Transarterial Medtronic CoreValve System Implantation for Degenerated Surgically Implanted Aortic Prostheses

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Background—To assess the results of transcatheter aortic valve implantation (TAVI) using the Medtronic CoreValve System (MCS), through the transarterial approach, in high-risk patients with degenerated surgically implanted aortic bioprostheses (SP).

Methods and Results—Of 241 patients who underwent TAVI, 10 (4%) had a degenerated SP. The approach was percutaneous transfemoral in 9 cases and surgical transaxillary in 1. Patients were age 75 ± 10 years of age. All were in New York Heart Association classes III or IV and at high risk for repeated surgery. Seven patients had stented, 2 stentless, and 1 homograft SP. The failure mode was predominant regurgitation in 7 cases and stenosis (aortic valve area, 0.7 ± 0.2 cm²; mean gradient, 58 ± 16 mm Hg) in 3. Based on the echographic measurements, 8 patients received a 26-mm, and 2 a 29-mm-diameter MCS. Procedural success rate was 100%. There was 1 in-hospital death, 1 stroke with moderate sequelae, and 1 pacemaker implantation. There were no other adverse events at 30 days. The mean postimplantation transprosthetic gradient was 13 ± 7 mm Hg; periprosthetic regurgitation was absent or trivial in 9 cases and grade 2 in 1. After a median follow-up of 5 months, there were no additional adverse events. All but 1 of the hospital survivors were in New York Heart Association classes I or II.

Conclusions—These results suggest that transarterial MCS implantation in degenerated SP is feasible and may lead to hemodynamic and clinical improvement in patients who are poor candidates for repeated surgery, pending confirmation in larger series with longer follow-up. (Circ Cardiovasc Interv. 2011;4:488-494.)

Key Words: transcatheter aortic valve implantation ■ valve in valve ■ bioprosthesis ■ reoperation ■ valve degeneration

Aortic stenosis (AS) is the most frequent valvular heart disease in the United States and Europe and especially concerns the elderly.1 In this population, bioprosthetic heart valves are preferred to mechanical valves to avoid anticoagulation therapy and to lower the risk of bleeding and thrombosis.2–4 However, with time, biological tissue is expected to degenerate. The standard treatment for a failing bioprosthesis is surgery, but redo surgery may lead to high morbidity and mortality in the presence of comorbidities.5–8

Today, transcatheter aortic valve implantation (TAVI) offers an alternative to conventional aortic valve replacement (AVR) for high-risk patients with severe symptomatic AS or with contraindications for surgery. With the development of the technique, TAVI may become an attractive option in high-risk elderly patients with a degenerated surgically implanted aortic bioprosthesis (SP), but experience is still limited. We describe our experience of transarterial Medtronic CoreValve System (MCS) implantation in this specific indication.
retrograde transfemoral or the left subclavian approach. TAVI was performed either under general anesthesia with TEE guidance or under local anesthesia with conscious sedation. The 18F transfemoral arterial access was obtained percutaneously using the Prostar 10 F XL (Abbot Vascular Devices, Redwood City, CA) as a preclosure device. The subclavian procedure was performed with surgical cut-down access and closure.

WHAT IS KNOWN

- Redo surgery is the standard treatment for failing bioprostheses, but it may lead to high mortality and morbidity in the presence of comorbidities.

WHAT THE STUDY ADDS

- Transcatheter aortic valve implantation might be an attractive option in this high-risk setting, but experience is still limited.
- We report a series of transarterial valve-in-valve implantation, using the Medtronic CoreValve System for degenerated aortic surgically implanted stented or stentless bioprostheses in high-risk patients.
- Our results suggest the feasibility of such an approach, with a high procedural success rate, immediate hemodynamic improvement, and acceptable clinical outcomes.
- If mid- and long-term outcomes remain favorable, this will have important clinical implications for treatment strategies of aortic stenosis in high-risk patients.

Several technical precautions were observed for valve-in-valve implantations. There was no balloon predilatation, even in stenotic bioprostheses, to avoid the risk of leaflet fracture and embolization. Rapid ventricular pacing (120 to 160 bpm) was used during MCS deployment, especially in regurgitant bioprostheses, to reduce cardiac motion and facilitate optimal positioning.

After surgery, patients received a combination of aspirin and clopidogrel for 3 months (then aspirin or clopidogrel alone), or clopidogrel and oral anticoagulation if otherwise indicated.

Follow-Up

Clinical follow-up and TTE were performed before discharge. All adverse events were prospectively recorded. The 30-day, 6-month, and 1-year medical visits and TTE were performed in our institution or by the patients’ own cardiologist, and data were collected by phone calls.

Definitions

Device success and clinical end point definitions were the standardized definitions of the consensus report from the Valve Academic Research Consortium (VARC).13

Statistical Analysis

Data are expressed as mean±SD. The paired Student t test was used to compare the means of continuous variables before and after the procedure. A probability value <0.05 was considered to indicate a statistically significant difference. Statistical analysis was performed using JMP 7.0.1 Statistical Discovery statistical software from SAS Institute Inc (Cary, NC).

Results

Patients

From October 2006 to November 2010, of the 241 patients who underwent TAVI in our institution, 10 (4%) were treated because of a failed aortic SP.

Patients’ clinical baseline characteristics are shown in Table 1. All had congestive heart failure class III or IV in New York Heart Association (NYHA) classification. Their mean age was 75±10 (57–87) years and mean STS score was 6±4%. Two patients had more than 1 prior cardiac surgery, 3 had an associated previous coronary artery bypass grafting, 1 had a previous percutaneous mitral commissurotomy, and all but 1 had more than 2 extracardiac comorbidities. Eight patients had an STS <10%, but reoperation was deemed to be high risk or contraindicated, based on clinical judgment, due to the presence of comorbidities that were not taken into account by the predictive mortality risk scores (Table 2).

Surgically Implanted Prostheses

The characteristics of failing SP are shown in Table 3. Seven SP were stented (5 Carpentier-Edwards pericardial valves, 1...
Carpentier-Edwards supra-annular porcine, and 1 St Jude X-Cell bioprosthesis), 2 were stentless, and 1 was a homograft. The smallest SP was a 21-mm Carpentier-Edwards supra-annular, corresponding to a 19-mm internal diameter, as measured by TEE. The mean delay from bioprosthesis surgical placement to dysfunction was 11 years (6–20).

The most frequent failure mode was a regurgitation (4 stented and 2 stentless SP, and 1 homograft), and a predominant stenosis was observed in 3 stented SP. Leaflet calcification and prolapse were the main mechanisms of prosthetic dysfunction. On baseline TTE, stenosed SP had a mean area measured at 0.76 cm² and a mean gradient at 58 mm Hg. All prevailing regurgitations were graded 3 or 4.

Procedure
Procedures were mostly performed by percutaneous transfemoral access (n=9) and 1 by surgical subclavian access. General anesthesia was used in 6 cases: the first 3 transfemoral cases and the 1 subclavian; in addition, 2 other patients for whom the procedure was begun using conscious sedation had to be converted to general anesthesia, in 1 case because of a paradoxical restlessness induced by the anesthetic drugs and in the other because of an intraprocedural stroke (patient 7). The 4 remaining patients underwent the entire procedure under local anesthesia and conscious sedation.

The procedural success rate was 100%, with neither paraprosthetic nor central aortic leak grade greater than 2+ as determined by TTE and/or TEE, and angiography. The final mean transcatheter gradient was 13 mm Hg. There was no need for surgical conversion, nor were there any intraprocedural deaths.

Thirty-Day Outcomes
The median hospital stay duration from procedure to discharge was 13 days (interquartile range, 3 to 33 days).

There was 1 in-hospital death: an 87-year-old woman (patient 10) had acute renal failure requiring hemodialysis before TAVI; a 26-mm MCS was implanted with no procedural complication; TAVI successfully improved hemodynamics but dialysis had to be maintained; a major hematoma on the venous femoral dialysis catheter occurred at day 10, and death occurred at day 11 in the context of sepsis and multiorgan failure.

There was 1 intraprocedural stroke (patient 7) consecutive to a long and difficult procedure in an 86-year-old woman with tortuous aorta and severe cyphoscoliosis, who had no alternative to the transfemoral approach. A first MCS could not be tracked through the aortic arch and had to be retrieved. A second MCS was successfully implanted in the correct position. However, half an hour after the end of the procedure, a coma occurred. MRI identified an ischemic thalamic stroke.

Table 2. Reasons for High Risk of Surgery in 8 Patients With STS Score <10%

<table>
<thead>
<tr>
<th>Patients</th>
<th>Reasons for High Risk of Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prior CABG with patent grafts</td>
</tr>
<tr>
<td>2</td>
<td>Prior CABG/ENT cancer treated with surgery and tracheotomy</td>
</tr>
<tr>
<td>3</td>
<td>Ascending aorta wrapping</td>
</tr>
<tr>
<td>5</td>
<td>Associated ascending aorta aneurism/frailty</td>
</tr>
<tr>
<td>6</td>
<td>Severe COPD</td>
</tr>
<tr>
<td>7</td>
<td>Severe chest deformation</td>
</tr>
<tr>
<td>8</td>
<td>Severe homograft calcification; moderate mitral stenosis, and regurgitation making subsequent need for reoperation likely, lack of compliance with Coumadin</td>
</tr>
<tr>
<td>9</td>
<td>Prior CABG with patent grafts</td>
</tr>
</tbody>
</table>

CABG indicates coronary artery bypass graft; ENT, ear, nose, and throat; and COPD, chronic obstructive pulmonary disease.

Table 3. Failed Bioprosthesis Characteristics in 10 Patients Treated by Transarterial Valve-in-Valve Implantation

<table>
<thead>
<tr>
<th>Patients</th>
<th>Degenerated Bioprosthesis</th>
<th>Failure Mode</th>
<th>Delay to Valve Dysfunction, Years (From Surgery to TAVI)</th>
<th>Mechanisms of Valve Dysfunction</th>
<th>TTE/TEE Internal Prosthesis Diameter, mm</th>
<th>Inner Ring Diameter (From Manufacturer), mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Stentless O’Brien 25</td>
<td>R</td>
<td>10</td>
<td>Deteriorated and torn leaflet tissue</td>
<td>25</td>
<td>23</td>
</tr>
<tr>
<td>2</td>
<td>Carpentier-Edwards supra-annular porcine 21</td>
<td>R</td>
<td>20</td>
<td>Leaflet calcification and prolapse</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>3</td>
<td>Carpentier-Edwards pericardial 25</td>
<td>S</td>
<td>7</td>
<td>Leaflet calcification</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>4</td>
<td>Carpentier-Edwards pericardial 25</td>
<td>R</td>
<td>9</td>
<td>Leaflet prolapse</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>5</td>
<td>Carpentier-Edwards pericardial 23</td>
<td>S</td>
<td>9</td>
<td>Leaflet calcification</td>
<td>21</td>
<td>22</td>
</tr>
<tr>
<td>6</td>
<td>Carpentier-Edwards pericardial 23</td>
<td>S</td>
<td>14</td>
<td>Leaflet calcification</td>
<td>21</td>
<td>22</td>
</tr>
<tr>
<td>7</td>
<td>St Jude X-Cell 25</td>
<td>R</td>
<td>15</td>
<td>Deteriorated and torn leaflet tissue</td>
<td>23</td>
<td>24</td>
</tr>
<tr>
<td>8</td>
<td>Homograft 23</td>
<td>R</td>
<td>12</td>
<td>Leaflet prolapse</td>
<td>23</td>
<td>NA</td>
</tr>
<tr>
<td>9</td>
<td>Carpentier-Edwards pericardial 25</td>
<td>R</td>
<td>6</td>
<td>Leaflet calcification</td>
<td>22</td>
<td>24</td>
</tr>
<tr>
<td>10</td>
<td>Stentless O’Brien 23</td>
<td>R</td>
<td>11</td>
<td>Deteriorated and torn leaflet tissue</td>
<td>21</td>
<td>21</td>
</tr>
</tbody>
</table>

TAVI indicates transcatheter aortic valve implantation; TTE, transthoracic echocardiography; TEE, transesophageal echocardiography; R, regurgitation; and S, stenosis.
stroke. Clinical status improved progressively, and the patient was discharged at day 33 with moderate sequelae. Permanent pacemaking was required in 1 patient (patient 3), who had a preexisting right bundle-branch block. The 30-day combined safety end point defined by VARC (all-cause mortality, major stroke, life-threatening bleeding, acute kidney injury, periprocedural myocardial infarction, major vascular complication, repeat procedure for valve-related dysfunction) concerned 2 of the 10 patients (20%).

The results of predischarge TTE are reported in Table 4. Prosthesis deployment was correct in all cases. In the patient with the degenerated homograft (patient 8), the MCS was implanted relatively high just at the level of the annulus (Figure 1); however, the function of the prosthesis was good. The mean transprosthetic gradient was $13 \pm 7$ (2–22) mm Hg. On average, the mean gradient of stenosed bioprostheses decreased from $58 \pm 16$ to $17 \pm 7$ mm Hg ($P=0.01$). The mean final prosthesis area was $1.6 \pm 0.4$ (1.2–2.2)cm$^2$. Paravalvular leaks were absent or trivial in all but 1 patient (patient 8). The latter had an extremely calcified and regurgitant homograft and received a 29-mm MCS; predischarge and 30-day TTE showed a grade 2+ paravalvular leak. However, a significant decrease of left ventricular dimensions was observed (baseline and diastolic left ventricular diameter decreased from...

Table 4. Hemodynamic Parameters in 10 Patients, Before and After Transarterial Valve-in-Valve Implantation for Failed Aortic Bioprosthesis

<table>
<thead>
<tr>
<th>Patients</th>
<th>Degenerated Bioprosthesis</th>
<th>MCS Diameter, mm</th>
<th>Baseline Mean Gradient, mm Hg</th>
<th>Baseline AVA, cm$^2$</th>
<th>Baseline AR Grade</th>
<th>Final Mean Gradient, mm Hg</th>
<th>Final AVA, cm$^2$</th>
<th>Final AR Grade</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Stentless O’Brien 25</td>
<td>29</td>
<td>6</td>
<td>1.7</td>
<td>3</td>
<td>4</td>
<td>2.0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>Carpentier-Edwards supra-annular porcine 21</td>
<td>26</td>
<td>28</td>
<td>1.3</td>
<td>4</td>
<td>20</td>
<td>1.2</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>Carpentier-Edwards pericardial 25</td>
<td>26</td>
<td>71</td>
<td>0.9</td>
<td>2</td>
<td>20</td>
<td>1.3</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Carpentier-Edwards pericardial 25</td>
<td>26</td>
<td>17</td>
<td>1.8</td>
<td>4</td>
<td>16</td>
<td>1.3</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>Carpentier-Edwards pericardial 23</td>
<td>26</td>
<td>64</td>
<td>0.5</td>
<td>1</td>
<td>22</td>
<td>1.2</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Carpentier-Edwards pericardial 23</td>
<td>26</td>
<td>40</td>
<td>0.9</td>
<td>0</td>
<td>9</td>
<td>2.1</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>St Jude X Cell 25</td>
<td>26</td>
<td>10</td>
<td>2.6</td>
<td>4</td>
<td>10</td>
<td>1.5</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>Homograft 23</td>
<td>29</td>
<td>13</td>
<td>3.4</td>
<td>4</td>
<td>10</td>
<td>2.2</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>Carpentier-Edwards pericardial 25</td>
<td>26</td>
<td>20</td>
<td>2.4</td>
<td>4</td>
<td>10</td>
<td>1.8</td>
<td>1</td>
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<tr>
<td>10</td>
<td>Stentless O’Brien 23</td>
<td>26</td>
<td>9</td>
<td>1.3</td>
<td>4</td>
<td>7</td>
<td>1.6</td>
<td>0</td>
</tr>
</tbody>
</table>

MCS indicates Medtronic CoreValve System; AVA, aortic valve area; and AR, aortic regurgitation.
71 mm to 65 mm and end-systolic left ventricular diameter from 48 mm to 44 mm at day 30). The mean impingement of the CoreValve on the anterior mitral leaflet was 10.6±2.7 (6–14) mm, with neither structural impact nor interaction on its motion or on mitral valve function.

The 30-day TTE confirmed hemodynamic improvement; the measurements were quite similar to predischarge results. Overall, the mean transprosthetic gradient was 14±5 (4–20) mm Hg and the mean prosthetic area was 1.7±0.4 (1.3–2.2)cm².

**Postdischarge Clinical Follow-Up**

Data were obtained in all patients. Median follow-up duration was 150 days, (range, 61—701). Follow-up exceeded 1 year in 2 patients. At last follow-up, there were neither additional adverse nonfatal nor fatal events. All but 1 of the survivors were in NYHA classes I or II (Figure 3). Despite some improvement, patient 9, who was initially in NYHA class IV, remained in class III, in the context of a preexisting left ventricular dysfunction.

**Discussion**

During the last few years, TAVI has emerged as a promising alternative to surgical AVR for high-risk patients with severe, symptomatic AS.14–22 The technique has recently been proposed in patients with SP failure,23–31 mostly using a transapical approach with the balloon expandable valve prostheses.29,32–40 To the best of our knowledge, this study reports the largest series of transarterial valve-in-valve implantation, using MCS for failed SP in high-risk patients.

Our results suggest the feasibility of such an approach, with a high procedural success rate, immediate hemodynamic improvement, and acceptable clinical outcomes, taking into account the very high risk of the patients. However, it does not allow conclusion that the results were better than those that might have been obtained with reoperation.

The MCS was successfully implanted in all the patients, comparing favorably with previous series.30,31 Although no direct comparison can be made, the gradients appeared to be lower in the present series.31 The only hospital death occurred in the context of end-stage renal failure requiring dialysis before TAVI and was not procedure-related. One stroke occurred in a patient for whom the transfemoral approach was the only option; today, direct transaortic access might also be discussed in this case. The only mild to moderate paravalvular leak occurred in the patient with a severely calcified failed homograft, reproducing the anatomy of a native aortic valve. This may be explained by the homogeneous apposition of the prosthesis on the circular sewing ring of the SP.31 Permanent pacemaking was needed in 1 patient with preexistent right bundle-branch block. It has been suggested that the risk of complete atrioventricular block may be decreased after valve-in-valve implantations, as compared with standard TAVI in native valves, because of the potential protection of the septal conduction tissue by the prosthesis ring. Additionally, post-discharge outcome was satisfactory, with dramatic functional improvement in most survivors. Neither adverse clinical events nor functional deterioration were observed at the last follow-up.

We decided to favor transarterial access over transapical because the procedure is less invasive and now possible under local anesthesia. Interesting characteristics of MCS in this indication may be (1) to offer sufficient safety for adequate positioning, due to the progressive prosthesis delivery and the possibility of readjusting placement during the first steps of deployment; (2) to allow treatment of all sorts of SP, including stentless and regurgitant, poorly calcified SP, due to its large anchorage zone. The role of rapid pacing should be emphasized for these latter situations, to increase the safety and precision of deployment, (3) to draw advantages from the supra-annular position of the leaflets, allowing better hemodynamic results than those obtained by a valve constricted within the inextensible ring of the SP. Predilation has previously been performed in a few cases but should be avoided because of the risk of fracture and embolization of the calcified failed leaflets, potentially leading to stroke or massive regurgitation.31,34

**Future Challenges**

Standardization of transcatheter valve-in-valve implantation represents a difficult issue because of the large variety of surgically implanted bioprostheses available. The feasibility of such procedures has been suggested by the current experience but must be confirmed. The development of transcatheter heart valves specifically dedicated to valve-in-valve implantation will be required to achieve optimal performances, particularly in small bioprostheses (≤21 mm). In our series, we had neither coronary obstruction nor peripheral embolic events, but this may remain an open issue. Further clinical validations and in vitro experiments are required to state the optimal sizing for different brands and sizes of SP.
Finally, the most important issue is the long-term outcome, which remains to be determined.

Limitations

This is a small, single-center, observational study, which did not aim to demonstrate any superiority in outcomes compared with surgical replacement for patients with degenerated SP. However, it represents the largest series in this indication with the use of the MCS.

Conclusion

The present results suggest that transarterial MCS implantation in degenerated aortic SP is feasible and may lead to hemodynamic and clinical improvement. However, these data are preliminary and will require further confirmation by larger series and longer follow-up. If mid- and long-term outcomes remain favorable, this will have important clinical implications for treatment strategies of AS in high-risk patients.

Disclosures

Dr Himbert is a proctor for Edwards Lifesciences and Medtronic Inc; Dr Vahanian received speaker’s fees from Edwards Lifesciences and Medtronic Inc; Dr Iung received speaker’s fees from Edwards Lifesciences and Medtronic Inc; Dr Nataf is a proctor for Medtronic Inc; Dr Himbert is a proctor for Edwards Lifesciences and Medtronic Inc; and Dr Nataf is a proctor for Medtronic Inc.

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