Progress and Current Status of Percutaneous Aortic Valve Replacement: Results of Three Device Generations of the CoreValve Revalving System

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Background—Percutaneous aortic valve replacement is a new emerging technology for interventional treatment of severe aortic valve stenosis in surgical high-risk patients. This study was intended to provide a summary of the development and current safety and efficacy status of the self-expanding CoreValve Revalving prosthesis.

Method and Results—Between 2005 and 2008, we have enrolled 136 consecutive patients with percutaneous aortic valve replacement using the CoreValve prosthesis. In this prospective nonrandomized, single-center trial, we analyzed procedural outcome, complications and clinical status up to 1 year. First, second, and third generation of the CoreValve prosthesis were implanted in 10, 24, and 102 consecutive high-risk patients (logistic EuroScore: 23.1±15.0%) with severe symptomatic aortic valve stenosis. Mean transvalvular pressure gradient was 41.5±16.7 mm Hg. The procedural success rate increased from generation 1/2 to 3 from 70.0%/70.8% to 91.2% (P=0.003). The 30-day combined rate of death/stroke/myocardial infarction was 40.0%/20.8%/14.7% (P=0.11) for generation 1, 2, and 3, with no procedural death in generation 3. Pressure gradients improved significantly with a final mean gradient of 8.1±3.8 mm Hg. Overall functional status assessed by New York Heart Association class improved from 3.3±0.5 (pre) to 1.7±0.7 (post) (P<0.001) and remained stable in the follow-up.

Conclusion—In experienced hands, percutaneous aortic valve replacement with the CoreValve system for selected patients with severe aortic valve stenosis has a high acute success rate associated with a low periprocedural mortality/stroke rate as well as remarkable clinical and hemodynamic improvements, which persist over time. Additional studies are now required to confirm these findings, particularly head-to-head comparisons with surgical valve replacement in different risk populations. (Circ Cardiovasc Intervent. 2008;1:167-175.)

Key Words: aortic valve disease ■ aortic stenosis ■ valve prosthesis ■ percutaneous approach

Surgical aortic valve replacement is the reference treatment standard for patients with symptomatic severe aortic valve stenosis. Despite the fact that the prognosis with medical management is poor, many patients do not undergo surgery because of an increased anticipated operative risk, driven by comorbidities such as severe obstructive pulmonary disease, porcelain aorta, etc.1–3 The results with balloon aortic valvuloplasty are beneficial in the acute phase with clinical improvements, but unfortunately only palliative and short lived.4–6 Percutaneous aortic valve replacement (PAVR) using stent-based prostheses has emerged as a promising new option in recent years and has been used by number of operators in different centers with incremental success in line with procedural experience.7–16 This has sparked the evolution of more sophisticated techniques ranging from the initial anterograde approach to gain access via the venous system with transseptal puncture, to the currently used retrograde approach using arterial access. The technology has significantly improved over the years, with the development of delivery catheters with smaller profiles and better prostheses with various size options. Presently, 2 different techniques are commercially available: the balloon-expandable Cribier-Edwards or Edwards SAPIEN prosthesis (Edwards Lifesciences, Irvine, Calif) and the CoreValve Revalving prosthesis (CoreValve, Inc, Irvine, Calif). Both devices have been described in detail in previous publications.11–16 Since their clinical introduction about 3 to 5 years ago, >2500 patients have now been treated with one of these devices with almost exponentially increasing numbers in the past 18 months.

In this article, we report the procedural and 12 months follow-up experience with 3 generations of the self-expanding CoreValve Revalving aortic valve prosthesis consecutively implanted in a single high-volume center. Of particular interest is the outcome of the 18F generation device.
that is presently the commercially available product and the comparison of this device with the previous generations. Multicenter results for generations 1 and 2 have already been reported by our group.14,16

Methods

Study Design and Patient Population

Between February 2005 and March 2008, a total of 136 consecutive patients with PAVR using the CoreValve Revalving device were included in this nonrandomized prospective clinical trial. The device generations used were generation 1 (25F) in 10 patients, generation 2 (21F) in 24 patients, and the current generation 3 (18F) in 102 patients.

Inclusion criteria were the following: (I) severe native aortic valve stenosis with an valve area <1 cm², with or without aortic valve regurgitation and (1) age ≥80 years or a logistic EuroSCORE ≥20% for the 25/21F group and age ≥75 years or logistic EuroSCORE ≥15% for 18F group, respectively; or (2) age ≥65 years with EuroSCORE ≥15% and at least one of the following complicating criteria: cirrhosis of liver, pulmonary insufficiency (FEV1 <1 L), previous cardiac surgery, pulmonary hypertension >60 mm Hg, porcelain aorta, recurrent pulmonary embolus, right ventricular insufficiency. (II) Echocardiographic aortic valve annulus diameter ≥20 mm and ≤27 mm; (III) diameter of the ascending aorta ≤45 mm at the sino-tubular junction.

Preinterventional patient screening included transthoracic as well as transesophageal echocardiography to confirm diagnosis, duplex ultrasonography to assess the access site, multislice computer tomography to assess aortic and aortic valve dimensions and morphology (grade and distribution of calcifications, annulus dimension in a multiplanar reconstruction, measuring from hinge point to hinge point) as well as the access, and invasive cardiac evaluation with coronary angiogram, supra-aortic angiogram and left ventriculography. The baseline operative risk of the patients was estimated by the logistic EuroSCORE as well as the Society of Thoracic Surgeons (STS) score. The patient was considered high risk if the inclusion criteria were met as confirmed by an independent senior cardiologist and senior cardiac surgeon.

Aim of the Study

The purpose of the clinical trial reported here was to demonstrate the progress among the various CoreValve Revalving device generations and to evaluate the current feasibility, safety, and efficacy status up to 12 months postimplantation, particularly of the third generation 18F CoreValve Revalving prosthesis compared with device generations 1 (25F) and 2 (21F) based on the data from an experienced high-volume center.

Device Description

Design characteristics of the self-expanding CoreValve Revalving prosthesis as well as the procedural characteristics have been described previously in detail.13,15 Briefly, the CoreValve prosthesis consists of a trileaflet bioprosthetic porcine pericardial tissue valve, which is mounted and sutured in a self-expanding nitinol stent frame (Figure 1). The lower portion of the prosthesis has high radial force to expand and exclude the calcified leaflets and to avoid recoil. The middle portion is constrained to avoid the coronary arteries, whereas the upper portion is flared to center and fix the stent frame firmly in the ascending aorta and to provide longitudinal stability and coaxial positioning. The sizes of 3 subsequently developed delivery systems have been gradually reduced from 25F to 18F over time to facilitate vascular access and deployment of the device. With generation 3 (18F), there are 2 different device sizes available for different annulus dimensions: the 26-mm prosthesis for aortic valve annulus sizes from 20 to 24 mm and the 29 mm prosthesis for aortic valve annulus sizes from 24 to 27 mm.

Procedure and Adjunctive Medication

Pretreatment included aspirin (100 mg/d, indefinitely) and clopidogrel (600 mg loading dose followed by 75 mg/d for 6 to 12 months) orally at least 1 day before the procedure. Heparin was administered according to the patient’s weight to achieve an activated clotting time >250 s. In the initial series with generations 1, 2, and the beginning of generation 3, the procedure was performed under general anesthesia whereas later in the study local anesthesia combined with a mild systemic sedative/analgescic medication was sufficient. Vascular access was obtained initially with standard surgical cut down of the common iliac artery or the subclavian artery. With introduction of the smaller generation 3, the common femoral artery was the predominant access site with standard percutaneous access techniques and percutaneous closure using a preloaded Prostar XL suture device (Abbott Vascular, Abbott Park, Ill).

After predilation, the prosthesis was deployed and implanted retrogradely within the aortic annulus over a stiff guide wire (Figure 2). Postdilatation of the CoreValve prosthesis was performed at the discretion of the operator depending on the perceived proper placement of the device angiographically and the aortic regurgitation grade. Clinical and echocardiographic follow-up was performed postprocedurally, at hospital discharge, 30 days, 6 and 12 months after device implantation. Routine postprocedural measurement of creatine kinase/creatine kinase-myocardial band was performed to

Figure 1. First generation (25F compatible, left) and third generation (18F compatible, right) of the CoreValve Revalving prosthesis.
detect myocardial ischemia. All patients provided written, informed consent before the procedure.

**Definitions**

Device success was defined as stable device placement and adequate function in the first attempt as assessed by angiography and echocardiography. Acute procedural success was defined as device success with absence of periprocedural major adverse cardiovascular and cerebral events including cardiac tamponade in the first 24 hours after device implantation. Major adverse cardiovascular and cerebral events consisted of death from any cause, myocardial infarction (creatine kinase-myocardial band \( >2 \times \) the upper limit of normal), and stroke (as assessed by routine neurological assessment before and after procedure and before hospital discharge). Clinical adverse events were adjudicated by an independent clinical events committee.

**Statistical Analysis**

Categorical variables are presented as frequencies and were compared by \( \chi^2 \) test or Fisher exact test. Continuous variables are presented as mean ± standard deviation. A 2-tailed unpaired Student \( t \) test for comparison of continuous data between groups and a paired Student \( t \) test for intragroup comparison was used. Ordinal variables were compared with the Mann-Whitney \( U \) test. A probability value of \( <0.05 \) was considered statistically significant. Analyses were conducted with SPSS version 13.0 (SPSS, Inc, Chicago, Ill). The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agreed to the manuscript as written.

**Results**

**Patient Population**

A total of 136 patients with a mean age of 81.5±6.9 years were included in the study. Detailed baseline patient characteristics are listed in Table 1. All patients had severe symptomatic aortic valve stenosis (mean transvalvular pressure gradient 41.5±16.7 mm Hg; mean calculated aortic valve area \( 0.67±0.9 \text{ cm}^2 \)). There were no differences in these baseline echo characteristics between the 3 study groups except more patients with renal insufficiency in the 18F...
Table 3. 18F—In-Hospital Mortality Group: Patient Details

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yr)</th>
<th>EuroScore (%)</th>
<th>Ejection Fraction (%)</th>
<th>Duration After Procedure</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>92.7</td>
<td>17</td>
<td>12.3</td>
<td>Day 8</td>
<td>Tamponade—surgery—heart failure</td>
</tr>
<tr>
<td>2</td>
<td>81.3</td>
<td>43.5</td>
<td>11.5</td>
<td>Day 8</td>
<td>Right heart failure</td>
</tr>
<tr>
<td>3</td>
<td>70.2</td>
<td>6.8</td>
<td>12.3</td>
<td>Day 9</td>
<td>Tamponade—surgery—multiorgan failure</td>
</tr>
<tr>
<td>4</td>
<td>76.7</td>
<td>50</td>
<td>8.9</td>
<td>Day 11</td>
<td>Right heart failure</td>
</tr>
<tr>
<td>5*</td>
<td>71.9</td>
<td>3.3</td>
<td>2.2</td>
<td>Day 15</td>
<td>Pneumonia—sepsis</td>
</tr>
<tr>
<td>6</td>
<td>77.7</td>
<td>6.6</td>
<td>5.4</td>
<td>Day 18</td>
<td>Mesenteric infarction</td>
</tr>
<tr>
<td>7</td>
<td>85.5</td>
<td>27.8</td>
<td>7.0</td>
<td>Day 18</td>
<td>Pneumonia</td>
</tr>
<tr>
<td>8</td>
<td>82.3</td>
<td>83</td>
<td>14.2</td>
<td>Day 19</td>
<td>Heart failure</td>
</tr>
<tr>
<td>9</td>
<td>78.8</td>
<td>30.1</td>
<td>15</td>
<td>Day 28</td>
<td>Heart failure</td>
</tr>
<tr>
<td>10</td>
<td>85.2</td>
<td>22.1</td>
<td>6.2</td>
<td>Day 30</td>
<td>Right heart failure</td>
</tr>
</tbody>
</table>

*Patient with porcelain aorta.
resuscitation the patient died on day 11 in progressive right heart failure with liver failure, renal insufficiency, and sepsis. Another patient presented a priori in a highly critical clinical state with decompensation and cardiac arrest with successful resuscitation the day before referral to our hospital. On day of admission, we performed a balloon valvuloplasty to stabilize the patient without significant clinical changes and, therefore, implanted the CoreValve prosthesis to offer a curative method the day after with still critical conditions. However, the patient never recovered and died on day 19. One patient underwent an uneventful procedure with a good hemodynamic result, but had a ventilation requiring respiratory failure due to global decompensation on day 7. Without evidence of device failure the patient died 7 days later in a low-output syndrome. The last patient presented with a severe pulmonary hypertension (systolic pulmonary artery pressure of >90 mm Hg) in addition to the aortic valve stenosis. Therefore, the procedure was performed in general anesthesia because pulmonary problems were expected given this comorbid condition. After the procedure, the patient remained respirator dependent and died on day 30 in right heart failure.

The need for permanent pacemaker implantations after PAVR including both procedure-related atrioventricular blocks as well as medication-related bradycardias in the presence of structural heart disease was observed in 10.0%/13.6%/33.3% of generation 1/2/3 cases, respectively.

Follow-Up Clinical Results

Follow-up clinical results are listed in Table 4. The overall mortality and major adverse cardiovascular and cerebral events (MACCE) rate at 30 days were 40%/8.3%/10.8% and 40.0%/20.8%/14.7% in the generation 1/2/3 groups, respectively. Overall functional status assessed by New York Heart Association class improved from 3.3±0.5 preprocedure to 1.7±0.7 postvalve implantation (P<0.001) without differences between the groups. Over a period of 12 months, the functional status remained stable in all 3 study groups. Beyond the 30-day follow-up, additional 8 deaths occurred, 3 in the 21F group and 5 in the 18F group. None of these were related to device dysfunction. There were no other late major adverse events reported in all 3 study groups (Figures 3 and 4).

Echocardiographic Results

In case of a successful device implantation, the mean pressure gradient decreased in the 18F group significantly from 41.6±16.4 mm Hg (pre) to 8.1±3.8 mm Hg (post) (P<0.001), and remained stable over the 12-month follow-up period. These effects were observed in generation 1 and generation 2 series as well, without significant differences between the groups or between the follow-up examinations in each group (Figure 5).

In 94 patients (69.2%), aortic regurgitation grade remained unchanged or even reduced postprocedure. In contrast, a worsening of the preinterventional aortic regurgitation grade after the procedure was observed in 33 patients (26%), mainly grade 0 to 1+ to 2+ or 1+ to 2+ (Figure 6). There were only 2 patients with worsened aortic regurgitation to grade 3+, which resolved over time with medical treatment in one patient, the other patient underwent interventional implantation of an AM- PLATZER vascular plug (AGA medical, Plymouth, Minn) in the paravalvular leak with successful reduction of aortic regurgitation to grade 1+ 2 months after the initial procedure. All of the observed cases with aortic regurgitation after CoreValve implantation were related to paravalvular leakages as determined by echocardiography. Severe postprocedural aortic regurgitation (4+) was not present in any patient at either short- or midterm follow-up.

Discussion

This study reports the largest single-center experience with the CoreValve Revalving prosthesis for PAVR, which has been published so far. The current status of the 18F prosthesis in comparison
with the previous generations with respect to feasibility, safety, and efficacy will be discussed in the following paragraphs.

Feasibility
Today, PAVR using the 18F CoreValve prosthesis is feasible and reliable in experienced hands with a high acute device success rate of about 97%. This is certainly related to an improved screening process on the one hand, which is crucial to identify suitable valvular and vessel morphologies. On the other hand, this reflects better device properties due to a reduced profile size as well as improved operator skills with growing knowledge on how to use the technique, where to deploy the device, and which landmarks are helpful to identify the correct landing zone (eg, calcifications of noncoronary cusp).

Multiple studies are currently ongoing to identify and scientifically validate screening tools to identify morphologically suitable patients. Multislice computer tomography assessment of the ventricle, aortic root, annulus, and aorta to femoral arteries is presently the most valuable method for screening patients. Factors that currently make the patients poor candidates for percutaneous implantation of the CoreValve prosthesis are femoral and iliac arteries <6 mm in diameter, severe kinking, and calcifications of the arterial course through which the valve has to pass, ventricles that are too horizontal when compared with the aortic root and annulus sizes that are too small or large. Calcification degrees and patterns of the aortic valve itself and their influence on success rates and outcome are currently subject for multiple ongoing studies.

The procedural learning curve over the past 3 years included the development of specific deployment techniques as well as various interventional bail-out strategies to deal with suboptimal initial PAVR results. The “step-deployment” technique, ie, temporarily halting device deployment after releasing the distal two third of the device (Figure 2) to ensure correct placement as opposed to rapid release of the entire
prosthesis, allows normal blood flow as the prosthetic valve is already functioning while still having the option to pull the prosthesis either slightly for fine adjustments, or even completely to retract and remove the device. Postdilation using larger balloons can be used to increase the expansion of the prosthesis in case of paravalvular leakages or restriction of the outward expansion in the lower part of the prosthesis due to high radial inward forces from the native valve. Implantation of a second prosthesis within the first in case of suboptimal implantation of the first prosthesis too low within the native valve area can be performed and was safely done in 3 patients of the current 18F series with good hemodynamic results as assessed by angiogram and echocardiography. If the prosthesis is implanted slightly too deep toward the ventricular site, gentle pulling using a standard snare is another option for fine adjustments (used in 6 cases of the 18F series).

All these techniques as well as the ability to identify the right indication of using any of the above obviously require experienced operators and adequate logistics. Therefore, a rigorous training program is in place for new and existing sites to maintain these standards.

Safety

PAVR has been introduced to offer a safe treatment option for candidates in whom surgical aortic valve replacement is considered not to be safe, balancing perioperative operative risk versus the natural course of the disease/medical treatment. Therefore, mortality is the key safety parameter in all present PAVR studies. In our series, the periprocedural mortality decreased from 10% and 8% for the 25 F and 21F groups, which is in line with the previous publications on generations 1 and 2 CoreValve implantations\textsuperscript{15,16} to 0% for the 18F group, with a 30 day mortality of 9.8%. Given a highly comorbid population with a logistic EuroScore around 20% in all 3 groups, this result for procedural mortality is certainly remarkable and promising. The accuracy of risk predictor scores such as the popular EuroScore is certainly controversial, probably overestimating risk given recent advances in modern cardiovascular surgery. However, 0% periprocedural mortality as well as a one-digit 30-day mortality in this high-risk population indicates that PAVR is a safe and beneficial treatment modality for this patient population.

Reasons for death in the 30-day follow-up period in the 18F series were mainly related to comorbidities with only 2 events directly procedure-related caused by periprocedural tamponades. Tamponade due to myocardial perforation with the guide wire or a pacemaker lead, observed in this study and reported by other groups as well, is certainly a dangerous but fairly rare event the operator should be aware of. To avoid
wire perforations, meticulous wire tip control in the ventricle is mandatory. During the course of the presently reported PAVR series, a manually shaped pigtail like wire tip has been identified to be less traumatic. This preshaping is now mandatorily implemented in the implantation process here-with successfully reducing the risk for myocardial perforations and subsequent tamponades.

Periprocedural strokes, initially observed in about 10% of patients with the first generations in our series and previously published series, is now around 3% with the 18F device, including 2% minor events. The successful reduction of these adverse events is potentially related to the profile reduction from 25F to 18F, which markedly facilitated the passage of the aortic arch as well as the insertability within the stenosed native valve.

The need for pacemaker implantations for treatment of AV conduction disturbances or postprocedural bradycardias, both procedure and medication related, increased from generations 1 to 3 in our center. This is certainly in parts related to our current local less restrictive implantation policy in case of any signs of imminent conduction problems. For instance, several patients received a permanent pacemaker already on the day of the PAVR procedure or the day after if there was any kind of documentation of a high-degree AV block or bradycardia related to slow atrial fibrillation in the first 2 to 6 hours after PAVR. In contrast, a more restrictive policy with a 48-hour period with a temporary pacemaker in place to give time for recovery has been followed in the beginning and is practice in other sites with comparable safety rates but lower rates of permanent pacemaker implantations. Reason for the policy change in our center was the intention to avoid complications more typically related to temporary pacing, such as fatal risk of lead dislocation in pacemaker-dependent patients.

Development of AV blocks after aortic valve interventions of any kind, either surgical replacement or percutaneous balloon valvuloplasty or percutaneous aortic valve implantations is a known risk given the proximity of atrio-ventricular conduction bundles and the aortic annulus/left ventricular outflow tract. Subtracting the cases with implantation of pacemakers due to nonprocedure-related bradycardias (medication related), the risk of directly PAVR-related pacemaker implantations still appears slightly higher compared with surgical series with a reported pacemaker rate of 3.2% to 8.5%. Whether one PAVR method is more likely to cause atrio-ventricular conduction disturbances than the other is presently unclear. The fact is that this is usually a benign and well-controlled event given the current practice of mandatory periprocedural temporary pacemaker backup for 48 hours in all PAVR patients.

If the patient is event-free up to 30-day follow-up, the short and midterm adverse event rate up to 12 months is promising given the high-risk patient characteristics with an average age of 82 years in association with multiple comorbidities. There were no late adverse device-related events in this period in our trial.

Efficacy

Once the CoreValve Revalving prosthesis is successfully implanted, the hemodynamic status improves immediately, and this applies to all 3 device generations. Any preprocedural gradient can be reliably reduced to a typical mean pressure gradient of around 8 to 10 mm Hg with the device in place. Postprocedural mild aortic regurgitation is common, probably related to incomplete coverage of native valve commissures particularly in cases with compact focal calcifications. However, there were only 2 cases with a higher grade aortic regurgitation (3+) after device placement at the end of the procedure observed in our 18F series, which improved over time with medical or interventional treatment. Strategies to deal periprocedurally with regurgitations are described above including postdilations using large balloons or snare utilization to adjust device placement. Implantation of a second prosthesis within a suboptimally implanted prosthesis is another option to improve the outcome but should be considered only a bail-out concept not just due to the technical challenges but also due to effects such as unpredictable coronary access given 2 overlying nitinol net frames.

At follow-up, initially achieved benefits persisted over time. There were no events of late acquired significant paravalvular or valvular regurgitations or late increase of valvular gradients in any of the 3 study groups.

Overall, the comparison of the CoreValve generations presented herein demonstrates that there was a learning curve for both engineers and clinicians. Comparing the first and second generation experience with the current device, which is commercially available, a remarkable reduction of periprocedural complications is detectable resulting in a higher procedural success rate and an improved midterm outcome. Given the smaller catheter size of 18F, there is no need for hemodynamic support, general anesthesia, or surgical support. The implantation is now solely guided by fluoroscopy with occasional contrast injections without additional visualization measures such as transesophageal echocardiography. This makes this procedure very tolerable for the patient, and reduces the procedure time to <45 minutes in experienced hands.

Study Limitations

The present study is a nonrandomized, single-center experience. Future studies are planned with conventional surgical as well as medical treatment arms as control. Follow-up of the patients is presently ongoing, so there was incomplete availability of midterm clinical and echocardiographic follow-up results particularly in the 18F group. Finally, the results to date also only apply to a high risk patient population as enrolled in this study. There are presently no data for patients with a standard low surgical risk profile.

Conclusion

PAVR with the CoreValve Revalving system for selected patients with severe aortic valve stenosis is associated with a very high acute success rate, with a comparably low acute and 30-day mortality and stroke rate as well as remarkable clinical and hemodynamic improvements, which persist over time. Additional studies are now required including head-to-head comparisons with surgical valve replacement in different risk populations and studies evaluating the suitability of
this device for patients who have predominant aortic regurgitation. Of utmost importance is the enforcement of a rigorous training program for new and existing sites to continuously maintain and improve standards in what is evolving into a rapidly expanding and promising field of interventional cardiology.

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Disclosures
Eberhard Grube is consultant to CoreValve. Ulrich Gerckens is clinical proctor for CoreValve. The other authors have nothing to disclose in relation to this article.

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