

Percutaneous Aortic Valve Replacement

An update on the current state of the CoreValve device.

**BY EBERHARD GRUBE, MD,
AND DINESH NAIR, MD**

Although symptomatic severe aortic stenosis is a major health burden, many patients do not undergo surgery for a variety of reasons, despite the fact that surgical aortic valve replacement is the reference standard therapy.¹⁻⁵ The prognosis with medical management for this disease is poor,^{4,5} and results with balloon aortic valvuloplasty are unfortunately only palliative and limited by restenosis occurring in the majority of patients at 6 months.^{6,7} Resulting from a need for alternative treatment modalities, percutaneous aortic valve replacement, or more accurately percutaneous aortic valve implantation, utilizing stent-based prostheses has emerged as a viable option in recent years, with reports of incremental success in line with procedural experience in several centers.⁸⁻¹⁷ The techniques involved have evolved rapidly from the initial antegrade approach to gain access via the venous system, to the currently used retrograde approach utilizing arterial access. This development has been coupled with technological advances, with the development of delivery catheters with smaller profiles and better prostheses of different sizes.⁸⁻¹⁷ In this article, we describe the percutaneous implantation of the self-expanding CoreValve aortic valve prosthesis (CoreValve Revalving System, CoreValve, Paris, France).

DEVICE DESCRIPTION AND IMPLANTATION

The CoreValve Prosthesis (CP) consists of a trileaflet bioprosthetic porcine pericardial tissue valve, which is mounted and sutured in a self-expanding nitinol stent (Figure 1). The prosthetic frame/stent is manufactured by a laser-cutting tool and has an overall length of 50 mm. The lower portion of the prosthesis has high radial force to expand against the calcified leaflets and to avoid recoil. The middle portion carries the valve and is constrained and narrower to avoid the coronary arteries, while the upper portion is flared to center and fix the stent firmly in the ascending aorta and to provide longitudinal stability. The device is deployed via a delivery system (Figure 2) into which the valve is loaded shortly before implantation. The CP is manufactured in two sizes, with the smaller prosthesis generally

(Continued on page 28)

(Continued from page 27)

used for aortic annulus sizes ≤ 23 mm. The larger valve fits annulus sizes up to 27 mm in diameter.

The sizes of the CoreValve delivery systems have been gradually reduced over time to allow easier deployment. The first-generation (25-F) and second-generation (21-F) delivery systems required a surgical cutdown under general anesthesia, whereas the current third-generation (18-F) system is deployed percutaneously under mild sedation. Intraprocedural echocardiographic visualization and hemodynamic support are currently not necessary, although they were used in the initial experience with this device. One venous and two arterial access sites are needed for the procedure to allow placement of a temporary pacing wire in the right ventricle (for rapid pacing during valvuloplasty), a pigtail catheter in the aorta, and for deployment of the device in the aortic annulus. A femoral artery is usually chosen for device placement due to the 18-F profile of the catheter. Access via the subclavian artery with a cutdown procedure is possible in cases of inadequate femoral access.

Aspirin, clopidogrel, and heparin are administered as per the usual practice for coronary angioplasty (clopidogrel is usually continued for 6 months postprocedure, whereas aspirin is continued indefinitely). Initially, a 9-F sheath is placed in the arterial access site for the CoreValve system for dilatation of this site. After removal of the 9-F sheath over the wire, the access site is then "preloaded" with two sutures perpendicular to each other in the anterior arterial wall at the entrance orifice with a 10-F, suture-based closure device (Prostar XL, Abbott Vascular, Santa Clara, CA). The sheath is then up-sized to 18 F with the sutures in place, further dilating the orifice and allowing these sutures to be tied to close the arterial access site at the end of the procedure. The pacing wire and pigtail catheter are placed in the right ventricle and the ascending aorta, respectively, and an Amplatz super-stiff wire (ST1), which is manually curved at the tip to reduce trauma, is placed in the left ventricle. Simultaneous pressure measurements are made in the aorta and ventricle before and after the procedure. Balloon valvuloplasty with a balloon appropriate for the aortic annulus size is performed in all cases over the stiff guidewire, with simultaneous rapid ventricular pacing prior to device placement. Rapid pacing is performed at 180 to 220 beats per minute to simulate relative ventricular standstill to allow a stable substrate for dilatation of the balloon within the annulus. The prior valvuloplasty needs to be effective, and therefore repeated if necessary, to allow adequate self-expansion of the nitinol frame within native valve when the CP is deployed.

The CoreValve delivery system is then passed through the 18-F sheath retrogradely within the aortic annulus over the stiff guidewire. The position of the device is checked against the annulus via supra-aortic contrast injection through the

pigtail catheter in the aortic root. The CP is then deployed under fluoroscopic guidance and constant hemodynamic monitoring but without rapid pacing because the flow through the aortic valve is not significantly impaired. Evaluation of postdeployment position and regurgitation is performed using a supra-aortic angiogram. After implantation, dilatation of the CP with a valvuloplasty balloon and repositioning of the CP with a snare device is possible in some cases, at the discretion of the operator, depending upon the perceived proper placement of the device and the aortic regurgitation grade, which are assessed angiographically. Implantation of the CP is shown in Figure 3. Trans-thoracic echocardiography is routinely performed after the procedure and prior to discharge to check the position and function of the CP.

REPORTED STUDIES

The first CP was successfully implanted by our group in February 2005 via a 25-F system.¹⁴ The patient in whom this was performed is currently well at 3-year follow-up. The subsequent first-in-man study done on 25 high-risk patients utilizing 25-F and 21-F delivery systems showed the feasibility



Figure 1. The CP. Porcine valve leaflets are sutured to the frame in a trileaflet configuration. Implantation is intra-annular, but the valve function is supra-annular.

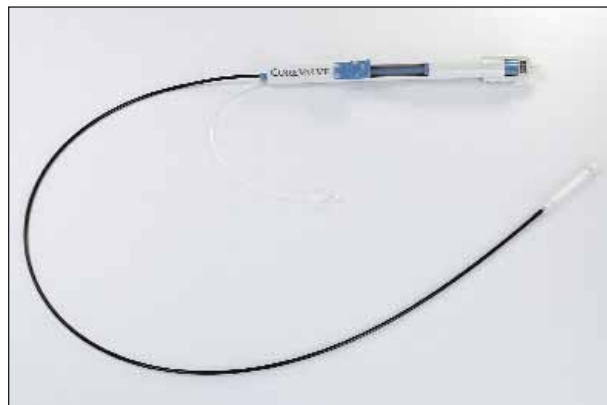


Figure 2. The 18-F over-the-wire delivery system. The CP is mounted at the tip for implantation. The system consists of an 18-F capsule, 12-F shaft, and a loading/releasing handle.

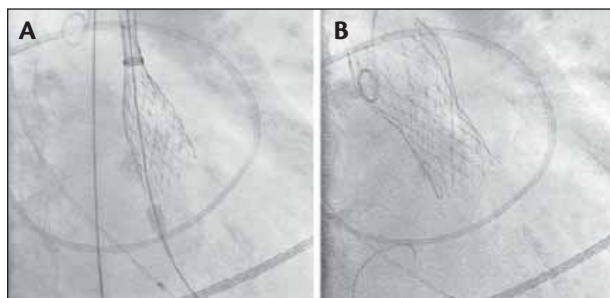


Figure 3. CoreValve implantation. The valve is positioned, and the sheath is retracted to partially release the self-expanding nitinol frame. The prosthesis can be repositioned at this stage (A). The fully deployed valve, with the delivery system and super-stiff wire removed (B).

ty of this procedure and that, when successful, there was marked hemodynamic and clinical improvement.¹⁵ Since then, numerous device modifications have been realized, resulting in the current 18-F device. The third publication by our group referred to the population treated with the 21-F and 18-F devices at three centers.¹⁷ In this study, patients with symptomatic, severe aortic valve stenosis (area <1 cm²) and age ≥80 years with a logistic EuroSCORE ≥20% (21-F group) or age ≥75 years with a logistic EuroSCORE ≥15% (18-F group), or age ≥65 years plus additional prespecified risk factors, were included.^{17,18} A total of 86 patients (21 F, n=50; 18 F, n=36) with a mean valve area of 0.66±0.19 cm² (21 F) and 0.54±0.15 cm² (18 F), a mean age of 81.3±5.2 years (21 F) and 83.4±6.7 years (18 F), and a mean logistic EuroSCORE of 23.4±13.5% (21 F) and 19.1±11.1% (18 F) were recruited.

Acute device success was 88%, and successful device implantation resulted in a marked reduction of aortic transvalvular gradients (mean preprocedural gradient = 43.7 mm Hg vs postprocedural gradient = 9 mm Hg; $P<.001$), with the aortic regurgitation grade remaining unchanged. The acute procedural success rate was 74% (21 F, 78%; 18 F, 69%). Procedural mortality was 6%, overall 30-day mortality was 12%, and the combined rate of death, stroke, and myocardial infarction was 22%. Therefore, the conclusion of this study was that treatment of severe aortic valve stenosis in high-risk patients with percutaneous implantation of the CP was feasible and associated with a lower mortality rate than predicted by risk algorithms.

DISCUSSION

The inclusion and exclusion criteria used for the initial studies were very stringent.^{15,17} However, clinical judgment is often used in borderline cases in the current post-CE mark registry. Presently, only patients deemed to have a high risk for surgery by the cardiothoracic sur-

geons, or those who have declined surgery, are considered for implantation of the CP. These are generally older patients with high preoperative risk. Evaluation of the patient is performed on clinical grounds, as well as by transthoracic echocardiography; transesophageal echocardiography; multislice CT (MSCT) angiography of the heart, aortic valve (including valve calcification grade and distribution), and the course of the aortic root to the femoral arteries; and angiographic assessment of the left ventricle, aortic root, and coronary arteries. Factors that would make the patients poor candidates for percutaneous implantation of the CP are femoral and iliac arteries <6 mm in diameter; severe kinking of the arterial course through which the valve has to pass; annulus sizes that are too small or large; severe calcification of the aortic valve and leaflets on MSCT, which prevents optimal balloon valvuloplasty; or when the angle between the ascending aorta and the ventricle is >70° (the so-called horizontal aorta).

Accurate device deployment of the CP is crucial, as evidenced by the fact that a small number of patients needed additional interventions, either by implantation of a second device or conversion to surgery, because of suboptimal implantation of the first prosthesis either too low or too high within the native valve area. The results to date only apply to the high-risk groups identified, and no control groups were used in these studies to enable head-to-head comparisons with standard therapy. The studies quoted cover a long period during which there were numerous changes in the treatment methods, access methods, supportive measures, delivery devices, wire preparation, and prostheses, and trace a learning curve, with better techniques and results developing toward the latter part of the series.

Overall, the mortality rate in the latest series was lower than the predicted operative risk of using the EuroSCORE risk algorithm.^{17,18} The true value and accuracy of these risk assessment scores are often debated, but these are the standard tools used for outcome stratification in high-risk surgical candidates worldwide. The CoreValve design provides several advantages that facilitate device deployment and reliable implantation: (1) a deployment error margin; (2) self-alignment properties; (3) beneficial anchoring characteristics in native valve area, as well as the ascending aorta; (4) the ability for device retrieval after partial implantation of the first two thirds of the prosthesis; and (5) the self-expanding nature of the nitinol stent, which exerts an outward force contributing to further expansion of the valve and the minimization of paravalvular leaks. The previously mentioned modified deployment technique, as opposed to the rapid complete deployment favored in the beginning of our experience, has been

introduced during the study course. Once the distal two thirds of the prosthesis (Figure 3A) is deployed, the valve is already functioning sufficiently, allowing further device positioning without significant hemodynamic consequences. In our most recent experience, valvular gradients and regurgitation are minimal and often reduce further due to the expansile nature of the nitinol stent and possible recoil of the annulus after dilatation.

Two percutaneous aortic valve replacement devices using the retrograde approach are currently in the market and have available published data.¹⁵⁻¹⁷ These devices are the CoreValve and the Sapien valve (Edwards Lifesciences Inc, Irvine, CA). The Edwards valve system (22-F and 24-F delivery systems) requires a surgical cut-down for arterial access, and the valve is implanted by balloon expansion during rapid ventricular pacing,¹⁶ unlike the CP, which is self-expanding and does not require rapid pacing during implantation. Improvements in design are continuously being made on both of these valves and their delivery systems, making each successive generation more appealing. In addition, promising next-generation retrievable devices are being developed and are undergoing first-in-man studies in our center and at other sites. Such devices include the Sadra or Lotus valve (Sadra Medical Inc, Campbell, CA) and the Direct Flow valve (Direct Flow Medical Inc, Santa Rosa, CA). Both of these devices can be retrieved up to a certain point of their deployment, allowing repositioning of the valve prior to final deployment, thereby reducing the potential need for surgical bailout or deployment of a second prosthesis.

The feasibility of the CoreValve procedure has been demonstrated in the studies mentioned previously, but the long-term durability of these results remains to be seen and will be reported in subsequent publications. Patients do not need to undergo general anesthesia and may be stepped down to general ward care by day 3 in the majority of cases and are able to ambulate soon afterward. Since the last data were published, the number of clinical sites implanting the CP has increased significantly, with the numbers implanted passing the 1,000-patient milestone in May this year. The current CP system is extremely user-friendly, and an uncomplicated procedure can be performed routinely from arterial puncture to closure in less than half an hour in experienced hands. In our center, we have implanted more than 150 CPs to date, with a 98% implantation success rate with the third-generation devices.

CONCLUSION

Percutaneous aortic valve replacement/implantation with the CoreValve Revalving system for selected patients with severe aortic stenosis comes with an impressive success rate, encouraging clinical improvement, and a comparably low

acute and 30-day mortality rate. Long-term data on patients receiving this therapy are currently being collected and analyzed, with the results due soon. Further progress is now needed in implantation technique, device positioning, as well as the device itself. Additional studies are also required to determine the suitability of this device for patients who have predominant aortic regurgitation or who are good candidates for surgical aortic valve replacement. Most importantly, a rigorous training program needs to be enforced for new and existing sites to continuously maintain and improve standards in what is now a truly percutaneous procedure. ■

Eberhard Grube, MD, is from the Heart Center Siegburg, Siegburg, Germany. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. He has disclosed that he is a paid consultant to CoreValve. Dr. Grube may be reached at +49 2241 182322; grubee@aol.com.

Dinesh Nair, MD, is from the Heart Center Siegburg, Siegburg, Germany. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Nair may be reached at +49 2241 182322; dineshnair666@hotmail.com.

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