Incidence and Management of CoreValve Dislocation During Transcatheter Aortic Valve Implantation

Sarah Geisbüsch, MD; Sabine Bleiziffer, MD; Domenico Mazzitelli, MD; Hendrik Ruge, MD; Robert Bauernschmitt, MD, PhD; Rüdiger Lange, MD, PhD

Background—Transcatheter aortic valve implantation is a highly specialized technique offering a new therapeutic option to patients at high risk for conventional surgery. Complications associated with this catheter procedure differ from complications after surgical aortic valve replacement. This is to report incidence, management, and impact on morbidity and mortality of CoreValve dislocation during catheter valve implantation.

Methods and Results—Between June 2007 and September 2009, the self-expandable CoreValve prosthesis (Medtronic Inc, Minneapolis, Minn) was implanted in 212 patients through a transarterial (femoral or subclavian) access. Patients with severe aortic stenosis who were at high risk for conventional surgery were included. We observed dislocation of the prosthesis during CoreValve implantation in 21 patients. In 16 cases, the CoreValve could be implanted in the correct annular position after retrieving it and reloading the catheter. In 4 patients, the completely deployed prosthesis had to be placed in the ascending or abdominal aorta before implanting a second one. One patient underwent open surgery. Overall 30-day mortality was 11.0%, 21.5% in the dislocation group and 9.9% in patients without dislocation (P=0.024). Coronary ischemia, stroke, and renal failure occurred more frequently in patients with dislocation, whereas pacemaker dependency did not differ significantly between the groups.

Conclusions—CoreValve dislocation during transcatheter aortic valve implantation occurred in 10% of the cases and significantly increases perioperative risk for severe complications or death. It requires individual specific management and can be managed either interventionally or, rarely, results in open surgery. (Circ Cardiovasc Interv. 2010;3:531-536.)

Key Words: complications ■ prosthesis ■ valves

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ince its first implementation in 2002 by Alain Cribier,1 transcatheter aortic valve implantation (TAVI) gained reliability as a feasible alternative to open heart surgery, with more than 8000 implantations worldwide.

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Surgical aortic valve replacement has clearly been shown to improve survival of patients with severe aortic valve stenosis,2,3 although the proof of the equality of the new TAVI procedures remains a field of current investigations. At present, TAVI is offered to patients at high risk with severe comorbidities that are refused for conventional surgery.4 Implantation techniques as well as materials have been improved over the years. Not yet supported by scientific data, it is only assumed that the periprocedural risk for morbidity and mortality may be reduced with the transcatheter techniques compared with conventional surgical aortic valve replacement. However, the transcatheter treatment is associated with complications different from other catheter procedures and different from conventional surgical aortic valve replacement, such as prosthesis dislocation during the procedure.

The present study reviews the incidence, management, and impact of CoreValve dislocation on morbidity and mortality in a cohort of 212 patients.

Methods

Of 337 patients who underwent interventional aortic valve implantation with the CoreValve or the Sapien prosthesis between June 2007 and September 2009 at the German Heart Centre Munich, 212 had implanted a CoreValve prosthesis through a transfemoral or subclavian access. Selection of access site and valve type has been previously described.3 Prosthesis dislocation did not occur with the Edwards-Sapien prosthesis. Data were analyzed retrospectively.

Patient Sample

Only patients who were at high risk for conventional surgical aortic valve replacement were selected for transcatheter valve implantation. The study sample consists of 101 men and 111 women with a mean age of 81±5 years. Patient baseline characteristics are summarized in Table 1. Before diagnostic evaluation, the operative risk was assessed using the EuroScore and STS score. Risk factors not registered by EuroScore and STS score, such as repeated previous cardiac surgery, liver disease, porcelain aorta, immobility caused by
Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Condition</th>
<th>All (n=212)</th>
<th>Dislocation (n=21)</th>
<th>No Dislocation (n=191)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary heart disease</td>
<td>103 (49%)</td>
<td>12 (57%)</td>
<td>91 (48%)</td>
<td>0.493</td>
</tr>
<tr>
<td>Peripheral arterial occlusive disease</td>
<td>33 (16%)</td>
<td>3 (14%)</td>
<td>30 (16%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Cerebral arterial occlusive disease</td>
<td>26 (12%)</td>
<td>3 (14%)</td>
<td>23 (12%)</td>
<td>0.728</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>47 (22%)</td>
<td>3 (14%)</td>
<td>44 (23%)</td>
<td>0.579</td>
</tr>
<tr>
<td>Previous heart operation</td>
<td>39 (18%)</td>
<td>7 (33%)</td>
<td>32 (17%)</td>
<td>0.076</td>
</tr>
<tr>
<td>Significant mitral or tricuspid disease</td>
<td>40 (19%)</td>
<td>2 (10%)</td>
<td>38 (20%)</td>
<td>0.379</td>
</tr>
<tr>
<td>Renal insufficiency, creatinine &gt;1.5</td>
<td>42 (20%)</td>
<td>4 (19%)</td>
<td>38 (20%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Previous apoplexy/transient ischemic attack</td>
<td>26 (12%)</td>
<td>5 (24%)</td>
<td>21 (11%)</td>
<td>0.150</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>47 (22%)</td>
<td>2 (10%)</td>
<td>45 (24%)</td>
<td>0.175</td>
</tr>
</tbody>
</table>

Orthopedic diseases, and so forth, were assessed clinically. All patients signed an informed consent. The study was approved by the local ethics committee (No. 2234/08).

Preprocedural Evaluation

All patients underwent transthoracic as well as transesophageal echocardiography to quantify the degree of aortic stenosis and measure the annulus diameter. In addition, computed tomography of the thorax, abdomen, and pelvis was performed. Three-dimensional reconstruction of the entire aorta and the aortic root was performed to detect severe calcifications, femoral or iliac stenosis, kinking, and aortic or iliac dissection.

Before aortic valve implantation, coronary angiography was performed in all patients and, in the case of coronary artery disease, intervention was performed before valve implantation.

Because the CoreValve delivery system comes with an 18F sheath, a minimum vessel diameter of 6.5 mm is required for implantation. In patients with contraindications for transfemoral valve implantation, that is, peripheral vessel disease, previous peripheral bypass surgery, or stenosis of the femoral or iliac vessels, the subclavian artery as an alternative access was chosen.

Prostheses and Implantation Technique

The CoreValve prosthesis (Medtronic Inc, Minneapolis, Minn) implanted in our patient sample is a porcine pericardial valve mounted in a self-expandable nitinol stent. The 18F delivery sheath implanted in our patient sample is a porcine pericardial valve.

Procedures between June 2007 and April 2009 were performed under general anesthesia (n=1100). Subsequently, 26 patients were operated in local anesthesia. All patients were operated in a surgical hybrid suite. Arterial and venous guide wires for potential femoral cannulation were placed into 1 groin before the procedure. Transfemoral valve implantation was performed by percutaneous punctation and device closure (ProStar XL, Abbott Park, Ill, n=129) or by surgical dissection of the femoral artery (n=69). For the subclavian access, the subclavian artery was dissected through a 5-cm subclavicular skin incision (n=14). A transient pacemaker wire was placed transvenously. A balloon valvuloplasty of the stenotic aortic valve was performed under rapid ventricular pacing at 180 to 200 beats per minute in all patients. Under fluoroscopy control, the prosthesis, crimped on the delivery catheter, was placed in the aortic annulus. The CoreValve prosthesis was then gradually released on the beating heart. Details of the implantation procedures have been described previously.

Table 2. Intraoperative Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>All (n=212)</th>
<th>Dislocation (n=21)</th>
<th>No Dislocation (n=191)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time, min</td>
<td>80 ± 33</td>
<td>101 ± 43</td>
<td>77 ± 31</td>
<td>0.002</td>
</tr>
<tr>
<td>Fluoroscopy time, min</td>
<td>26.8 ± 11</td>
<td>33 ± 14</td>
<td>26 ± 10</td>
<td>0.007</td>
</tr>
<tr>
<td>Radiation dose, μGy/cm²</td>
<td>28 950 ± 21 425</td>
<td>43 444 ± 24 155</td>
<td>27 314 ± 20 531</td>
<td>0.001</td>
</tr>
<tr>
<td>Contrast agent, mL</td>
<td>142.8 ± 57</td>
<td>200 ± 88</td>
<td>137 ± 49</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Prosthesis function was assessed by angiography and intraoperative transesophageal or transthoracic echocardiography.

Data Collection and Statistical Analysis

Prosthesis dislocation was defined as a valve position outside the native aortic annulus. Patient demographic data, operative data, and postoperative complications were prospectively recorded in a computerized data base. Data are presented as mean ± SD and as percentages. Differences between groups were tested with the Wilcoxon rank-sum test or the Fisher exact test as appropriate. Survival analysis was performed by the Kaplan–Meier estimate and differences between groups were tested with the log-rank test. The causes of death were classified according to the guidelines for reporting mortality and morbidity after cardiac valve interventions.

Statistical significance was achieved at a probability value of P < 0.05.

Results

Baseline characteristics are shown in Table 1. There were no significant differences in the preoperative parameters of patients with valve dislocation compared with those with uneventful implantation. Common comorbidities included the presence of coronary heart disease, peripheral or cerebral occlusive disease, pulmonary hypertension, chronic obstructive pulmonary disease, renal insufficiency, or significant mitral or tricuspid disease.

Intraoperative parameters changed significantly when dislocation occurred. Mean operation time in all patients was 80 ± 33 minutes. Management of intraoperative dislocation of the valve resulted in extension of time needed for the intervention with a mean operation time of 101 ± 43 minutes compared with 77 ± 31 minutes in the nondislocation group (P = 0.002). Also, fluoroscopy time, amount of contrast agent applied, and radiation dose were increased in patients with CoreValve dislocation (Table 2).

Management of Dislocation

Intraprocedural dislocation of the CoreValve occurred in 21 of 212 patients. In 16 of these patients, a partially deployed CoreValve prosthesis dislocated into the ascending aorta (Figure 1). Fifteen patients could be treated by retrieval of the partially deployed prosthesis through the introducer sheath and reimplantation of the same prosthesis. In 1 patient with isolated aortic insufficiency, we terminated the procedure after having dislocation a second time.

In 5 patients, a completely deployed CoreValve prosthesis dislocated into the ascending aorta (Figure 2). The prosthesis could be retracted with a “gooseneck” catheter into the...
ascending or descending aorta in 4 patients, and a second prosthesis was implanted in the correct annular position (Figure 3). In 2 of these patients, the prosthesis dislocated during a redilation maneuver. We retracted the valve into the abdominal aorta and implanted a new one. In 1 case, the second prosthesis redislocated. After retrieval of the valve and reloading of the catheter, the CoreValve was implanted successfully.

One patient underwent surgical removal of the CoreValve prosthesis and conventional aortic valve replacement when it was impossible to retract the prosthesis. She was discharged on postoperative day (POD) 50 after a prolonged stay in the intensive care unit.

Postoperative Complications and Survival

Forty-three deaths occurred in this cohort after CoreValve implantation. Survival rates at a follow-up of 30 days, 6 months, and 1 year were 90.1%, 81.9%, and 79.6% in the nondislocation group and 78.5%, 52.4%, and 52.4% in patients who had dislocation ($P=0.024$, see Figure 4).

Seven patients with a history of dislocation died during follow-up. Four of these 7 patients died of valve-related complications: 1 patient after pericardial effusion and CPR on POD 2, another with intracerebral bleeding after collapsing on POD 92, and 2 were found dead (sudden death) on POD 73 and POD 88. Ventricular rupture after wire perforation on the day of the implantation led to death in 1 case, and intracerebral bleeding after cerebral medial artery infarction on POD 7 was fatal in another patient. Acute respiratory distress syndrome after pneumonia ended in death in 1 case.

In 6 patients (6 of 21 patients; 29%) with a history of dislocation, a pacemaker implantation was necessary after surgery for bradyarrhythmia (n=3) and AV block (n=3).

The percentage of pacemaker dependency was slightly lower in patients without dislocation (49 of 191; 26%; $P=0.795$) and referred to AV block (43 of 49 patients),
To prevent complications caused by mismatch of the annulus and valve size, precise annulus measurements by echocardiography and CT are essential. To achieve a solid anchoring in the annulus, the chosen valve size may not be too small.

Furthermore, instability in the aortic root caused by severe arrhythmia causes unpredictable movements of the beating heart. To improve stabilization of the valve during deployment, higher rate ventricular pacing may be performed.

If redilation of a deployed CoreValve prosthesis is performed, rapid ventricular pacing should only be stopped after complete deflation of the redilation balloon to avoid dislocation of the prosthesis and balloon by the beating heart.

In some settings, correct patient selection may avoid dislocation. Unfavorable angulation of the aortic root and thoracic or abdominal aortic kinking lead to a delay of manipulations from the groin to the implantation site. Transapical access for valve implantation may be superior in this patients.

Instability of catheter and valve after severe regurgitation after balloon valvuloplasty require extremely careful catheter handling to avoid dislocation during deployment.

A completely deployed CoreValve prosthesis may also dislocate accidentally after successful deployment during retraction of the delivery system if the anchors are not fully released from the deployment catheter or if the tip of the deployment catheter gets caught at the proximal end of the prosthesis. Reassurance that both anchors are released by exposing them in different imaging levels is essential and necessary to prevent this complication.

Furthermore, by pulling on the intraventricular Amplatz super-stiff wire, the conical tip of the delivery system is centered and can be removed without touching the proximal valve stent.

**Management of Dislocation**

Dislocation of a partially or completely deployed CoreValve prosthesis can be managed interventionally in most cases: A partially deployed CoreValve prosthesis can be retracted and retrieved through the introducing sheath and reloaded on the delivery catheter. A completely deployed dislocated CoreValve or Sapien prosthesis can be retracted into the ascending or descending aorta with a gooseneck catheter, and a second valve can be implanted in the annular position. In some cases, retrieval of the prosthesis is impossible. This complication may only be treated surgically. Embolization of the Edwards-Sapien prosthesis into the ventricle has been described to occur under circulatory support with the heart-lung-machine with retrograde perfusion from the femoral artery. This complication may only be treated surgically.

**Postoperative Complications**

Regarding the postoperative complications, we found that coronary ischemia as a rather rare complication was more often seen in patients with dislocation of the valve (10% versus 2%; \( P=0.078 \)). Mean hospital length of stay was 8.8 ± 5.2 days and was not prolonged in patients with dislocation, although renal failure with increase of serum creatinine of >1 mg/dL or need for dialysis occurred more frequently (33% versus 14%; \( P=0.024 \)). The incidence of stroke was twice as high when additional manipulation and replacement of the valve was necessary and was 14% and 7%, respectively (3 of 21 patients; 13 of 191 patients; \( P=0.201 \)), see Table 3.

**Discussion**

Individuals who potentially benefit from TAVI are at high risk for conventional surgery, and complications associated with this catheter procedure are different from complications after surgical aortic valve replacement. Procedure-related intraoperative complications require specific management and often interdisciplinary acute intervention. Not only significant comorbidities in elderly patients, but also sudden complications significantly increase the perioperative risk.

As we gather experience with the new technique of valve implantation, prosthetic dislocation is one of the complications our team is suddenly confronted with, and it requires specific individually adjusted management. Expert knowledge of catheter handling is indispensable, and emergent surgery can be necessary in some cases. The incidence of CoreValve dislocation was 10% in our series (21 of 212). Grube et al\(^a\) reported an incidence of 3% and good results after repositioning.

Dislocation of the Edwards-Sapien prosthesis has been reported to occur in 4% to 11% in 5 series,\(^{10-14}\) whereas our group did not have this complication in >100 patients receiving a Sapien prosthesis.

**Avoidance of Dislocation**

The most common and the most serious complication of TAVI is dislocation of the prosthesis, which occurs in 2% to 10% of patients. Dislocation complicates aortic-valve implantation and outlines chronic renal failure as the strongest single predictor of mortality in late follow-up. Impairment of renal function is clearly associated with short-term outcomes.

Table 3. Postoperative Complications

<table>
<thead>
<tr>
<th></th>
<th>All (n=212)</th>
<th>Dislocation (n=21)</th>
<th>No Dislocation (n=191)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemaker implantation</td>
<td>55 (26%)</td>
<td>6 (29%)</td>
<td>49 (26%)</td>
<td>0.795</td>
</tr>
<tr>
<td>Bradyarrhythmia</td>
<td>8 (4%)</td>
<td>3 (14%)</td>
<td>5 (3%)</td>
<td>...</td>
</tr>
<tr>
<td>AV block</td>
<td>45 (21%)</td>
<td>3 (14%)</td>
<td>43 (23%)</td>
<td>...</td>
</tr>
<tr>
<td>Sick sinus syndrome</td>
<td>1 (0.5%)</td>
<td>0</td>
<td>1 (0.5%)</td>
<td>...</td>
</tr>
<tr>
<td>Coronary ischemia</td>
<td>5 (2)</td>
<td>2 (10%)</td>
<td>3 (2%)</td>
<td>0.078</td>
</tr>
<tr>
<td>Renal failure</td>
<td>34 (16%)</td>
<td>7 (33%)</td>
<td>27 (14%)</td>
<td>0.024</td>
</tr>
<tr>
<td>Stroke</td>
<td>16 (8%)</td>
<td>3 (14%)</td>
<td>13 (7%)</td>
<td>0.201</td>
</tr>
<tr>
<td>Mean hospital length of stay, d</td>
<td>8.8±5.2</td>
<td>9.3±6.2</td>
<td>8.8±5.1</td>
<td>0.843</td>
</tr>
</tbody>
</table>
and long-term morbidity and mortality. In our study sample, renal failure was significantly higher in patients with prolonged operation time caused by valve repositioning and is certainly related to higher doses of contrast agent applied (see Table 2). A minimum amount of contrast agent of 50 mL had to be administered during CoreValve application, whereas this varied individually and resulted in an amount of 374 mL in 1 patient in whom the deployed valve had to be retracted in the ascending aorta and a new valve had to be implanted.

The risk of perioperative cerebrovascular events for patients ages ≥80 years undergoing cardiac surgery is increased and described to be approximately 10% for patients undergoing isolated coronary artery bypass grafting and 15% for combined surgery (coronary artery bypass grafting plus aortic valve replacement) by Alexander et al in 2000. Over a period of almost 10 years, Brown et al14 reported stroke rates for isolated aortic valve replacement between 2.2% (1997) and 2% (2006) for patients ages 80 to 85 and 4.1% (1997) and 2.4% (2006) for patients ages 85 to 90 years. We observed stroke in 8% in our study sample. Other studies report incidences ranging from 0% to 9%. A recently published report by Webb et al15 showed an overall stroke rate of 5.3% for transarterial procedures and basically calls calcific emboli responsible while observing lower stroke rates in patients with transapical aortic valve implantation (1.8%; P=0.43). Stroke rates were increased in our patient sample that had valve dislocation, presumably caused by prolonged catheter manipulation and valve retrieval through a calcified aortic arch. In summary, CoreValve dislocation is associated with higher postoperative morbidity and mortality. During a follow-up period of 1 year, survival rates of patients with history of dislocation are significantly lower (P=0.024; see Figure 4). Overall, 30-day mortality was 11%, which is consistent with the data published earlier.

As described above, dislocation of the CoreValve prosthesis during implantation is influenced by different variables. Besides morphological or patient-related factors, we presume that the experience of the operator also may have an impact. Analyzing a period of almost 3 years in which we have been implanting the CoreValve prosthesis in our institution, the incidence of dislocation decreased constantly with increasing experience. In 2008, we had a dislocation rate of 12% (13 dislocated valves in 110 patients), whereas in 2009 and 2010 the incidence was 10% (9 of 93) and 3% (1 of 38), respectively. During our initial experience in 2007, in which a proctor was present in every case, the dislocation rate was 0% (none of 42 patients).

Conclusions
Transcatheter aortic valve implantation is a highly invasive procedure with specific procedure- and patient-related complications. Although dislocation of CoreValve prosthesis can be managed interventionally in most cases, surgical intervention is inevitable in some cases.

Dislocation of the valve significantly increases morbidity and mortality and therefore must be prevented in any circumstances. Precise diagnostic evaluation is mandatory and may itself prevent certain complications. In addition, a highly specialized, interdisciplinary team should perform all procedures to gain expert knowledge.

Disclosures
Prof Bauernschmitt and Dr Mazzitelli are consultants of Edwards Lifesciences and Medtronic. Prof Lange is a member of the Medtronic advisory board.

References
Transcatheter aortic valve replacement is a highly specialized technique offering patients at high risk a new therapeutic option. With more than 20,000 implantations worldwide, it gained reliability as a feasible alternative to open heart surgery. Complications associated with this invasive procedure are different from those after conventional aortic valve replacement and require individual specific management. Between June 2007 and September 2009, 212 patients with severe aortic stenosis had implanted the self-expandable CoreValve prosthesis (Medtronic Inc, Minneapolis, Minn) through a transfemoral or subclavian access at the German Heart Centre Munich. CoreValve dislocation during transcatheter aortic valve implantation occurred in 10% of the cases. Patients with dislocation of the valve showed a remarkably higher incidence of severe complications, such as coronary ischemia, stroke, and renal failure. Mortality significantly increased when dislocation occurred. In the present study, we report our experience with intraprocedural valve dislocation with special focus on possible causes and different management strategies of dislocation as well as possibilities of how this complication might be avoided.
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