regurgitation. Further assessment includes: device success defined as successful delivery and deployment of the heart valve; NYHA heart failure functional class; quality of life and economic costs associated with cardiovascular resource utilization for the index hospitalization. In the present report, early and 30-day results are presented.

Device description

The design and the procedural characteristics of the two models have been described previously.\textsuperscript{11–13} Briefly, the Edwards SAPIEN valve is a bioprosthetic valve made of bovine pericardial tissue mounted into a balloon expandable stainless steel open-cell stent. The valve is available in two sizes (23 and 26 mm) and can be implanted using the transfemoral (TF) (Retroflex delivery catheter; 22/24 Fr introducers) or TA (Ascenda catheter; 26 Fr) approach depending on the peripheral access. The CoreValve consists of a trileaflet bioprosthetic porcine pericardial tissue valve, mounted into a self-expandable nitinol frame available in two sizes, 26 and 29 mm (18 Fr introducer), and is generally implanted using the TF arterial approach.

Procedure and adjunctive medication

Patients were assessed with transthoracic echocardiography (TTE) and if necessary transoesophageal echocardiography (TEE), selective coronary angiography, angiography of the aortic root and the aortoiliacofemoral system, and CT scan of the aortoiliacofemoral vessels and the entire aorta. Transfemoral and TA procedures were performed as previously described.\textsuperscript{11–13} There was no pre-specified recommendation for the choice of the TF or TA approach. Transarterial access was performed either percutaneously or after surgical cut-down, whereas TA access was obtained by anterior minithoracotomy. Implantation of the valve was preceded by balloon dilatation of the native aortic valve. Burst rapid pacing was used to reduce cardiac output during Edwards SAPIEN prosthesis deployment. The femoral access was closed either surgically or percutaneously (Prostar XL; Abbott, Inc., Chicago, IL, USA). All subjects received aspirin (at least 160 mg daily) and clopidogrel (300 mg loading dose, and then 75 mg daily) prior to procedure and for at least 1 month. Decision of general or local anaesthesia for TF implantation was left at the discretion of each team.

Data collection and quality control

Data were recorded using a standardized electronic case report form and sent to the central database (AXONAL, Nanterre, France) via Internet. Quality control was performed on all patients of randomly selected centres. Source document verification vs. data collected in the central database was performed on selected essential data. Missing and/or inconsistent data were completed on site.

Statistical analysis

The results are expressed as the mean ± SD, unless otherwise stated. Comparison between groups and univariable analysis of the variables associated with 30-day mortality was performed using Student’s t-test, ANOVA or non-parametric tests for continuous variables, and the χ\textsuperscript{2} test or Fisher’s exact test where applicable for categorical variables. Variables with a P-value of <0.20 in the univariable analysis were included in a multiple logistic model and selected backward with a
were at high risk for surgery as reflected by a mean logistic myocardial infarction (23.7%), and stroke (10%). All patients (41.3%), diabetes (27%), previous thoracotomy (25.4%), prior myocardial infarction (23.7%), and stroke (10%). All patients were at high risk for surgery as reflected by a mean logistic EuroSCORE of 25.6 ± 11.4% and a mean STS score of 18.9 ± 12.8%. All patients were highly symptomatic (NYHA functional class III or more in 74.5%). Baseline left ventricular ejection fraction was 50.8 ± 13.9%. Mean femoral artery diameter was smaller in the TA patients when compared with TF patients: 7.1 ± 2.6 (TA) vs. 8.6 ± 1.1 (TF Edwards) vs. 8.2 ± 1.5 (TF CoreValve), P < 0.001.

Results

The results are presented for the whole population and according to the approach and valve used.

Baseline characteristics

Transcatheter aortic valve implantation was attempted in a total of 244 patients. Mean age was 82.3 ± 7.3 years (range 47–99 years) and 43.4% were female. Severe AS was confirmed in all with a mean AVA of 0.68 ± 0.16 cm² and a mean gradient of 46.2 ± 15.6 mmHg (Table 1). There were no major differences in baseline characteristics between the four groups. The approach was TF in 160 patients (65.6%), TA in 71 (29.1%), subclavian (SC) in 12 (4.9%), and retroperitoneal (iliac conduit) in 1 (0.4%). Patients treated by the TA or SC approach had more previous peripheral arterial disease (PAD) surgery (P = 0.039) and more frequent aortic abdominal aneurysms (P = 0.019). Common comorbidities included the presence of associated coronary artery disease (41.3%), diabetes (27%), previous thoracotomy (25.4%), prior myocardial infarction (23.7%), and stroke (10%). All patients were at high risk for surgery as reflected by a mean logistic EuroSCORE of 25.6 ± 11.4% and a mean STS score of 18.9 ± 12.8%. All patients were highly symptomatic (NYHA functional class III or more in 74.5%). Baseline left ventricular ejection fraction was 50.8 ± 13.9%. Mean femoral artery diameter was smaller in the TA patients when compared with TF patients: 7.1 ± 2.6 (TA) vs. 8.6 ± 1.1 (TF Edwards) vs. 8.2 ± 1.5 (TF CoreValve), P < 0.001.

Procedural results

Data were available for 100% of patients. Device success (defined as stable device placement and adequate function in the first attempt as assessed by angiography ± echocardiography) was 98.3% (240 of 244) (Table 2). Reasons of failure were: technical failure (one patient), too low valve position (one patient) leading to additional valve in valve implantation, and device migration in the ascending aorta (two patients) leading to death in one. Acute procedural success (defined as device success with the absence of periprocedural major cardiovascular events including death, tamponade, coronary artery occlusion in the first 24 h after device implantation) was 92.6% (226 of 244). Edwards SAPIEN bioprosthesis was implanted in 166 (68%) patients using the TF (n = 95, 57%, including one retroperitoneal case) or the TA (n = 71, 43%) approach, whereas the CoreValve was implanted in 78 (32%) patients using the TF (n = 66, 84%) or the SC (n = 12, 5%) approach. The vast majority of the procedures was performed under general anaesthesia (83.1%) in the cath lab (66.8%) with TEE guidance (74.1%).

Early results

Aortic valve area increased from 0.68 ± 0.16 to 1.74 ± 0.47 cm² and mean gradient decreased from 46.2 ± 15.6 to 10.7 ± 5.0 mmHg. Paravalvular leak as assessed by TTE and/or TEE was absent or minimal in 90.5% of patients. It was grade II in 9.0%

Table 1 Patients’ baseline characteristics (n = 244)

<table>
<thead>
<tr>
<th>Approach and type of valve</th>
<th>Total (n = 244)</th>
<th>TF Edwards* (n = 95)</th>
<th>TF CoreValve (n = 66)</th>
<th>TA Edwards (n = 71)</th>
<th>SC CoreValve (n = 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>82.3 ± 7.3</td>
<td>83.2 ± 7.3</td>
<td>82.5 ± 5.9</td>
<td>82.1 ± 7.3</td>
<td>75.5 ± 11.0</td>
</tr>
<tr>
<td>Female [n [%]]</td>
<td>106 (43.4)</td>
<td>41 (44.1)</td>
<td>34 (51.5)</td>
<td>25 (35.7)</td>
<td>6 (50.0)</td>
</tr>
<tr>
<td>Hypertension [n [%]]</td>
<td>168 (68.8)</td>
<td>62 (65.3)</td>
<td>48 (72.7)</td>
<td>52 (73.2)</td>
<td>6 (50)</td>
</tr>
<tr>
<td>Diabetes [n [%]]</td>
<td>65 (27)</td>
<td>24 (25.3)</td>
<td>22 (33.3)</td>
<td>18 (25.3)</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Previous MI [n [%]]</td>
<td>55 (22.5)</td>
<td>28 (29.7)</td>
<td>14 (21.2)</td>
<td>10 (14)</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Previous bypass surgery [n [%]]</td>
<td>62 (25.4)</td>
<td>23 (24.2)</td>
<td>15 (22.7)</td>
<td>20 (28.2)</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>Previous PAD surgery [n [%]]</td>
<td>18 (7.3)</td>
<td>4 (4.2)</td>
<td>3 (4.5)</td>
<td>8 (11.3)</td>
<td>3 (25)</td>
</tr>
<tr>
<td>AAA [n [%]]</td>
<td>14 (5.7)</td>
<td>2 (2.1)</td>
<td>2 (3.0)</td>
<td>8 (11.3)</td>
<td>2 (16.7)</td>
</tr>
<tr>
<td>Previous stroke [n [%]]</td>
<td>25 (10.2)</td>
<td>8 (8.4)</td>
<td>8 (12.1)</td>
<td>6 (8.4)</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>CAD [n [%]]</td>
<td>101 (41.3)</td>
<td>34 (35.8)</td>
<td>28 (42.4)</td>
<td>33 (46.5)</td>
<td>6 (50)</td>
</tr>
<tr>
<td>NYHA III or more [n [%]]</td>
<td>182 (74.5)</td>
<td>70 (73.7)</td>
<td>53 (74.6)</td>
<td>53 (75.7)</td>
<td>6 (50)</td>
</tr>
<tr>
<td>Logistic EuroSCORE [%]</td>
<td>25.6 ± 11.4</td>
<td>25.6 ± 11.3</td>
<td>24.7 ± 11.2</td>
<td>26.8 ± 11.6</td>
<td>24.6 ± 14.5</td>
</tr>
<tr>
<td>STS score [%]</td>
<td>18.9 ± 12.8</td>
<td>17.4 ± 11.3</td>
<td>21.3 ± 14.6</td>
<td>18.4 ± 12.1</td>
<td>21.0 ± 17.2</td>
</tr>
<tr>
<td>Pacemaker [n [%]]</td>
<td>35 (14.3)</td>
<td>17 (17.9)</td>
<td>11 (16.7)</td>
<td>4 (5.6)</td>
<td>3 (25.0)</td>
</tr>
<tr>
<td>Aortic annulus diameter (mm)</td>
<td>21.0 ± 1.7</td>
<td>21.7 ± 1.8</td>
<td>22.4 ± 1.8</td>
<td>21.5 ± 1.5</td>
<td>22.6 ± 2.3</td>
</tr>
<tr>
<td>Mean aortic gradient (mmHg)</td>
<td>46 ± 16</td>
<td>45 ± 16</td>
<td>46 ± 15</td>
<td>48 ± 16</td>
<td>41 ± 8</td>
</tr>
<tr>
<td>Aortic valve area (cm²)</td>
<td>0.68 ± 0.16</td>
<td>0.66 ± 0.16</td>
<td>0.71 ± 0.16</td>
<td>0.68 ± 0.17</td>
<td>0.69 ± 0.17</td>
</tr>
<tr>
<td>Ejection fraction [%]</td>
<td>51 ± 14</td>
<td>47 ± 14</td>
<td>51 ± 15</td>
<td>54 ± 12</td>
<td>51 ± 12</td>
</tr>
</tbody>
</table>

PAD, peripheral artery disease; AAA, aortic abdominal aneurysm; CAD, coronary artery disease; PASP, pulmonary artery systolic pressure.

*Including one retroperitoneal implantation.
and grade IV in only one patient (0.5%). For the TF approach, percutaneous arterial closure was used in 26% of cases, more frequently after CoreValve implantation.

Complications and 1-month outcome

Data on mortality and complications were available for 100% of patients at 1 month. The complications are detailed in Table 3. One-month mortality rate was 12.7% (31 patients). In multivariate analysis, success rate (odds ratio 0.024; 95% CI: 0.002–0.278) and prior coronary artery bypass grafting (odds ratio, 0.156; 95% CI: 0.032–0.766) were the only two factors significantly associated with a better survival at 1 month. Of note, 81% of deaths occurred within the first week, from cardio-vascular in the majority of them (two out of three). Three patients had acute per-procedural coronary occlusion. Arterial iliofemoral vessel dissection or rupture occurred in eight patients requiring balloon angioplasty in two, stenting in two, and vascular surgery in one. Rupture of the thoracic descending aorta in one led to immediate death. Two patients developed arterial thrombosis, of the femoral artery in one TA case (treated by thrombectomy) and of the SC artery in one SC case. Other severe vascular complications included retroperitoneal haematoma in two, distal thrombo-embolization in one (leading to

### Table 2 Procedural characteristics (n = 244)

<table>
<thead>
<tr>
<th>Approach and type of valve</th>
<th>Total (n = 244)</th>
<th>TF Edwards* (n = 95)</th>
<th>TF CoreValve (n = 66)</th>
<th>TA Edwards (n = 71)</th>
<th>SC CoreValve (n = 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site</td>
<td>Operative room [n (%)]</td>
<td>53 (21.7)</td>
<td>10 (10.5)</td>
<td>12 (18.2)</td>
<td>26 (36.6)</td>
</tr>
<tr>
<td></td>
<td>Cath lab [n (%)]</td>
<td>163 (66.8)</td>
<td>66 (69.5)</td>
<td>52 (78.8)</td>
<td>39 (54.9)</td>
</tr>
<tr>
<td></td>
<td>Hybrid room</td>
<td>28 (11.4)</td>
<td>19 (20.1)</td>
<td>2 (3.0)</td>
<td>6 (8.4)</td>
</tr>
<tr>
<td></td>
<td>General anaesthesia [n (%)]</td>
<td>203 (83.1)</td>
<td>70 (73.7)</td>
<td>54 (82)</td>
<td>70 (100)</td>
</tr>
<tr>
<td></td>
<td>Per-procedure TEE [n (%)]</td>
<td>181 (74.1)</td>
<td>63 (66.3)</td>
<td>45 (68.2)</td>
<td>69 (98.6)</td>
</tr>
<tr>
<td></td>
<td>Pharmacologic haemodynamic support [n (%)]</td>
<td>62 (25.4)</td>
<td>18 (18.9)</td>
<td>17 (25.8)</td>
<td>26 (37)</td>
</tr>
<tr>
<td></td>
<td>Contrast volume (mL)</td>
<td>140 ± 67</td>
<td>141 ± 56</td>
<td>154 ± 72</td>
<td>123 ± 70</td>
</tr>
<tr>
<td></td>
<td>X-ray time (min)</td>
<td>16.4 ± 15.8</td>
<td>16.4 ± 12.6</td>
<td>24.1 ± 19.6</td>
<td>9.9 ± 10.4</td>
</tr>
</tbody>
</table>

TEE, transoesophageal echocardiography.
*Including one retroperitoneal implantation.

### Table 3 Early complications (one patient could have more than one event)

<table>
<thead>
<tr>
<th>Approach and type of valve</th>
<th>Total (n = 244)</th>
<th>TF Edwards* (n = 95)</th>
<th>TF CoreValve (n = 66)</th>
<th>TA Edwards (n = 71)</th>
<th>SC CoreValve (n = 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thirty-day mortality</td>
<td>31 (12.7)</td>
<td>8 (8.4)</td>
<td>10 (15.1)</td>
<td>12 (16.9)</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>Tamponade</td>
<td>5 (2.0)</td>
<td>2 (2.1)</td>
<td>2 (3.0)</td>
<td>0</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>Stroke</td>
<td>9 (3.6)</td>
<td>4 (4.2)</td>
<td>3 (4.5)</td>
<td>2 (2.8)</td>
<td>0</td>
</tr>
<tr>
<td>Coronary occlusion</td>
<td>3 (1.2)</td>
<td>2 (2.0)</td>
<td>1 (1.5)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>New pacemaker</td>
<td>29 (11.8)</td>
<td>5 (5.3)</td>
<td>17 (25.7)</td>
<td>4 (5.6)</td>
<td>3 (25.0)</td>
</tr>
<tr>
<td>Vascular complications: Total</td>
<td>16 (7.3)</td>
<td>6 (6.3)</td>
<td>5 (7.5)</td>
<td>4 (5.6)</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>Aortic rupture</td>
<td>2 (0.8)</td>
<td>2 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Iliofemoral dissection</td>
<td>8 (3.2)</td>
<td>4 (4.2)</td>
<td>3 (4.5)</td>
<td>1 (1.4)</td>
<td>0</td>
</tr>
<tr>
<td>Thrombosis/distal embolization</td>
<td>3 (1.2)</td>
<td>0</td>
<td>0</td>
<td>2 (2.8)</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>Retroperitoneal haematoma</td>
<td>2 (0.8)</td>
<td>0</td>
<td>2 (3.0)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>LV apex bleeding (re-surgery)</td>
<td>1 (0.4)</td>
<td>NA</td>
<td>NA</td>
<td>1 (1.4)</td>
<td>NA</td>
</tr>
<tr>
<td>Renal failure requiring dialysis</td>
<td>4 (1.6)</td>
<td>1 (1.0)</td>
<td>1 (1.5)</td>
<td>2 (2.8)</td>
<td>0</td>
</tr>
<tr>
<td>Infection</td>
<td>7 (2.8)</td>
<td>1 (1.0)</td>
<td>1 (1.5)</td>
<td>5 (7.0)</td>
<td>0</td>
</tr>
<tr>
<td>Transfusion (&gt;1 blood units)</td>
<td>52 (21.3)</td>
<td>8 (8.4)</td>
<td>9 (13.6)</td>
<td>25 (27.4)</td>
<td>10 (83.3)</td>
</tr>
</tbody>
</table>

Values are given in n (%).
NA, not applicable.
*Including one retroperitoneal implantation.
*Pulmonary in five; erisypela in one, unknown in one.
foot amputation), and surgical reintervention in one for persistent apical bleeding. Five patients (2%) experienced tamponade. Aortic annulus rupture in one and left ventricular perforation in one were documented, leading to death in both cases. Stroke occurred in nine patients (3.6%), haemorrhagic in one. A pacemaker was implanted in 29 patients (11.8%), more frequently after CoreValve implantation ($P < 0.001$). First-degree atioventricular block was present in 2 of the 29 patients (6.9%) needing a pacemaker vs. 20 of the 215 patients (9.3%) who did not need a pacemaker ($P = 0.67$). Left bundle branch block was present in 4 of the 29 patients (13.8%) needing a pacemaker vs. 23 of the 215 patients (10.7%) who did not need a pacemaker ($P = 0.62$). Marked improvement of symptoms was observed in the vast majority of patients, 87.7% of them being in NYHA functional class II or less at 1 month ($P < 0.001$ vs. baseline). At 1 month, mean aortic gradient remained low (10.05 ± 4.16 mmHg) and unchanged compared with post-implantation measurement, ejection fraction increased from 50.8 ± 13.9% to 55.1 ± 12.9%, $P < 0.0001$, and pulmonary systolic pressure decreased from 47 ± 16 to 41.1 ± 13.6 mmHg, $P < 0.0004$. Serum creatinine level which increased from 124.4 ± 72.1 to 150 ± 105 $\mu$mol/l after implantation was 123.1 ± 71.1 $\mu$mol/l at 1 month. Haemoglobin which dropped from 12.1 ± 1.8 to 9.9 ± 4.4 g/l after implantation increased to 11.3 ± 1.6 g/l at 1 month.

Discussion

This study reports the early results of the French multicentre experience using the two commercially available transcatheter heart valves. To our knowledge, our prospective registry is the first to report the combined experience on the two available valves using either the TF, TA, or SC approach.

Feasibility and efficacy

The device success rate is very high and consistent with previous single-centre reports. It appears that with careful screening, current techniques, proper training, and proctoring, short-term procedural success can be achieved in most patients. Efficacy has been already clearly demonstrated on early and mid-term outcomes with both devices.\textsuperscript{14–16} Final post-implantation mean transvalvular gradient is consistently low, 10 mmHg in average. Our immediate and 1-month results on valve function are as expected consistent with previous published data. The excellent haemodynamic results observed in our series resulted in improved left ventricular function as already reported\textsuperscript{17} with remarkable clinical improvement. The rate of procedures performed under local anaesthesia without TEE guidance was quite low. It is likely that this rate will increase with growing experience and technical improvements in the devices such as reduction in introducer size.

Safety and early complications

In this elderly population of very sick patients, a 30-day mortality of 12.7% compares favourably with standard estimates of mortality. High-risk population is well reflected by the elevated logistic EuroSCORE and STS score observed in our series. One-third of deaths occurred within 24 h and 80% within the first week. Our results compare favourably with the recent published series evaluating separately the two valves. Webb et al.\textsuperscript{14} reported a 30-day mortality of 14.3% in the initial half of their monocentric series of 168 patients treated with TF or TA Edwards SAPIEN valve. In the Canadian registry (6 centres; 339 patients) using the Edwards valves, 30-day mortality was 10.4%.\textsuperscript{18} In the single-centre study evaluating the CoreValve, Grube et al.\textsuperscript{16} reported a 30-day mortality of 10.8% in 102 patients treated with the last generation 18 Fr device. In our series, the mortality rate at 30-day was 8.4% (TF Edwards SAPIEN) vs. 15.1% (TF CoreValve) vs. 16.9% (TA) vs. 8.3% (SC). Severe complications are mostly represented by vascular complications due to large introducer sizes ($\geq$18 Fr). However, our vascular complication rate of 7.2% compares favourably with the results reported by Webb et al.\textsuperscript{14} and Himbert et al.\textsuperscript{15} who used the TF approach in similar proportion (two-third). In Webb et al.’s series, major vascular injury rate was 8% using the TF approach and 3.6% using the TA approach and the rate was shown to decrease with experience. Similarly, Himbert et al.\textsuperscript{15} reported a rate of 11% in their series including both TF and TA approaches. Worsening of renal function as assessed by creatinine elevation was noted in our series leading to acute renal failure requiring temporary dialysis in 1.6% of patients. In the vast majority of case, serum creatinine level returned to baseline value at 1 month.

Procedure type

The TF approach was used in 66% of procedures. The TA approach (Edwards SAPIEN) or SC approach (CoreValve) was most often selected as an alternative to the TF approach in case of inadequate peripheral vascular access. In the few centres implanting the two valves, because of the smaller introducer size, TF CoreValve could be preferred to TA Edwards SAPIEN when the femoral artery diameter was between 6 and 7 mm. As similarly reported,\textsuperscript{10,14,15} patients treated by TA had more comorbidities than patients selected for TF, in particular more peripheral vascular disease which is known to increase the mortality risk. In our series, the EuroSCORE did not exceed 27% which may reflect the better 1-month survival in the TA group when compared with PARTNER EU trial (35%), presented by Schaechinger at EuroPCR meeting (Barcelona 2009) or Webb’s cohort (33.8%).\textsuperscript{14} The results driven from that prior studies with higher risk population and higher mortality rate may have led to more restrictive use of the TA approach in France in less-risk patients.

Valve type

Clearly, the CoreValve has today the advantage of a smaller introducer size (18 Fr) for TF access in comparison with the 22/24 French size necessary for Edwards SAPIEN valve implantation. This size allows for a larger use of TF implantation in smaller arteries (6.0 mm). As the TA approach is an alternative to TF for the Edwards SAPIEN device, the SC approach with the CoreValve is an alternative in patients with peripheral vascular disease. However, the current data remain limited\textsuperscript{16,19} and further evaluation is obviously needed. The only statistical difference between the two models of prosthesis is the higher rate of pacemaker implantation after CoreValve in comparison with Edwards SAPIEN. This has been consistently reported\textsuperscript{16,20–22} and well documented by Piazza et al.\textsuperscript{23} and may result from a deeper
intraventricular insertion of the self-expanding CoreValve beyond the non-coronary cusp.

Large-scale long-term follow-up is still unavailable and will require further assessment. Webb et al.14 demonstrated no valve dysfunction in 168 patients followed for up to 3 years. However, long-term durability of these prostheses must be proved prior to considering the expansion of the current indications to patients at a lower risk for AVR. Our registry is aimed to achieve a 3-year follow-up in all patients.

**Study limitations**

The study has the limitation of a registry, with no adjudication of patient inclusion, data collection, and analysis. The uniform assessment of selection strategy is questionable. More particularly, the rate of similarly ill patients not selected for TAVI but operated on or treated medically over the study period is not available. Finally, it is a non-randomized study which does not allow one to draw any formal conclusions on the risk/benefit of each prosthesis and approaches used.

**Conclusion**

Transcatheter aortic valve implantation allows patients who are at very high-surgical risk or with contraindications to surgical AVR to benefit from an effective treatment of severe AS. The availability of both transarterial and TA approaches and two devices increases the number of patients who can be treated. Our early results are satisfactory in terms of feasibility as well as short-term haemodynamic and functional improvement and safety given the high-risk patients’ profile. Longer follow-up is mandatory to assess long-term durability and subsequently better define the indications and the respective places of devices and approaches.

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**Conflict of interest:** Helene Eltchaninoff, proctor (Edwards Lifesciences).

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