TAVI Using the CoreValve Revalving System

An update on device data and the latest trial findings.

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Degenerative aortic stenosis is a progressive disease that affects 2% to 5% of the population who are older than 75 years.[1,2] The pathogenesis of aortic stenosis relates to the progressive fibrosis and calcification of the aortic valve leaflets. Calcification of the valve begins at the bases and progresses into the sinus of Valsalva, leading to severe limitation of the mobility of the aortic valve (Figure 1). Although many patients remain asymptomatic until the aortic valvular narrowing has become severe, the prognosis changes dramatically when the cardinal symptoms of chest pain, shortness of breath, or syncope develop.[3] Surgical aortic valve replacement (SAVR) remains the preferred treatment for symptomatic patients with severe aortic stenosis.[4] More than 70,000 aortic valve replacements are performed in the United States each year, with excellent outcomes in many elderly patients.

Despite favorable surgical outcomes in most elderly patients, approximately 10% of patients undergoing SAVR have an estimated 30-day mortality rate of approximately 13.3% (range, 8.38%–46.8%) based on conventional risk-scoring systems.[5] These so-called high-risk patients often have significant comorbidities that limit their chance for survival, such as obstructive pulmonary disease, renal insufficiency, liver disease, reduced left ventricular function, or previous coronary artery bypass surgery or chest wall radiation. It is also estimated that an additional 33% of patients are judged to have prohibitive surgical risk by their primary care physicians or general cardiologists and are not even offered SAVR.[6] A number of risk scores have been used to predict the risks for patients undergoing consideration for SAVR. The logistic EuroSCORE tends to overestimate the surgical risk (by up to a factor of 3),[7] and the Society for Thoracic Surgery risk score tends to slightly underestimate procedural risk.[5] In addition, these conventional risk scores do not account for a number of

Figure 1. A calcific aortic valve with thickening of the leaflets and calcified deposits at the bases.

TABLE 1. MATRIX FOR COREVALVE IMPLANTATION

Elements Below Reflect Indications for Use According to the CE Mark								
Diagnostic Findings	**Noninvasive**		**Angiography**				**Selection Criteria**	
	Echo	CT/MRI	LV	Ao Root	CAG	Vascular	Recommended	Not Recommended
Atrial or ventricular thrombus	x						Not present	Present
Subaortic stenosis	x	x	x				Not present	Present
LV ejection fraction	x		x				≥ 20%	< 20% without contractile reserve
Mitral regurgitation	x						≤ Grade 2	> Grade 2 organic reason
Vascular access diameter		x				x	≥ 6-mm diameter	< 6-mm diameter
Aortic and vascular disease		x				x	None to moderate	Severe vascular disease
Indications for 26-mm CoreValve Device								
Annulus diameter	x	x					20-23 mm	< 20 mm or > 23 mm
Ascending aorta diameter		x		x			≤ 40 mm	> 40 mm
Indications for 29-mm CoreValve Device								
Annulus diameter	x	x					23-27 mm	< 23 mm or > 27 mm
Ascending aorta diameter		x		x			≤ 43 mm	> 43 mm
General Medical Guidance for Use of CoreValve[a]								
Diagnostic Findings	**Noninvasive**		**Angiography**				**Selection Criteria**	
	Echo	CT/MRI	LV	Ao Root	CAG	Vascular	Recommended	Moderate–High Risk
LV hypertrophy	x	x					Normal to moderate 0.6–1.6 cm	Severe ≥ 1.7 cm
Coronary artery disease		x			x		None, mid, or distal > 70%	Proximal lesions > 70%
Aortic arch angulation		x				x	Large radial turn	Sharp turn
Aortic root angulation		x				x	< 30°	30 - 45°
Aortic and vascular disease		x				x	No or light vascular disease	Moderate vascular disease
Vascular access diameter		x				x	> 6 mm	Calcified and tortuous < 7 mm
Anatomic Considerations for 26-mm CoreValve Device								
Sinus of Valsalva width	x	x		x			≥ 27 mm	< 27 mm
Sinus of Valsalva height	x	x		x			≥ 15 mm	< 15 mm
Anatomic Considerations for 29-mm CoreValve Device								
Sinus of Valsalva width	x	x		x			≥ 29 mm	< 29 mm
Sinus of Valsalva height	x	x		x			≥ 15 mm	< 15 mm

[a]General medical guidance reflects the experience to date with the product, but final judgment remains with the implanting physician(s). Consult with a certified proctor to determine if your patient is moderate-high risk.

Echo, echocardiography; LV, left ventricle; Ao Root, aortic root.

Reproduced from de Jaegere P, et al. Implantation of the CoreValve Revalving System in Transcatheter Aortic Valve Implantation: Tips and Tricks to Avoid Failure, Eds: Serruys PW, Piazza N, Cribier A, Webb JG, Laborde JC, de Jaegere P. Informa Healthcare 2010, New York.

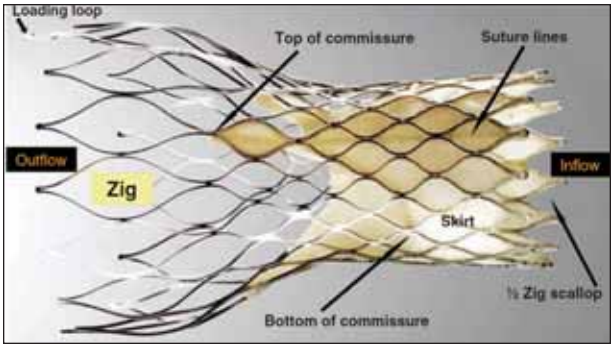

Figure 2. The components of the CoreValve frame. Reproduced from Michiels R, CoreValve Revalving System for Percutaneous Aortic Valve Replacement, In: Transcatheter Aortic Valve Implantation: Tips and Tricks to Avoid Failure. Eds: Serruys PW, et al. Informa Healthcare 2010, New York.

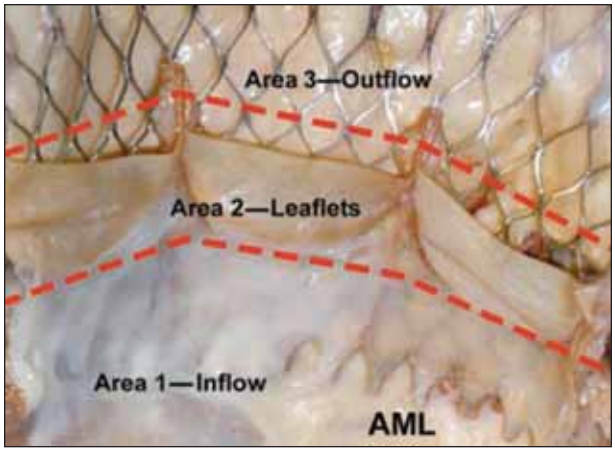

Figure 3. CoreValve frame at 350 days. Gross photograph showing the three areas of the valve and pannus growth extending into the base of the prosthetic leaflets. Reprinted from EuroIntervention, Vol 5, Noble S, et al. Anatomo-pathological analysis after CoreValve revalving system implantation, p. 78-85, 2009, with permission from Europa Edition.

contraindications to conventional SAVR, including porcelain aortas and extreme frailty, as judged by the consulting surgeon.

In these patients who are deemed high risk or inoperable for conventional SAVR, percutaneous aortic valve replacement (PAVR) alternatives have been developed using either balloon-expandable[8] or self-expanding valve[9,10] deployment systems. This article focuses on CoreValve (Medtronic, Inc., Minneapolis, MN) PAVR and its benefits, risks, and potential use as an alternative to SAVR.

THE COREVALVE REVALVING SYSTEM

The CoreValve percutaneous aortic valve is composed of three parts: a self-expanding nitinol support frame with a diamond-cell configuration that anchors a trileaflet porcine pericardial tissue valve, an 18-F delivery catheter, and a disposable loading system. The CoreValve frame is currently available in two sizes: a 26-mm design for aortic annular sizes between 20 and 23 mm and a 29-mm design for aortic annular sizes between 23 and 27 mm.

The multilevel nitinol frame was specifically designed for optimal functionality, stability, and durability (Figure 2). The inflow portion of the frame exerts high radial expansive force to secure the frame within the annular location. The strength of this self-expanding portion of the frame prevents annular recoil, allowing the frame to partially conform to the noncircular shape of the aortic annulus. The constrained center portion of the frame has very high hoop strength that resists size and shape deformation. This is critical because this portion of the frame contains the valve leaflets, which are supra-annular. The center portion of the frame is concave to avoid the coronaries and allows coronary cannulation after implantation. The largest part of the frame is the outflow portion that exerts only low radial forces and primarily serves to orient the frame to the aorta to allow optimal flow through the valve.

Porcine pericardium was selected due to its lower profile (compared with bovine pericardium) and its durability. The trileaflet valve is constructed from six individual pieces of porcine pericardium, with three pieces used to construct a skirt at the inflow section of the valve to prevent aortic regurgitation and three leaflet elements that are constructed with long commissures (similar to a suspension bridge) that more uniformly distribute the aortic pressure load to the valve leaflets and the commissural posts. An angled take-off of the posts further reduces the stress and optimizes leaflet motion.

The ability to maintain functionality in a nonround shape is a critical feature of the CoreValve device. In a series of 30 patients who underwent multislice computed tomography after CoreValve PAVR, the difference between the orthogonal smallest and largest diameters at the ventricular end was 4.4 mm, which decreased progressively toward the outflow.[11] There was incomplete and nonuniform expansion of the CoreValve frame at the inflow, but the functionally important midsegment was well expanded and almost symmetrical.[11] Cine imaging of the CoreValve frame 1 year after PAVR has failed to identify abnormalities in frame integrity, including fractures.[12]

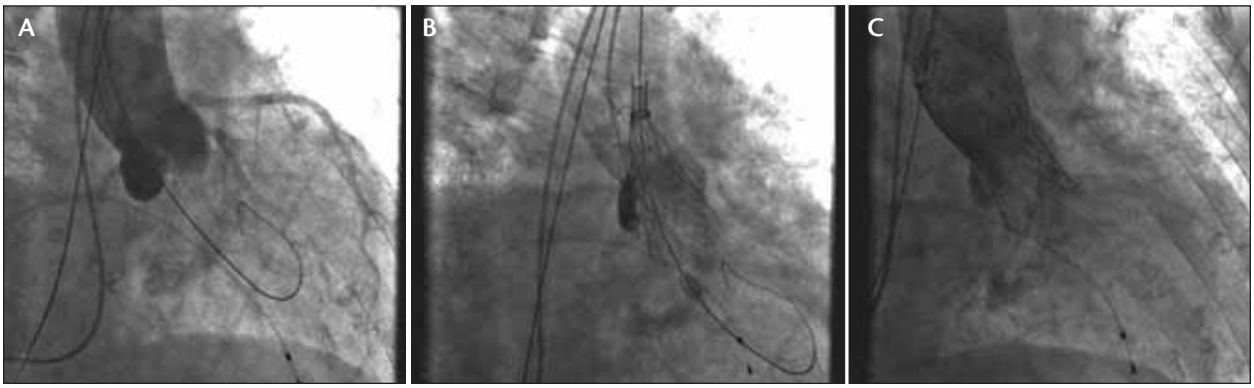

Figure 4. CoreValve (18 F) implantation. Angiography before (A) and after (C) percutaneous aortic valve replacement. Image B shows an intermediate step that allows normal blood flow through functioning prosthetic valve in the lower third of the prosthesis, whereas the upper part is still attached to the catheter. This allows for positioning corrections during the deployment process. Reproduced from Grube E, et al. Progress and current status of percutaneous aortic valve replacement: results of three device generations of the CoreValve revalving system. Circ Cardiovasc Interv. 2008;1:167-175.[9]

ANATOMIC PATHOLOGICAL FINDINGS AFTER COREVALVE IMPLANTATION

Four patients died at 3, 13, 104, and 350 days, respectively, after CoreValve implantation, and macroscopic and microscopic analysis were performed at autopsy.[13] The device was divided into three parts during pathological assessment: the lower portion, leaflets, and upper part. Histopathology examination showed fibrin deposition and inflammatory response early after valve implantation followed by neointimal coverage with progressive regression of the inflammatory response over time.[13] Thrombus adjacent to the frame was noted up to 104 days after implantation. At 350 days, gross examination showed neointimal tissue covering most of the frame struts in contact with the aortic wall, but areas of high-velocity blood flow were bare.[13] There was no excessive pannus formation occurring over the valve leaflets (Figure 3).[13]

PATIENT SELECTION

In patients who are deemed to be at high risk or inoperable for conventional SAVR, CoreValve PAVR has been successful in more than 10,000 patients worldwide. Despite the potential benefits to these patients, a number of anatomic factors may influence the suitability of patients for the CoreValve revalving system. A matrix has been established for the important anatomic features required for successful CoreValve implantation (Table 1).

ALTERNATIVE VASCULAR ACCESS SITES

In patients whose peripheral vascular anatomy is unsuitable for a transfemoral approach, a number of reports have suggested that subclavian (ie, axillary) or transaortic access may be useful.[14-16] In a series of 54 cases treated via the subclavian approach in the Italian National Registry, procedural success was achieved in 100% of cases. There were no specific complications such as vessel rupture or vertebral or internal mammary ischemia associated with subclavian access.[17] There were no deaths at 30 days in this series, and the 6-month mortality rate was 9.4% and was not different from those who underwent a transfemoral approach.[17]

INITIAL CLINICAL SERIES

Between 2005 and 2008, 136 consecutive patients were treated at the Siegburg Heart Center in Siegburg, Germany using first- (n = 10), second- (n = 24), and third-generation (n = 102) versions of the CoreValve prosthesis.[9] All patients were all deemed to be high risk (logistic EuroSCORE, 23.1% ± 15%) with severe, symptomatic aortic valve stenosis (Figure 4). The mean transvalvular pressure gradient was 41.5 ± 16.7 mm Hg. The procedural success rates for first- and second-generation devices were 70% and 70.8% and increased to 91.2% with the third generation (P = .003).[9] The 30-day combined rate of death, stroke, and myocardial infarction was 40%, 20.8%, and 14.7% (P = .11) for generations one, two, and three, respectively, with no procedural death in generation three.[9] Pressure gradients improved significantly, with a final mean gradient of 8.1 ± 3.8 mm Hg. Similar favorable findings have also been reported by others (Figure 5).[18-20]

A multicenter, expanded evaluation registry was established 1 year after CE Mark approval was obtained for marketing of the CoreValve device in Europe.[10] A total of 646 patients with symptomatic, severe aortic stenosis and a logistic EuroSCORE ≥ 15%, age ≥ 75

years, or age ≥ 65 years, as associated with predefined risk factors, were included. Mean age was 81 ± 6.6 years, mean aortic valve area was 0.6 ± 0.2 cm^2, and logistic EuroSCORE was 23.1% ± 13.8%. After valve implantation, the mean transaortic valve gradient decreased from 49.4 ± 13.9 to 3 ± 2 mm Hg. All patients had paravalvular aortic regurgitation ≤ grade 2. The rate of procedural success was 97%. At 30 days, the all-cause mortality rate (including procedural) was 8%, and the combined rate of death, stroke, and myocardial infarction was 9.3%.

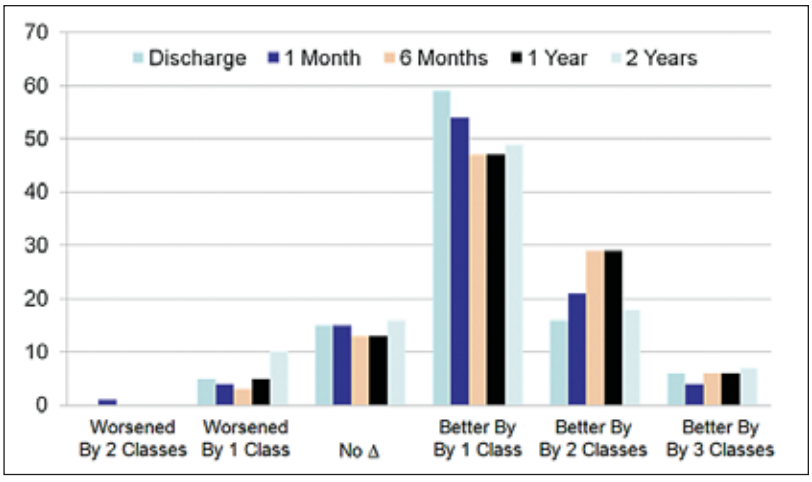

Figure 5. Functional improvement after 2 years with CoreValve PAVR. Adapted from Gerckens U. Presented at: EuroPCR 2010; May 25–28, 2010; Paris, France.[19]

Echocardiographic Findings

In a series of 33 consecutive patients with aortic stenosis who underwent successful PAVR, echocardiography was performed before and after treatment and late (80 days) after discharge.[21] After PAVR, the mean transaortic valve gradient decreased (46 ± 16 mm Hg before treatment, 12 ± 7 mm Hg after treatment, and 9 ± 5 mm Hg after discharge; $P < .001$), and the mean effective orifice area increased (0.75 ± 0.23 cm^2 before treatment, 1.97 ± 0.85 cm^2 after treatment, and 1.72 ± 0.45 cm^2 after discharge; $P < .001$). There was no significant change in mean ejection fraction (41% ± 12% before treatment, 46% ± 15% after treatment, and 44% ± 13% after discharge; $P = .44$).

COMPLICATIONS

Strokes and Transient Ischemic Attacks

The etiology of cerebrovascular events after PAVR likely relates to the embolization of atherothrombotic material during advancement of the device to and across the aortic valve.[22] Microembolization shown via magnetic resonance imaging is common with both balloon-expandable and self-expanding percutaneous valves, as well as with SAVR,[23] but clinical strokes are infrequent (2.9%–5.1%).[9,20] A more inclusive definition of stroke that includes transient ischemic attacks (< 24 hours in duration) with new structural defects on imaging studies may increase the reporting of this complication in contemporary series.[24] Novel embolic protection devices to protect cerebral circulation are under development.

Aortic Regurgitation

Significant aortic regurgitation due to paravalvular leak is uncommon after CoreValve PAVR and primarily relates to low positioning of the CoreValve frame, incomplete expansion of the frame into the eccentrically shaped annulus, rigidity of the underlying aortic annulus due to calcium, or undersizing of the valve relative to the aortic annular size. When the CoreValve frame is underexpanded, postdeployment valvuloplasty may be useful, and when the CoreValve frame is positioned too low after being deployed, retraction of the frame loops using a retrieval snare may allow appropriate positioning within the annulus.[25,26]

Vascular Access Complications

Due to the relatively large-caliber sheath (18 F) required for placement, vascular complications may occur. In a series of 91 consecutive patients treated with TAVI using the 18-F CoreValve system, vascular events were encountered in 13 patients (13%); seven of these cases (54%) were related to incomplete arteriotomy closure with the Prostar device (Abbott Vascular, Santa Clara, CA).[27] Depending on how major vascular complications were defined, the incidence varied from 4% to 13%.[27] Meticulous preprocedural screening using computed tomographic angiography, vascular ultrasound guidance for arterial access,[28] and alternative (eg, subclavian) access have allowed better case selection to avoid vascular complications.

Conduction System Disturbances

AV conduction disturbances and heart block may occur in some patients after CoreValve PAVR.[29] In a series of 30 patients with severe, symptomatic aortic stenosis who underwent CoreValve PAVR, 10 underwent permanent pacemaker implantation during the same admission (33.3%).[30] Permanent pacemaker place-

ment was indicated for prolonged high-grade AV block in four cases, episodic high-grade AV block in five cases, and sinus node disease in one case.[30] The need for a pacemaker was correlated to left axis deviation at baseline (P = .004; r = 0.508) and left bundle-branch block with left axis deviation (P = .002).[30] It was related to diastolic interventricular septal dimension on transthoracic echocardiography > 17 mm (P = .045; r = 0.39) and the baseline thickness of the native noncoronary cusp (P = .002; r = 0.655).[30] Current attention to avoiding septal trauma during balloon valvuloplasty prior to CoreValve implantation and higher CoreValve placements (< 6 mm below the sinus) may decrease the need for permanent pacemakers after CoreValve PAVR.

Coronary Artery Occlusion

Coronary occlusion after CoreValve PAVR is a rare occurrence and is most often due to expansion of the native aortic valve across the orifice of the coronary ostium. Careful preprocedural screening to ensure adequate sinus of Valsalva width (30 mm) and height (15 mm) will minimize this occurrence. Rescue percutaneous coronary intervention can be performed when coronary occlusion occurs.[31]

ONGOING INVESTIGATIONS

Valve-in-Valve

In the first reported valve-in-valve procedure, the CoreValve was used to treat a stenotic 21-mm aortic bioprosthesis with initial success.[32] Other series have reported similar success.[33] One report shows the feasibility of using the balloon-expandable Sapien device (Edwards Lifesciences, Irvine, CA) for CoreValve failure.[34]

United States CoreValve Pivotal Trial

The planned United States CoreValve Pivotal trial will examine the safety and efficacy of the CoreValve revalving system in patients deemed inoperable for SAVR (vs optimal medical therapy including balloon aortic valvuloplasty) and in patients deemed high risk for SAVR (vs conventional AVR). Randomized studies in these patient populations will provide needed information relating to the relative value of surgery, medical therapy, and CoreValve PAVR.

SURTAVI

SURTAVI is a multicenter, randomized clinical study, primarily based in Europe, which will evaluate the safety and efficacy of CoreValve PAVR compared with SAVR in a broader patient population, including those with intermediate risk for SAVR. SURTAVI will use a heart team approach, in which the interventional cardiologist and surgeon will collaborate to determine patient eligibility and inclusion and will randomize patients to PAVR or SAVR. The four principal investigators for the study are Stephan Windecker, Pieter Kappetein, Peter de Jaegere, and Thomas Walther.

> "The ability to perform PAVR has transformed the treatment paradigm in symptomatic patients with severe aortic stenosis . . . "

ADVANCE

The ADVANCE registry is a prospective, observational, international postmarket study that will include 1,000 patients at up to 50 clinical sites where the CoreValve system is commercially available. The primary endpoint of the study is 30-day major adverse cardiac and cerebrovascular events. Patients will be followed for 5 years after the study. The ADVANCE clinical study began enrolling patients in early March 2010.

ADVANCE-II

This multicenter registry will evaluate the best practice outcomes of high-risk and inoperable patients treated with the CoreValve device at seven to 10 experienced European centers. The ADVANCE-II registry will focus on documenting the intermediate-term (up to 1 year) outcomes in these patients and defining best practice event rates including 30-day and 1-year mortality, stroke, vascular complications, aortic regurgitation, and the development of conduction disturbance requiring permanent pacemaker placement. Enrollment will start for this study in the early fall of 2010.

FUTURE PERSPECTIVES

The ability to perform PAVR has transformed the treatment paradigm in symptomatic patients with severe aortic stenosis, particularly in those who are high risk or inoperable for SAVR. Future technical developments will include reducing the device profile, enhancing device positioning and retrievability, and promoting valve durability with anticalcification treatments. When coupled with an expanded evidence base from sound clinical trials, it is likely that PAVR will remain a valuable treatment alternative to SAVR in selected patients with severe aortic stenosis. ■

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