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First Successful Transapical Aortic Valve Implantation with the Corevalve *Revalving*™ System: A Case Report

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ABSTRACT

On June 26, 2007, the Clinic for Cardiovascular Surgery at the German Heart Center Technical University in Munich successfully implanted a bioprosthetic valve via the apex of the heart within the framework of the CoreValve TAVR ReValving (Corevalve Inc., Irvine, CA, USA) clinical trial. The self-expanding aortic valve prosthesis is primarily designed for retrograde delivery across the aortic valve. The described transapical approach, however, now allows for treatment in those patients who have, for instance, no adequate "access" in the groin vessels due to peripheral vascular disease. Therefore, its feasibility must be considered as a major step in treating high-risk patients.

INTRODUCTION

In patients with symptomatic aortic valvar disease and significant comorbid conditions the operative mortality is high. Therefore, surgery often is declined in these high-risk patients. Transcatheter aortic valve implantation techniques have been developed by different groups. Despite being at an early stage of development, several devices have already been introduced into clinical practice at selected centers. In 2002, Cribier and coworkers [Crieier 2002] performed the first human implantation of a balloon-expandable aortic valve prosthesis. Others have shown that percutaneous implantation of the self-expanding CoreValve aortic valve prosthesis in high-risk patients was feasible and resulted in marked hemodynamic and clinical improvement [Grube 2006]. The CoreValve (Corevalve Inc., Irvine, CA, USA) frame design was designed to simplify the implantation procedure and reduce paravalvular leaks. However, in case of no adequate "access" in the groin vessels due to peripheral vascular disease, or any significant aortic disease such as aneurysm formation, the transapical approach now allows for yet another treatment of those high-risk patients.

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MATERIALS AND METHODS

The 87-year-old patient with an aortic valvar orifice area of 0.3 m^2 and a peak gradient of 100 mmHg was assigned to NYHA class III. In addition, her additive EuroSCORE [Nashef 1999] equaled 13, which accounts for a Logistic EuroSCORE (mortality%) of 36.33%. Informed consent within the "Feasibility Study of Transapical Aortic Valve Implantation with the CoreValve Aortic Valve Prosthesis in Patients at High Risk for Surgical Valve Replacement and Presenting Aorto-Iliac Diseases Contraindicating Transarterial Implantation (COR-2007-01)" was obtained. The operation was performed in a hybrid operation theater.

RESULTS

The procedure was performed with the patient under general anesthesia and a single lumen endotracheal tube. A pacing catheter was placed into the right ventricle, and an anterolateral minithoracotomy (3 cm) was then performed to access the apex of the heart. The pericardium was incised and fixed with stay sutures allowing persistent ventilation of the lungs. Next, a femoral arterial sheath of 18 French size was inserted. A wire was placed through the apex of the heart, then delivered into this femoral access. An aortic root pigtail catheter through the right radial artery allowed for angiographic visualization throughout the procedure. Low-dose heparin (5000 IU) was used for the procedure with a target activated clotting time of above 160 seconds. Balloon valvuloplasty was performed during a brief episode of rapid ventricular pacing. The balloon catheter was then withdrawn and the transapical delivery sheath inserted. A Terumo stiff wire 0.035 (Ann Arbor, MI, USA) and an Amplatz Super Stiff wire 0.035 (Boston Scientific, Maple Grove, MN, USA) helped to cross the native valve. Fluoroscopic and echocardiographic imaging were used to position the valve. During a second brief episode of rapid ventricular pacing the valve was released. Valve function was immediately assessed. With the valve being competent, the intraoperative gradient was

15 mmHg (Movie 1). The transapical sheath was removed and the apex securely closed. The pericardium was partially closed over the apex and a left lateral chest tube inserted. The incision was closed in a standard fashion (3/0 prolene sutures with pledgets). Postoperative medical therapy consisted of clopidogrel 75 mg daily and warfarin because the patient had atrial fibrillation. The postoperative course was uneventful. At 10 days, echocardiography showed only a trace of paravalvar leakage. Preprocedure ejection fraction was 50% and remained unchanged at discharge.

DISCUSSION

Transapical aortic valve implantation has become a treatment option for selected patients at some specialized institutions [Walther 2007]. The short distance from the apex to the aortic valvar region allows for a straightforward placement of both a balloon and the device. Neither retrograde traversing the often severely calcified aortic valve, nor any exaggerated manipulation of the aorta and the aortic arch are necessary. The CoreValve, a porcine pericardial valve mounted on a nitinol frame, has been studied at several centers with favorable results. Importantly, the prosthetic valve expands itself and requires no suturing. The CoreValve technique differs also from other transapical approaches under clinical investigation in that it does not require the use of a bulky introducer sheath, thus reducing the size of the puncture in the heart, which may contribute to a further reduction of trauma to the patient. Furthermore, the design of the valve allows for some repositioning while the stent is only half-released. Rapid pacing is not during this phase, because ventricular ejection is not impeded. Prospective randomized studies might help compare transapical, as well as transfemoral transcatheter valve implantation techniques, to conventional aortic valve replacement surgery.

DISCLOSURES

The authors wish to thank CoreValve for providing the valve within the approved "Feasibility Study of Transapical Aortic Valve Implantation with the CoreValve Aortic Valve Prosthesis in Patients at High Risk for Surgical Valve Replacement and Presenting Aorto-Iliac Diseases Contraindicating Transarterial Implantation (COR-2007-01)."

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Movie1

Successful transapical aortic valve implantation with CoreValve *ReValving*™ System.