Transcatheter aortic valve implantation combined with elective coronary artery stenting: a simultaneous approach

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Abstract

OBJECTIVES: Many patients referred for transcatheter aortic valve implantation (TAVI) also require percutaneous coronary intervention (PCI). The aim of the study was to identify whether combined treatment of patients with aortic stenosis and coronary artery disease (CAD) with TAVI and PCI has comparable results to treatment of patients with no CAD or with CAD with non-significant lesions who receive only TAVI.

METHODS: Between April 2008 and August 2013, 730 consecutive patients underwent transapical TAVI at our institution. In our study population of 593 patients, 285 (48.1%) had no CAD and received TAVI only (Group I); 232 (39.1%) presented with CAD but no highly significant coronary artery lesion(s) and also received TAVI only (Group II), and 76 (12.8%) had CAD and highly significant coronary lesion(s) and underwent combined, single-staged TAVI and PCI (Group III). Three transapical TAVI patients who received PCI because of iatrogenic coronary artery obstruction during TAVI and 134 transapical TAVI patients with previous CABG were excluded from this study.

RESULTS: Group II showed a calculated mean SYNTAX score of 5.7 ± 7.4. However, Group III showed a statistically significantly higher mean SYNTAX score of 8.0 ± 5.7 than Group II (P < 0.001) before the combined procedure. Combined TAVI and PCI reduced the mean SYNTAX score significantly from 8.0 ± 5.7 to 3.0 ± 4.9 (P < 0.001) in those patients presenting with severe aortic stenosis and highly significant CAD (Group III). The thirty-day all-cause mortality rate was 5.3, 3.9 and 2.6% for Group I, II and III, respectively (P = 0.609). Patients with highly significant CAD undergoing TAVI and PCI had similar survival up to 3 years as patients without CAD undergoing TAVI only. Radiation time and amount of contrast agent were higher during combined treatment in Group III (P < 0.05). However, no difference in acute kidney injury post-procedurally was observed.

CONCLUSIONS: Single-stage combined treatment of severe aortic stenosis and highly relevant coronary lesions is a safe and feasible procedure. Early survival and survival up to 3 years are comparable to that observed in patients presenting without CAD who received TAVI only. PCI effectively reduces the complexity of coronary lesions. Although more contrast agent is applied during the combined treatment, the rate of acute kidney injury was not higher.

Keywords: Aortic valve stenosis • Transcatheter aortic valve implantation • Coronary artery disease • Percutaneous coronary intervention

INTRODUCTION

About two thirds of patients referred for transcatheter aortic valve implantation (TAVI) present with concomitant coronary artery disease (CAD) [1, 2]. Several studies have already attempted to answer the question of whether TAVI and percutaneous coronary intervention (PCI), performed either in a staged [3-5] or combined [1, 5] fashion, is a feasible and safe procedure. It is not clear how CAD can be optimally treated in patients undergoing TAVI. Almost from the introduction of TAVI at our institution, we adopted a strategy to treat it simultaneously [1]. To prevent postoperative myocardial infarction, only highly significant lesions were treated. The aim of the present study was to investigate our results in a larger group of patients and to establish whether the preliminary results were maintained during the following experience. In particular, we analysed the impact of the SYNTAX score on our results [6].
PATIENTS AND METHODS

Patients

From April 2008 through August 2013, transapical TAVI was performed in 730 consecutive patients with severe aortic valve stenosis at our institution.

Only patients undergoing transapical TAVI were considered in this study.

Three transapical TAVI patients requiring PCI because of iatrogenic coronary artery obstruction during TAVI were excluded from this study. Owing to difficulties with comparability and the calculation of an angiographic risk score, 134 transapical TAVI patients with previous CABG were also excluded.

In the resulting study population of 593 patients, 285 (48.1%) had no CAD and received TAVI only (Group I); 232 (39.1%) presented with CAD but no highly significant coronary artery lesion(s) as defined previously [1] and received TAVI only (Group II). Seventy-six (12.8%) patients presented with CAD and highly significant coronary artery lesion(s) and underwent combined single-staged TAVI and PCI (Group III).

Written informed consent was obtained from all patients or their representatives. Our institutional review board approved the study.

Methods

Our TAVI team consists of five cardiac surgeons, two cardiologists and two anesthesiologists with expertise in echocardiography. A perfusionist was present and a heart–lung machine was on standby in the hybrid operating room (OR). Transapical TAVI was performed through a left anterior minithoracotomy using balloon-expandable transcatheter stent-prosthetic xenograft valves of 23, 26 and 29 mm diameter with their delivering systems (Edwards SAPIEN THV, Edwards Lifesciences, Irvine, CA, USA). TAVI was performed as originally described, with some modifications [7, 8]. Clinical and anatomical selection criteria and device size selection have been described elsewhere [9]. The procedure was monitored by fluoroscopy, angiography and continuous intraoperative transoesophageal echocardiography (TOE).

TAVI was always done before PCI. PCI was routinely performed via transfemoral access and the femoral artery puncture site was subsequently closed using the Proglide vascular closure device (Abbott Vascular, Abbott Park, IL, USA). Standard catheters, guidewires and stents from several manufacturers were used as for a standard PCI at our institution. The contrast agent iopromide (ULTRAVIST®-370, Bayer AG, Leverkusen, Germany) was used for angiography.

All procedures were performed under general anaesthesia in the hybrid OR with a monoplane angiography system (Siemens Artis ZEE, Siemens AG, Munich, Germany).

Principles of percutaneous coronary intervention during a combined procedure at our institution

The most important issue in this study was the definition of what counts as highly significant CAD. Our approach originates from a tried and tested surgical strategy that has been developed over the past 20 years in the treatment of octogenarians with severe aortic valve stenosis and CAD [1, 10]. Coronary artery bypass grafting was only performed on relevant coronary artery lesions to keep the aortic cross-clamp time and operative time as short as possible.

Our criteria for simultaneous PCI and TAVI were [1] as follows:

(i) left main coronary artery stenosis if >50%;
(ii) coronary stenosis of 90% or more in the proximal or mid-left anterior descending (LAD) or
(iii) coronary stenosis of 90% or more in the proximal or mid-right coronary artery (if dominant artery) or
(iv) coronary stenosis of 90% or more in the proximal or mid-left circumflex artery (if dominant).

Our strategy of combined TAVI and PCI was not aimed at the treatment of CAD in general but was designed to prevent post-operative complications without increasing the risks of the procedure. The advantage of simultaneous TAVI and PCI is the prevention of post-procedural myocardial infarction. Both pathologies—aortic stenosis and CAD—are treated at the same time and hence there is no need for further interventions [1].

Coronary artery stenosis was regarded as highly significant only if the diseased artery vascularized a large myocardial territory and the stenosis put a large myocardial area at risk [1]. The coronary lesion should be technically amenable to straightforward PCI [1] and PCI should be able to be performed with a very high probability of success [1]. Exceptionally, a complex PCI combined with TAVI was accepted but only in patients for whom conventional surgery was considered not to be suitable [1].

Follow-up

The follow-up regarding death or survival was 100%. We obtained official information regarding death from the state administrative office. Information for all patients living in Germany was obtained from the German Register of Residents. All patients living in foreign countries were contacted via telephone, email or letter. The date of the last contact was noted.

Post-procedural anticoagulation and antiplatelet therapy

Our institutional anticoagulation protocol was applied peri- and postoperatively.

We do not preload patients with antiplatelet therapy before the combined procedure. However, some of our patients had been treated with aspirin or double antiplatelet therapy by their cardiologists before TAVI.

Intraoperatively, 100 IU/kg heparin was given and controlled by activated clotting time. If no bleeding tendency was seen at the end of TAVI procedure, we did not antagonize heparin with protamine routinely.

Postoperatively, heparin was continued intravenously in all patients until good mobilization was reached. The dose was maintained according to the activated partial thromboplastin time (50–60 s).

After combined TAVI and PCI, our antiplatelet strategy consists of 600 mg clopidogrel and 100 mg aspirin given once as a loading dose after the procedure at the ICU, 75 mg clopidogrel per day for 6 months for bare-metal stents and for 12 months for drug-eluting stents and, additionally, 100 mg aspirin per day permanently.

Antiplatelet therapy for patients undergoing only TAVI is 75 mg clopidogrel per day for 6 months and 100 mg aspirin per day permanently from the first postoperative day.
SYNTAX score calculation

For this study, all coronary angiography and SYNTAX scores were calculated and analysed retrospectively by one observer using SYNTAX Score Calculator version 2.11. A small number of SYNTAX scores in our database were calculated prospectively; these scores were recalculated and checked by one observer prospectively. The SYNTAX score for patients without CAD was set at zero. The score for patients with CAD but no highly significant coronary lesion(s) was calculated and analysed retrospectively.

Pre- and post-procedural SYNTAX scores for 76 patients having received combined TAVI and PCI were calculated and analysed retrospectively. For calculation of the post-procedural SYNTAX score, the lesion score for a successfully stented lesion site was set at zero. Multivariable regression methods were used to evaluate the differences between groups for the following variables: SYNTAX score, radiation time, contrast agent, 30-day mortality, acute kidney injury stage 1 and 3 and periprocedural and spontaneous myocardial infarction. Variables were adjusted for age, gender, logistic EuroSCORE and previous pacemaker/implantable cardioverter-defibrillator implantation. Under the results section, we present only data for group differences and not for the adjusting variables.

Analysis of survival was calculated according to Kaplan–Meier estimation and compared using the log-rank test. A P-value of <0.05 was considered statistically significant. SPSS for MAC version 20 was used for statistical analysis.

RESULTS

We performed elective simultaneous TAVI and PCI in 76 patients and only TAVI in 517 patients. The 76 patients represent 10.4% of all 730 patients who underwent transapical TAVI at our institution between April 2008 and August 2013.

Differences in baseline characteristics

The baseline demographic factors, risk factors, haemodynamic measurements and laboratory values of the three study groups are given in Table 1.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>No CAD (n = 285)</th>
<th>Non-significant CAD (n = 232)</th>
<th>Significant CAD (n = 76)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>80.0</td>
<td>81.0</td>
<td>83.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>IQR 75–84.0</td>
<td></td>
<td>IQR 76.0–85.0</td>
<td>IQR 78–86.0</td>
<td></td>
</tr>
<tr>
<td>Female gender</td>
<td>202 (70.9%)</td>
<td>203 (79.0%)</td>
<td>144 (62.1%)</td>
<td>0.066</td>
</tr>
<tr>
<td>Body mass index (kg/m2)</td>
<td>27.3 ± 5.4</td>
<td>27.3 ± 5.5</td>
<td>28.5</td>
<td>0.151</td>
</tr>
<tr>
<td>Logistic EuroSCORE (%)</td>
<td>24.3</td>
<td>IQR 15.6–38.9</td>
<td>IQR 18.4–45.0</td>
<td>0.007</td>
</tr>
<tr>
<td>STS mortality score (%)</td>
<td>9.1</td>
<td>10.1</td>
<td>11.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>IQR 5.1–14.6</td>
<td></td>
<td>IQR 6.1–18.6</td>
<td>IQR 7.4–18.5</td>
<td></td>
</tr>
<tr>
<td>pBNP (pg/ml)</td>
<td>1929</td>
<td>2353</td>
<td>2828</td>
<td>0.246</td>
</tr>
<tr>
<td>IQR 731–4285</td>
<td></td>
<td>IQR 1108–5507</td>
<td>IQR 816–5226</td>
<td></td>
</tr>
<tr>
<td>NYHA class</td>
<td>3.3 ± 0.5</td>
<td>3.3 ± 0.5</td>
<td>3.4 ± 0.5</td>
<td>0.372</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>14 (6.0%)</td>
<td>14 (6.0%)</td>
<td>5 (6.6%)</td>
<td>0.676</td>
</tr>
<tr>
<td>FEV1 (%)</td>
<td>81 ± 23.8</td>
<td>77.4 ± 24.9</td>
<td>75.7 ± 23.8</td>
<td>0.337</td>
</tr>
<tr>
<td>Systolic PAP &gt;50 mmHg</td>
<td>103 (36.1%)</td>
<td>79 (34.0%)</td>
<td>33 (43.4%)</td>
<td>0.337</td>
</tr>
<tr>
<td>Creatinine (mg/dl)</td>
<td>1.1 ± 0.7</td>
<td>1.2 ± 0.9</td>
<td>1.1 ± 0.4</td>
<td>0.286</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>61 (21.4%)</td>
<td>83 (35.8%)</td>
<td>16 (21.1%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Troponin I (mg/ml)</td>
<td>0.08 ± 0.5</td>
<td>0.3 ± 2.1</td>
<td>0.04 ± 0.07</td>
<td>0.286</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>91 (31.9%)</td>
<td>70 (30.2%)</td>
<td>71 (17.1%)</td>
<td>0.039</td>
</tr>
<tr>
<td>Stroke/cerebral lesion</td>
<td>56 (19.6%)</td>
<td>59 (25.4%)</td>
<td>15 (19.7%)</td>
<td>0.254</td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
<td>161 (56.5%)</td>
<td>160 (69.0%)</td>
<td>50 (65.8%)</td>
<td>0.012</td>
</tr>
<tr>
<td>Previous pacemaker/ICD</td>
<td>37 (13.0%)</td>
<td>12 (5.2%)</td>
<td>7 (9.2%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Previous aortic valve replacement</td>
<td>10 (3.5%)</td>
<td>4 (1.7%)</td>
<td>3 (3.9%)</td>
<td>0.401</td>
</tr>
<tr>
<td>Previous coronary artery bypass grafting</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>n.s.</td>
</tr>
<tr>
<td>Previous mitral valve repair/replacement</td>
<td>12 (4.2%)</td>
<td>2 (0.9%)</td>
<td>0</td>
<td>0.016</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>60.0</td>
<td>50.0</td>
<td>55.0</td>
<td>0.081</td>
</tr>
<tr>
<td>IQR 46.3–60</td>
<td></td>
<td>IQR 41.3–60</td>
<td>IQR 40–60</td>
<td></td>
</tr>
<tr>
<td>LVEDD (mm)</td>
<td>48.3 ± 7.9</td>
<td>48.1 ± 7.4</td>
<td>47.9 ± 7.2</td>
<td>0.885</td>
</tr>
<tr>
<td>Mean transvalvular gradient (mmHg)</td>
<td>48.9 ± 15.3</td>
<td>47.5 ± 14.0</td>
<td>47.3 ± 16.2</td>
<td>0.514</td>
</tr>
<tr>
<td>Aortic valve area (cm2)</td>
<td>0.67 ± 0.18</td>
<td>0.69 ± 0.18</td>
<td>0.64 ± 0.17</td>
<td>0.105</td>
</tr>
<tr>
<td>Annulus, TOE (mm)</td>
<td>22.4 ± 2.1</td>
<td>22.7 ± 2.3</td>
<td>21.9 ± 2.5</td>
<td>0.037</td>
</tr>
</tbody>
</table>

CAD: coronary artery disease; TOE: transoesophageal echocardiography; IQR: interquartile range; STS: society of thoracic surgeons; pBNP: pro brain natriuretic peptide; NYHA: New York Heart Association; FEV1: forced expiratory volume in one second; PAP: pulmonary artery pressure; ICD: implantable cardioverter-defibrillator; LVEF: left-ventricular ejection fraction; LVEDD: left-ventricular end diastolic diameter.
Patients receiving combined TAVI and PCI were older and had higher risk scores than patients receiving only TAVI. Interestingly, patients presenting with CAD were more likely to have peripheral arterial disease and diabetes mellitus. However, patients without CAD showed a higher rate of previous mitral valve repair/replacement and pacemaker implantation.

SYNTAX score before procedure

The SYNTAX score for patients presenting with severe aortic stenosis but without CAD (Group I) was set at zero. Patients presenting with no highly significant CAD (Group II) showed a calculated mean SYNTAX score of 5.7 ± 7.4. However, patients with highly significant CAD (Group III) had a statistically significantly higher mean SYNTAX score of 8.0 ± 5.7 compared with Group II (P < 0.001 between all groups) before the combined procedure (Fig. 1).

Figure 1: SYNTAX score before procedure. CAD: coronary artery disease.

SYNTAX score after combined transcatheter aortic valve implantation and percutaneous coronary intervention

Combined TAVI and PCI reduces the mean SYNTAX score significantly from 8.0 ± 5.7 to 3.0 ± 4.9 (P < 0.001) in those patients presenting with severe aortic stenosis and highly significant CAD (Group III, Fig. 2).

Early mortality

The thirty-day all-cause mortality rate in patients with highly significant CAD who underwent simultaneous PCI and TAVI (Group III) was 2.6% (2 of 76 patients died). The early mortality rate in patients without CAD (Group I) and with no highly significant CAD (Group II) who underwent TAVI only was 5.3% (15 of 285 patients) and 3.9% (9 of 232 patients), respectively. No statistically significant difference could be determined between groups with respect to early mortality.

Follow-up survival

Kaplan–Meier survival analysis was performed for the three groups up to 5 years after TAVI (Fig. 3). The overall survival rates for all groups are shown in Table 2. No significant difference in survival over 5 years could be observed between groups (P = 0.104). There is a numerical difference between groups after 3 years without statistical significance. However, the number of patients at risk is low.

Target vessels and stent characteristics

Isolated PCI of one target vessel was performed in 65 (85.5%) patients. A minority of patients (11 of 76, 14.5%) had a complex PCI involving either the left main (2 of 13 patients) or two coronary arteries (9 of 11 patients). The mean count of implanted stents per patient was 1.3 ± 0.7, with a range from 1 to 5 stents.

Figure 2: SYNTAX score after combined TAVI and PCI. TAVI: transcatheter aortic valve implantation; PCI: percutaneous coronary intervention.

Figure 3: Kaplan–Meier curves for overall survival for both TAVI only groups (blue and green) and the TAVI + PCI group (orange). CAD: coronary artery disease; TAVI: transcatheter aortic valve implantation; PCI: percutaneous coronary intervention.
Table 2: Survival over 5 years for all groups

<table>
<thead>
<tr>
<th></th>
<th>1st year</th>
<th>2nd year</th>
<th>3rd year</th>
<th>4th year</th>
<th>5th year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I (no CAD)</td>
<td>81.8 ± 2.4% (n = 184)</td>
<td>73.8 ± 2.9% (n = 113)</td>
<td>65.7 ± 3.6% (n = 60)</td>
<td>61.0 ± 4.3% (n = 30)</td>
<td>51.0 ± 5.9% (n = 8)</td>
</tr>
<tr>
<td>Group II (non-significant CAD)</td>
<td>76.1 ± 3.0% (n = 138)</td>
<td>65.8 ± 3.6% (n = 81)</td>
<td>54.1 ± 4.3% (n = 44)</td>
<td>44.3 ± 5.4% (n = 11)</td>
<td>44.3 ± 5.4% (n = 1)</td>
</tr>
<tr>
<td>Group III (significant CAD)</td>
<td>78.3 ± 5.2% (n = 46)</td>
<td>70.7 ± 5.9% (n = 30)</td>
<td>56.6 ± 7.9% (n = 13)</td>
<td>30.7 ± 11.4% (n = 3)</td>
<td>No data</td>
</tr>
</tbody>
</table>

CAD: coronary artery disease.

Radiation time and use of contrast agent during transcatheter aortic valve implantation and percutaneous coronary intervention

Radiation time during combined TAVI and PCI is significantly longer than in the standard TAVI procedure: 12.9 ± 8.0 min (Group III) vs 7.2 ± 4.9 min (Group I, P < 0.01) and 6.5 ± 4.0 min (Group II, P < 0.01).

Likewise, the amount of contrast agent applied during combined TAVI and PCI is significantly greater than during the standard TAVI procedure: 162.7 ± 87.5 ml in Group III vs 105.8 ± 49.8 ml in Group I (P < 0.01) and 102.2 ± 42.1 ml in Group II (P < 0.01).

Acute kidney injury

Regarding acute kidney injury, we examined all patients postoperatively according to the Valve Academic Research Consortium II (VARG II) criteria [11]. We observed no significant difference in acute kidney injury between groups: 14.7% (Group I), 15.5% (Group II) and 13.3% (Group III) of patients experienced stage 1 acute kidney injury according to the AKIN classification. Furthermore, 3.5% (Group I), 3% (Group II) and 7.9% (Group III) experienced Stage 3 acute kidney injury.

Myocardial infarction

For peri- and post-procedural myocardial infarction the VARG II criteria were again applied [11]. There was no significant difference in peri- or post-procedural myocardial infarction between the study groups: 0.7% (Group I), 0.4% (Group II) and 0% (Group III) of patients experienced periprocedural myocardial infarction, while 0% (Group I), 1.3% (Group II) and 1.3% (Group III) of patients had post-procedural myocardial infarction.

DISCUSSION

Our initial results with combined TAVI and PCI demonstrated the feasibility and safety of the combined single-stage procedure [1]. It showed no increase in the procedural difficulty of transapical TAVI when PCI was performed in a combined fashion. As mentioned above, the aim of a simultaneous approach was to prevent postoperative myocardial infarction without increasing procedural risks. Importantly, our policy is to perform PCI only for highly significant lesions and PCI should be able to be performed with a very high probability of success [1].

Our study demonstrates comparable survival up to 3 years after TAVI between patients without CAD receiving TAVI only, patients with CAD but no highly significant stenosis receiving TAVI only and patients with highly significant CAD receiving combined treatment. However, there seems to be an overall trend towards higher mortality in patients with CAD after 3 years due to higher preoperative risk and comorbidity profiles.

The complexity of coronary lesions, as assessed by the SYNTAX score, for patients with highly significant CAD (Group III) is higher preprocedurally than in patients with no highly significant CAD (Group II). However, after combined intervention, these patients show a lower mean SYNTAX score. The combined revascularization strategy might prove beneficial for their further clinical outcome.

Although procedural complexity during single-staged treatment is greater, early mortality for patients undergoing combined TAVI and PCI is not higher than that for patients receiving isolated TAVI. Thirty-day outcome showed no difference between the three study groups. Two recent studies in which PCI was performed prior to TAVI show comparable results, with 30-day mortality rates of 2–6% [3, 4].

Limited reports in the literature demonstrate higher mortality rates in patients with relevant CAD who received TAVI only, with the coronary lesion left untreated [12]. The risk of myocardial infarction peri- or post-procedurally may be elevated. Furthermore, coronary access might be hindered or complicated by prosthetic valve geometry after TAVI.

On the other hand, performing PCI before TAVI may increase the risk of decompensation during PCI and bleeding complications during later TAVI due to antiplatelet therapy. Data on this two-staged strategy are limited. The two previously mentioned studies where PCI was performed prior to TAVI did not report any valve-related complications [3, 4].

The beauty of a combined single-staged approach is that it eliminates the possible complications associated with leaving a pathology untreated [1].

Kidney function after transcatheter aortic valve implantation and percutaneous coronary intervention

It is our institutional policy to limit the amount of contrast agent used to a minimum. Patients undergoing combined TAVI and PCI necessarily receive a higher amount of contrast agent than patients receiving TAVI only. Nevertheless, no increase in acute kidney injury as assessed according to the VARG II criteria [11] was observed post-procedurally. These findings match a recent study stating that acute kidney injury after TAVI was associated with higher mortality but that the amount of contrast agent applied did not affect the risk of it developing [13].
Radiation time during the combined procedure

After introduction and implementation of a structured training programme for transapical TAVI at our institution [14, 15], the radiation time was reduced by 15% [16] for isolated TAVI. However, radiation time during the elective, combined procedure almost doubles compared with that for isolated TAVI. Every member of the TAVI team should be aware of this and protective measures and preventive steps should be taken in the hybrid OR [17].

Transfemoral transcatheter aortic valve implantation and percutaneous coronary intervention

During the study period from April 2008 through August 2013, 398 transfemoral TAVI cases were performed at our institution. Of those 398 patients, 4 (1%) underwent elective simultaneous PCI and 3 (0.75%) underwent simultaneous PCI because of iatrogenic coronary artery obstruction during TAVI. Thirteen patients (3.27%) had undergone previous CABG.

In patients with planned elective stenting, we prefer transapical TAVI because it enables easier handling of possible complications and easier institution of cardiopulmonary bypass. At the same time, it allows angiographic diagnostics.

For transfemoral implantation we need on one side of the groin an opening for the valve catheter and, on the other side, we have a small sheath for angiography and stenting catheters. In transfemoral TAVI, in the case of a necessity to put the patient on femorofemoral bypass, it would be cumbersome to put it in the already occupied groin (although it is possible to do it). The strategy to perform transapical TAVI is to have one side of the groin free for possible CPB. Although it is a very rare occurrence, in such catastrophic situations, it makes the procedure much easier.

Especially, at the introduction of concomitant TAVI and PCI, we were very cautious, since at that time there was limited experience with this procedure.

Study limitations

Limitations of this study include that the patients were not randomized and that there was no control group of patients with highly significant CAD who fulfilled the criteria for simultaneous PCI but were not treated with simultaneous PCI.

Further, due to difficulties with comparability and the calculation of an angiographic risk score, 134 transfemoral TAVI patients with previous CABG were excluded. Our intention in excluding the patients with prior CABG was to simplify the analysis and have a homogeneous group.

CONCLUSIONS

Single-stage combined treatment of severe aortic stenosis and highly relevant coronary lesions is a safe and feasible procedure. Early survival and survival up to 3 years are comparable with results for patients presenting without CAD and receiving isolated TAVI. PCI reduces the complexity of coronary lesions effectively. Although the amount of contrast agent applied during combined treatment was greater, no increased rate of acute kidney injury was observed.

Based on our experience, simultaneous interventional revascularization is a sound option for patients with relevant CAD undergoing TAVI.

ACKNOWLEDGEMENTS

Other members of the TAVI team are Christoph Klein, Guna Tetere, Tom Gromann, Natalia Solowjowa and Katrin Schäfer. We thank Julia Stein for advice and support in statistical analyses. We thank Rosemarie Günther for secretarial help and Anne Gale and Anne Carney for editorial assistance.

Conflict of interest: Miralem Pasic, Stephan Dreyssse, Semih Buz, Thorsten Drews and Axel Unbehaun served as proctors for Edwards Lifesciences from 2009 to 2012.

REFERENCES

APPENDIX. CONFERENCE DISCUSSION

Dr W. Wisser (Vienna, Austria): The topic presented is important and of clinical relevance, and it is nice that you have been able to show that PCI doesn’t impose any additional risk when it is performed simultaneously with a TAVI. However, my main concern is that, if I remember the previous presentation from this same group correctly, there seems to be a difference in numbers, because your co-worker presented a paper with 46 elective PCIs during the same series and the same time period of these six years. So perhaps you can comment on that, whether all these patients are really included in both presentations.

Additionally, coronary artery disease usually does not raise the EuroSCORE when added to the EuroSCORE. Can you comment on that? I wonder why the logistic EuroSCORE rises in your patient cohort from 30 to 37 only when a coronary artery disease is added. What did you do with the patients who had nonsignificant coronary artery disease? I wonder if there are any additional confounders and other variables which increase this EuroSCORE.

Thirdly, you present a rather long time period of five years. Could you comment on how many patients are really at risk at a five-year follow-up?

And lastly, you treated significant lesions. Probably I missed that, but what is your definition of “significant lesions”? Did you treat all lesions based on an FFR or only some of them, and what happened to the patients afterwards? Did you routinely perform reangiography on all these patients? What did you do with the patients who had nonsignificant coronary artery disease? Did you check them a couple of years later?

Dr Penkalla: Okay. The first question, you mentioned a series of 46 patients. I think you are talking about the paper which was published at the beginning of 2012.

Dr Wisser: I am talking about the previous presentation. He presented PCI with 46 patients electively, as far as I remember, and you were talking about 76 or something like that.

Dr M. Pasic (Berlin, Germany): Dr Pasic, can you help out?

Dr J. Kempfert (Bad Nauheim, Germany): Dr Pasic, can you help out?

Dr M. Pasic: In the previous presentation, Dr Buz mentioned 730 patients divided into three groups: those with severe calcification, those without calcification, and a medium group with moderate calcification. The last group was excluded from the study of Dr Buz, and the patients in this current presentation belong in the group that was excluded.

Dr J. Kempfert: After clarifying this, maybe we can focus on the other question that was mentioned. Do you plan to do any FFR measurements? I assume that you defined significant stenosis as 70% as we typically do?

Dr Penkalla: There is a published definition which says more than 50% of the left main, or more than 90% of a proximal or mid LAD, or right coronary stenosis if it’s dominant, or left circumflex if it’s dominant, is significant. That is the definition.

Dr M. Romano (Massy, France): I saw from your excellent presentation that you take into account patients with significant coronary artery disease in the left anterior descending and right circumflex, but when you have severe tight left main stenosis, or the equivalent of left main stenosis, if it is very proximal ostial LAD, ostial circumflex, severe lesion on the right, what do you do? Do you still proceed with your strategy, or do you turn down the patient, or do you redirect the patient to surgery, or did you ever consider the possibility of at the same time doing a transaortic implantation of the valve preceded by an OPCAB with complete revascularization, not leaving important arteries aside?

Dr Penkalla: Yes, we have such cases, but they are not included here. They are more complicated cases.

Dr Romano: This happens very frequently, because patients with left main and triple vessel disease are commonly seen among the population of patients with aortic valve stenosis, and in the elderly population to redirect to conventional surgery is a high risk for mortality and morbidity. And we know from recent literature (Philippe Kohl published a paper five years ago concerning the mortality for combined AVR and CABG), this is increased by the length of the procedure. The length of cross-clamp and CPB time is an independent predictor of mortality for this population of patients. So my question is, did you consider undertaking OPCAB and transaortic in the same session, eliminating CPB, cross-clamping, and complete revascularization?

Dr Penkalla: We also do TAVI and OPCAB, or open TAVI and OPCAB, in difficult cases. So we have minimal clamping time.

Dr J. Kempfert (Bad Nauheim, Germany): It would be a good idea to present this issue next year. It’s a completely different topic, I think. His purpose here was to show the safety of doing combined TAVI and PCI, if I understood correctly. Only one last question in regard to that, as I think this is important to discuss. What is your anticoagulation regimen? Do you preload with clopidogrel?

Dr Penkalla: After the procedure they get clopidogrel, preload doses, and aspirin.

Dr Kempfert: But no preloading?

Dr Penkalla: No. They get it the same day but not before the procedure.