PREVAIL TRANSAPICAL: multicentre trial of transcatheter aortic valve implantation using the newly designed bioprosthesis (SAPIEN-XT) and delivery system (ASCENDRA-II)†

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Abstract

OBJECTIVES: Transapical (TA) aortic valve implantation (AVI) has evolved as an alternative procedure for high-risk patients. We evaluated the second-generation SAPIEN XT™ prosthesis in a prospective multicentre clinical trial.

METHODS: A total of 150 patients (age: 81.6 ± 5.8 years; 40.7% female) were included. Prosthetic valves (diameter: 23 mm (n = 36), 26 mm (n = 57) and 29 mm (n = 57)) were implanted. The ASCENDRA-II™ modified delivery system was used in the smaller sizes. Mean logistic EuroSCORE was 24.3 ± 7.0%, and mean STS score 7.5 ± 4.4%. All patients gave written informed consent.

RESULTS: Off-pump AVI was performed using femoral arterial and venous access wires as a safety net. All but two patients received TA-AVI, as planned. The 29-mm valve showed similar function as the values of two other diameters did. Three patients (2%) required temporary cardiopulmonary bypass support. Postoperative complications included renal failure requiring long-term dialysis in four, bleeding requiring rethoracotomy in four, respiratory complication requiring reintubation in eight and sepsis in four patients, respectively. Thirty-day mortality was 13 (8.7%) for the total cohort and 2/57 (3.5%) for patients receiving the 29-mm valve, respectively. Echocardiography at discharge showed none or trivial aortic incompetence (AI) in 71% and mild-AI in 22% of the patients. Post-implantation AI was predominantly paravalvular and ≥2+ in 7% of patients. One patient required reoperation for AI within 30 days.

CONCLUSIONS: The PREVAIL TA multicentre trial demonstrates good functionality and good outcomes for TA-AVI, using the SAPIEN XT™ prosthesis and its second-generation ASCENDRA-II™ delivery system, as well successful introduction of the 29-mm SAPIEN XT™ valve for the benefit of high-risk elderly patients.

Keywords: Aortic stenosis • Aortic valve implantation • Transcatheter • Transapical

INTRODUCTION

Transcatheter (T) aortic valve implantation (AVI) has been introduced into clinical practice to allow for minimally invasive therapy of elderly and high-risk patients with aortic stenosis. The retrograde transfemoral (TF) and the antegrade transapical (TA) access have been studied at multiple sites, using the first-generation CoreValve™ (Medtronic, Inc., St Paul, MN, USA) or SAPIEN™ (Edwards Lifesciences Inc., Irvine, CA, USA) transcatheter xenografts [1–3]. Transcatheter aortic valve implantation (TA-AVI) has been performed using the SAPIEN™ prosthesis and the ASCENDRA™ delivery system (Edwards Lifesciences, Inc., Irvine, CA, USA) [4, 5]. Meanwhile, refinements of the systems led to the SAPIEN XT™ transcatheter heart valve and the Ascendra-II™ delivery system for the TA approach. The indication for the use of T-AVI has been defined by an international position statement of the European Society for Cardiology and the European Association for Cardiothoracic Surgery, as such patients with an increased risk profile are deemed appropriate candidates for T-AVI [6]. Under these circumstances, the aim of the present study was to assess the functionality of the new
and dilated fashion) (Figure 1: Sapien XT™ transcatheter heart valve (upper image) and Ascendra-II™ transapical delivery system (lower images, valve on balloon catheter in a crimped and dilated fashion) (both Edwards Lifesciences Inc., Irvine, CA, USA).

ASCENDRA-II™ delivery system together with the implantation of the modified SAPIEN XT™ transcatheter heart valve as well as the evaluation of the new 29-mm prosthesis by means of a multicentre European study.

METHODS

The study was performed in Europe after CE-approval had been granted for the first-generation TA-AVI system, the SAPIEN™ valve and the Ascendra™ delivery system (both Edwards Lifesciences, Inc., Irvine, CA, USA), which occurred back in 2008. The SAPIEN XT™ transcatheter heart valve and the Ascendra-II™ TA delivery system (both Edwards Lifesciences, Inc., Irvine, CA, USA) that were used in this trial are shown in Fig. 1. Improvements in comparison with the first-generation SAPIEN valve and Ascendra delivery system are as follows: Semi-closed leaflet position of the valve to allow for safer closure during diastole, pusher integration into the handle of the Ascendra-II system to allow for easier pusher retrieval during valve implantation, easier deairing mechanism of the system and some diameter reduction to 24 F sheaths for patients who are receiving 23- and 26-mm valves, respectively.

In this study, early implantations were performed using the 23 and 26-mm SAPIEN XT™ prostheses, as the 29-mm SAPIEN XT™ valve was introduced slightly later during this trial (December 2009).

All participating centres had previous TA-AVI clinical experience. The study protocol was approved by local ethical committees and by governmental authorities. All patients gave written informed consent after discussing all aspects in detail. Data were monitored by experienced personnel, and the statistical analysis performed by a statistician (all employees of Edwards Lifesciences, Inc., Irvine, CA, USA). Data were adjudicated by the independent clinical events committee. Echocardiography (ECHO) and electrocardiogram data were assessed by independent core laboratories.

A total of 150 high-risk elderly patients with symptomatic aortic stenosis were prospectively included from 2 September 2009 until 17 August 2010. Twelve centres in Europe participated in this study (number of patients included in brackets): Essen (33), Leipzig (30), Karlsruhe (16), Bad Bevensen (15), Hamburg (15), London (15), Cologne (8), Bad Nauheim (8), Paris (5), Vienna (4) and Munich DHZ (1). Patients with a high-operative risk, as indicated by a logistic EuroSCORE between 15 and 40%, were included in this study; patients on chronic dialysis were excluded.

TA-AVI was performed using a standard technique, as described previously [7]. In brief, patients were treated under general anaesthesia and were positioned supine on the OR table. A femoral arterial sheath (6 F) and a femoral venous guidewire were placed, and a pigtail catheter was positioned into the ascending aorta. A left lateral minithoracotomy centred at the mid-clavicular line was then made in the fifth intercostals space. Following longitudinal pericardiotomy, retention stitches yielded an improved exposure of the left ventricular apex. An epicardial pacing wire and two Teflon reinforced apical purse-string sutures (Prolene 2–0) were placed. The C-arm was then positioned. The apex was punctured and a soft tip wire introduced antegrade into the ascending aorta followed by a 14 F sheath. A superstiff guidewire was then positioned to the descending aorta by means of a right Judkins catheter. The 20-mm valvuloplasty balloon was inserted, and balloon valvuloplasty performed during a brief episode of rapid ventricular pacing. Then the 24 F Ascendra-II™ sheath (26 F sheath for the 29-mm prosthesis) was inserted bluntly. The crimped SAPIEN XT™ valve was attached by means of the loader and the system deaired. The valve was then positioned intra-annularly, the pusher retrieved and valve implantation performed after control angiography and under rapid ventricular pacing. The system was retrieved and after functional control, the apex closed with the purse-string sutures, followed by chest closure.

Valve size selection was performed by the local Heart Teams; usually it was based on transoesophageal ECHO measurements of the aortic annulus diameter while taking computerized morphometric measurements into account at some of the centres as well. In general, a 23-mm SAPIEN XT™ valve (frame height 14.3 mm) was used when the aortic annulus diameter was 18–22 mm, a 26 mm SAPIEN XT™ valve (frame height 17.2 mm) for an aortic annulus diameter of 21–25 mm and a 29 mm SAPIEN XT™ valve (frame height 19.1 mm) for an aortic annulus diameter of 24–27 mm, respectively.

Data evaluation was performed using a standardized database. Statistical evaluation was performed using logistic regression analyses (multivariable analysis for mortality at 30 days), Fisher’s exact test or Student’s t-test (univariable analysis comparing 30-day mortality and baseline risk factors) and Kaplan–Meier analysis (point in time analysis for time to death at 30 days, and 6 months, as well as time to adverse event).
Baseline characteristics of the 150 patients are given in Table 1, which indicates the preoperative status. Overall, elderly patients (mean age 81.6 ± 5.8 years) with a high-risk profile (mean logistic EuroSCORE 24.3 ± 7.0% and mean STS Score 7.5 ± 4.4%) were enrolled. The majority of patients (59%) were males, which may explain why 57 patients presented with a large aortic annulus and received a 29-mm SAPIEN XT™ prosthesis in this study. Incidence of comorbidities such as coronary artery disease, carotid artery disease or preoperative permanent pacemaker implantation was high, as shown in Table 1.

Operative data and outcomes are depicted in Table 2. A total of 148/150 patients received TA-AVI as scheduled. In one patient, conversion to conventional surgery was required due to a ventricular access complication (listed in Table 2). The second patient had a 27-mm aortic annulus (measured preoperatively) and was planned to receive a 29-mm SAPIEN XT™ prosthesis. However, intraoperative annular dimensions were found to be 25 mm and therefore the patient received a 26-mm SAPIEN XT™ prosthesis by means of TF-AVI.

Results at up to 30 days post-implant are given in Table 3. The relatively high degree of patients having ‘transitional psychosis’ is due to some definitions at German sites. This includes elderly patients having some temporary type of confusion in the early postoperative course, all of them with full recovery.

Thirty-day mortality was 13 (8.7%) for the total cohort and 3.5% (2/57) for patients receiving the 29-mm valve, respectively. The survival curves for the total cohort as well as for the different valve size subgroups are given in Fig. 2.

Causes of mortality at 30 days are listed in Table 4. Within this study, risk factors for an adverse clinical outcome at 30 days

Table 1: Baseline characteristics in 150 patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD or n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>81.6 ± 5.8</td>
</tr>
<tr>
<td>Logistic EuroSCORE (%)</td>
<td>24.3 ± 7.0</td>
</tr>
<tr>
<td>STS risk score (%)</td>
<td>7.5 ± 4.4</td>
</tr>
<tr>
<td>Female</td>
<td>61 (40.7)</td>
</tr>
<tr>
<td>NYHA III–IV</td>
<td>123 (82.0)</td>
</tr>
<tr>
<td>NYHA III–IV</td>
<td>133 (82)</td>
</tr>
<tr>
<td>CAD &gt;50%</td>
<td>58 (38.7)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>131 (87.3)</td>
</tr>
<tr>
<td>Diabetes, insulin-treated</td>
<td>17 (11.3)</td>
</tr>
<tr>
<td>Arrhythmia/conduction abnormality</td>
<td>55 (36.7)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>93 (62.0)</td>
</tr>
<tr>
<td>Ejection fraction (%)</td>
<td>56.9 ± 11.6</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>25 (16.7)</td>
</tr>
<tr>
<td>Mitral regurgitation ≥ grade 2</td>
<td>92 (61.3)</td>
</tr>
<tr>
<td>Tricuspid regurgitation ≥ grade 2</td>
<td>62 (41.3)</td>
</tr>
<tr>
<td>Previous stroke/TIA</td>
<td>34 (22.7)</td>
</tr>
<tr>
<td>Previous syncope</td>
<td>20 (13.3)</td>
</tr>
<tr>
<td>Carotid stenosis &gt;50%</td>
<td>29 (19.3)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>49 (32.7)</td>
</tr>
<tr>
<td>Porcelain aorta</td>
<td>8 (5.3)</td>
</tr>
<tr>
<td>COPD</td>
<td>41 (27.3)</td>
</tr>
<tr>
<td>FEV1 &lt;1.0</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>47 (31.3)</td>
</tr>
<tr>
<td>Creatinine</td>
<td>1.3 ± 0.4</td>
</tr>
<tr>
<td>PTCA</td>
<td>41 (27.3)</td>
</tr>
<tr>
<td>CAGB</td>
<td>43 (28.7)</td>
</tr>
<tr>
<td>Carotid endarterectomy/stent</td>
<td>15 (10.0)</td>
</tr>
<tr>
<td>Vascular stent/PTA</td>
<td>10 (6.7)</td>
</tr>
<tr>
<td>Permanent pacemaker</td>
<td>20 (13.3)</td>
</tr>
</tbody>
</table>

Table 2: Operative data

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valve size (mm)</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>36 (24)</td>
</tr>
<tr>
<td>26</td>
<td>57 (38)</td>
</tr>
<tr>
<td>29</td>
<td>57 (38)</td>
</tr>
<tr>
<td>Procedure duration (min)</td>
<td>96.5 ± 33.4</td>
</tr>
<tr>
<td>Fluoroscopy (min)</td>
<td>6.9 ± 4.0</td>
</tr>
<tr>
<td>Contrast dye (ml)</td>
<td>129.5 ± 66.6</td>
</tr>
<tr>
<td>Procedure completed as planned</td>
<td>148/150 (98.7)</td>
</tr>
<tr>
<td>Correct implantation</td>
<td>145/148 (98.0)</td>
</tr>
<tr>
<td>Too high</td>
<td>1</td>
</tr>
<tr>
<td>Too low</td>
<td>2</td>
</tr>
<tr>
<td>Valve in valve</td>
<td>2/148 (1.4)</td>
</tr>
<tr>
<td>Too low n = 1</td>
<td></td>
</tr>
<tr>
<td>Ventricular septum defect n = 1</td>
<td></td>
</tr>
<tr>
<td>Coronary impingement/occlusion</td>
<td>None</td>
</tr>
<tr>
<td>Leaflet dysfunction</td>
<td>None</td>
</tr>
<tr>
<td>Conversion to open surgery (same day)</td>
<td></td>
</tr>
<tr>
<td>Annular dissection</td>
<td>1/150 (0.7)</td>
</tr>
<tr>
<td>Ventricular access complication</td>
<td>1/150 (0.7)</td>
</tr>
<tr>
<td>Use of left ventricular support</td>
<td></td>
</tr>
<tr>
<td>CPB (cardiopulmonary bypass)</td>
<td>1/150 (0.7)</td>
</tr>
<tr>
<td>CPB and IABP (intra-aortic balloon pump)</td>
<td>1/150 (0.7)</td>
</tr>
<tr>
<td>ECMO</td>
<td></td>
</tr>
<tr>
<td>IABP</td>
<td>1/150 (0.7)</td>
</tr>
<tr>
<td>CBP and ECMO</td>
<td>1/150 (0.7)</td>
</tr>
<tr>
<td>Endocarditis at 30 days</td>
<td>None</td>
</tr>
<tr>
<td>New onset pacemaker implant (80% due to AV-block)</td>
<td>17/150 (11.3)</td>
</tr>
</tbody>
</table>

Table 3: Clinical outcomes at 30 days

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pericardial effusion treated medically</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Pleural effusion requiring therapy</td>
<td>39 (26.0)</td>
</tr>
<tr>
<td>Medical treatment of pleural effusion</td>
<td>57 (38)</td>
</tr>
<tr>
<td>Pleural effusion left-sided</td>
<td>16 (11)</td>
</tr>
<tr>
<td>Pleural effusion right-sided</td>
<td>4 (3.0)</td>
</tr>
<tr>
<td>Pleural effusion both sides</td>
<td>19 (13)</td>
</tr>
<tr>
<td>Renal failure</td>
<td></td>
</tr>
<tr>
<td>Long-term dialysis*</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Temporary dialysis</td>
<td>13 (7.3)</td>
</tr>
<tr>
<td>Respiratory failure req. respiratory assistance</td>
<td>13 (8.7)</td>
</tr>
<tr>
<td>Stroke–embolic/ischaemic</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Transitional psychosis</td>
<td>30 (20.0)</td>
</tr>
</tbody>
</table>

*Defined as dialysis ≥30 days or patient died before 30 days.
were analysed. Cardiac rhythm paced, concomitant carotid artery stenosis, previous vascular stent/PTA, relevant tricuspid valve regurgitation and significant stenosis of the right coronary artery were identified as having statistical significance upon outcome by univariable analysis (Table 5), using Student’s t-test for continuous variables and Fisher’s exact test for categorical variables. For the multivariable logistic regression analysis, previous vascular stent implantation/PTA, tricuspid regurgitation ≥2 and pulmonary disease with an FEV1 <1.0 were identified as independent predictors for an increased 30-day mortality (Table 5).

**DISCUSSION**

TA-AVI has evolved as a routine procedure over the past 5 years. It has been applied to elderly high-risk patients with symptomatic aortic stenosis. As such, TA-AVI is an alternative to TF-AVI. Many centres apply a ‘TF-first’ strategy, as it has been used in the recently published US PARTNER trial [8, 9]; this is equivalent to screening high-risk patients for potential TF implantation and using the TA approach only whenever comorbidities are severe, rendering the TF approach unfeasible. In the medical literature, there is no proof on the concept of ‘TF-first’ strategy. As such, there is one publication proving the equivalence of TF- and TA-AVI in a non-randomized trial design with similar survival at 1 and 2 years [10]. When evaluating the results of this multicentre non-randomized Canadian trial, it has to be kept in mind that patients in the TA group had a higher risk profile according to the STS score (10.5 versus 9%) when entering the study. Within the current PREVAIL TA study, a balanced approach (directing equivalent numbers of potential patients towards TF-AVI versus TA-AVI) may have been chosen at some centres, whereas others follow a TF-first strategy.

PREVAIL TA is a multicentre study to analyse the technical performance and the clinical results of the SAPIEN XT™ transcatheter heart valve, together with the ASCENDRA-II™ delivery system for the 23-mm and 26-mm valves (ASCENDRA-I™ (26 F) for the 29-mm valve) for TA-AVI in high-risk patients. The results from this study on 150 patients prove the excellent function as well as the good outcomes of TA-AVI when using this second-

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**Figure 2:** Survival after TA-AVI using the Sapien XT™ transcatheter heart valve: results for the total cohort (n = 150) and for the different valve size subgroups.

**Table 4: Causes of mortality at 30 days**

<table>
<thead>
<tr>
<th>Cause</th>
<th>30 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low cardiac output/heart failure</td>
<td>5</td>
</tr>
<tr>
<td>Multi-organ failure/abdominal</td>
<td>3</td>
</tr>
<tr>
<td>Annular dissection</td>
<td>1</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
</tr>
<tr>
<td>Respiratory</td>
<td>1</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>1</td>
</tr>
<tr>
<td>Unknown/sudden death</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>13 (8.7%)</td>
</tr>
</tbody>
</table>

**Table 5: Predictors for 30-day mortality by univariable and multivariable analysis**

<table>
<thead>
<tr>
<th>Predictor</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Univariable analysis</td>
<td></td>
</tr>
<tr>
<td>Cardiac rhythm paced</td>
<td>0.03</td>
</tr>
<tr>
<td>Carotid artery stenosis &gt;50%</td>
<td>0.004</td>
</tr>
<tr>
<td>Previous vascular stent/PTA</td>
<td>0.0004</td>
</tr>
<tr>
<td>Tricuspid regurgitation ≥grade 2</td>
<td>0.008</td>
</tr>
<tr>
<td>Multivariable analysis</td>
<td></td>
</tr>
<tr>
<td>Previous vascular stent/PTA</td>
<td>0.0003</td>
</tr>
<tr>
<td>Tricuspid regurgitation ≥grade 2</td>
<td>0.02</td>
</tr>
<tr>
<td>Pulmonary disease FEV1 &lt;1.0</td>
<td>0.04</td>
</tr>
</tbody>
</table>

**Table 6: Echocardiographic results**

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Discharge</th>
<th>30 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>$V_{max}$ (m/s)</td>
<td>4.1 ± 0.8</td>
<td>2.0 ± 0.4</td>
<td>2.1 ± 0.4</td>
</tr>
<tr>
<td>$\text{EF} %$</td>
<td>56.9</td>
<td>56.4</td>
<td>59.2</td>
</tr>
<tr>
<td>$P_{min}/P_{mean}$ (mmHg)</td>
<td>69.4/41.8</td>
<td>17.3/9.0</td>
<td>18.4/9.6</td>
</tr>
<tr>
<td>AOA (cm²)</td>
<td>0.7 ± 0.2</td>
<td>1.7 ± 0.4</td>
<td>1.7 ± 0.4</td>
</tr>
<tr>
<td>Total aortic insufficiency (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>19.3</td>
<td>40.6</td>
<td>36.0</td>
</tr>
<tr>
<td>1+</td>
<td>28.0</td>
<td>29.7</td>
<td>30.7</td>
</tr>
<tr>
<td>2+</td>
<td>37.3</td>
<td>21.7</td>
<td>22.8</td>
</tr>
<tr>
<td>3+</td>
<td>13.3</td>
<td>7.2</td>
<td>4.4</td>
</tr>
<tr>
<td>4+</td>
<td>0.7</td>
<td>0</td>
<td>2.6</td>
</tr>
<tr>
<td>NAV</td>
<td>1.3</td>
<td>0.7</td>
<td>3.5</td>
</tr>
</tbody>
</table>

*AI 2+ or higher mostly paravalvular.*
generation TA transcatheter heart valve system. Most importantly, this is the first multicentre study on TA-AVI ever proving better than 90% survival at 30 days in a high risk and all-comers population with symptomatic aortic stenosis. This good outcome is most certainly due to technical improvement in the valve functionality, due to the advanced application system as well as due to the learnings and experiences of the teams of cardiac surgeons, interventional cardiologists and cardiac anaesthetists at the implanting sites. Thus, TA-AVI—using the SAPIEN XT™ prosthesis and the ASCENDRA-II™ application system—provides a high standard of care for the respective patients.

Within this trial, 98.7% of patients were treated as planned, which eludes into a high procedural standardization and safety with the TA-approach. The overall outcomes were excellent with a low rate of malposition and a high rate of perfect valve functioning, which is underlined by low incidence of conversion to surgery and valve-in-valve procedures. Leaflet dysfunction after implantation, which may be leading to severe aortic incompetence, a situation that had occurred in some patients when implanting the previous generation SAPIEN™ prosthesis, has not been observed with the SAPIEN XT™ prosthesis: The semi-closed position of the leaflets within the frame contributes to this improved functionality.

The overall outcomes are good, especially with regard to the high-risk profiles of the patients. However, based on data evaluation from the SOURCE registry [11], patients with a very high-risk profile were excluded from the trial: As such, patients with a logistic EuroSCORE between 15 and 40% were only eligible for the trial. This proved to be useful criteria to obtain suitable results. Longer-term outcomes will have to be studied. Currently planned studies even aim at including patients with lower risk profiles. In the future, however, very high-risk patients will have to receive T-AVI as well. Especially, patients on chronic dialysis may benefit from minimally invasive transcatheter approaches. Causes of mortality in this trial (as shown in Table 4) were comparable with those published in previous multicentre studies on high-risk elderly patients with AS [11]. The majority of deaths during the early 30-day period were due to cardiac complications, with procedure-related causes in some. However, the 30-day mortality is reflecting the high-risk profile of these patients as well. Overall, the present results of a multicentre study are in accordance with those of currently published, other series on transapical aortic valve implantation [12–16].

There is some discussion on the safety and efficacy of the TA approach to deliver a transcatheter heart valve in the medical community. However, in this multicentre trial, there was only 1/150 patients (0.7%) having problems related to the ventricular apical access. Therefore, it clearly demonstrates effectiveness and safety of the TA approach. Ventricular function was clearly preserved, which was proved by follow-up ECHO assessment. The TA access is associated with stable and well-preserved left ventricular function. As such, TA-AVI is a standard procedure already [7], and the present study demonstrated this very clearly. The antegrade TA approach is safe and is associated with a low complication rate. Stroke occurred in four patients (2.7%) only with one reported dead (0.7%). Using TA-AVI approach, any potential peripheral arterial damage could be clearly avoided, which is of benefit for high-risk elderly patients.

Within this PREVAIL TA trial, the new 29-mm SAPIEN XT™ transcatheter heart valve has been successfully introduced into clinical practice. This valve allowed for the first time to treat patients with an aortic annulus between 24 and 27 mm by using the Edwards SAPIEN XT™ valve. Therefore, it is a major step towards a broader feasibility of transcatheter procedures, thus offering the full spectrum of valve sizes that will suit almost 95% of patients that are presenting. Based on the results of the subgroup of 57 patients within this PREVAIL TA trial receiving the 29-mm valve it received CE approval in February 2011. Because to the fact that the 29-mm valve is presently available only for a TA-AVI, this subgroup represents a ‘TA-first’ approach at some centres which only use the Edwards SAPIEN™ system. In parallel, there were centres that—at the same time of PREVAIL TA—also performed TF CoreValve™ (Medtronic, Inc., Minneapolis, MN, USA) implantations. The TA-first’ approach at some sites with the 29-mm SAPIEN XT™ valve may be one of the explanations for the superior outcomes in this subgroup. Another aspect that has to be considered is that some of the patients with a large annulus have been on a waiting list, as the 29-mm valve was available for implantations in the trial later than the smaller prostheses (December 2009). This may lead to improved results, as sicker emergent patients would have been treated otherwise in the meantime. Practically the 29-mm valve proved good functionality with routine clinical implantation. The larger balloon requires slightly longer inflation times; an improved set of syringes and larger diameter tubings will catch up for this in the future. Further follow-up will have to be performed even in larger patient numbers to study the longer-term benefit and function of the promising 29-mm SAPIEN XT™ valve.

In summary, this multicentre PREVAIL TA trial demonstrated excellent outcomes for an all-comers consecutive clinical study using the SAPIEN XT™ transcatheter heart valve in high-risk elderly patients. For the first time, higher than 90% survival at 30-days has been shown in a multicentre ‘all-comers’ trial, using the TA-AVI approach. By means of the European feasibility trial, the safety and efficacy of the Ascendra-II™ TA delivery system and the SAPIEN XT™ balloon expandable transcatheter heart valve were proved. In addition, the 29-mm SAPIEN XT™ prosthesis was successfully introduced into clinical practice. The TA approach has proved to be very safe with 1/150 (0.7%) ventricular access related clinical event only. The SAPIEN XT™ transcatheter heart valve, together with the TA Ascendra-II™ delivery system offers a standard and safe approach and new size options to treat most elderly high-risk patients with symptomatic aortic stenosis.

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REFERENCES


APPENDIX. CONFERENCE DISCUSSION

Dr. L. Hamilton (Newcastle Upon Tyne, UK): At every annual meeting of EACTS there is a ‘hot topic’, and there is no doubt that TAVI has been the hot topic for this meeting.

This PREVAIL study was to get the CE mark for the two smaller sizes of valves and also introduce the new 29, which I think is an exciting development. The CE mark has been achieved, and I think in your talk you have anticipated and answered any of the technical questions I might have asked.

You are actively involved in all these developments, and, indeed, you have a paper I think later in the morning on a new self-expandable device. So my question really would be philosophical more than specific and technical, and that is, where do you think we are going with this technology? For the wider group of surgeons out there, where is the technology going in terms of delivery systems and valves, where is the balance going to be in transapical versus transfemoral, and what sort of patients do you think we should be aiming for with these devices?

Dr Walther: To answer all this is probably beyond what I can do. I hope we will be moving towards better outcomes. I hope we will continue to have a very fair arrangement with the cardiologists. And as there is no evidence for one or the other approach, a 50/50 split after a team discussion I think is best, as it is at my new site. We were sitting together during the first week and we discussed it and it is fixed, at least at present.

Insurance companies may restrict the even broader use in younger risk patients at present because these procedures are cost-effective. We will have to look into randomized clinical trials. But my most important thought in these days at this meeting is that we really have to go back home and talk to our cardiologists to have a fairer split of patients.

Regarding new technology, Joerg is presenting one new approach, and I don’t want to talk too much about that, some anatomical rotation which can be accomplished with the SAPIEN XT. Matching commissure to commissure I think is one step forward to avoid any coronary problems. You saw there were no coronary problems in this series even though we didn’t rotate it anatomically in all centers. But this can be done with the SAPIEN XT, it can be done with other devices, and the next step definitely will be retrievability and seal for paravalvular leaks.

Dr. J. Pepper (London, UK): The question of durability is never going to get answered by examining patients in their middle 80s. So you are going to have to put these devices in patients who are 50, and I know that is happening in some centres, particularly in your country, and that raises a number of interesting points, but I would just like to have your reflection on that. You will never know about durability unless you put it in the younger patients whom many surgeons would be reluctant to give up to TAVI.

Dr Walther: Durability is a very broad field. There are experimental studies showing that the crimping may affect the device. We know that some of the new devices have thinner materials to make the transfemoral approach feasible and so on (some of the older devices have different materials. But maybe durability will be an issue that will be in favor of the transapical approach, because they are not limited to sheath diameter. We just need to broaden that knowledge to others that we have to have a good standard valve with good long-term durability.

On the other hand, if you had a clinical problem with bad durability, you just put in a second valve later on.

Dr G. Dohmen (Aachen, Germany): Just a short question, Thomas. What do you think about the rotation of the valve? Do you think we increase the risk of stroke when we rotate the new valve within the aortic valve stenosis?

Dr Walther: It is a good point. I don’t really believe that you could even do that in the left outflow tract. For the SAPIEN XT and for other devices, you have to present how it goes inside the sheath, and it definitely doesn’t lead to an increased stroke risk.