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First Successful Aortic Valve Implantation with the CoreValve *ReValving*™ System via Right Subclavian Artery Access: A Case Report

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ABSTRACT

We successfully implanted a bioprosthetic aortic valve via the right subclavian artery within the framework of the CoreValve transapical aortic valve replacement (TAVR) *ReValving*™ (CoreValve, Irvine, CA, USA) clinical trial on November 20, 2007, at the Clinic for Cardiovascular Surgery at the German Heart Center Munich, Technical University Munich. The self-expanding aortic valve prosthesis is primarily designed for retrograde delivery across the aortic valve. The described approach via the right subclavian artery was performed because of severe peripheral vascular disease of the femoral and iliac arteries, as well as the left subclavian artery, and because a transapical delivery system was not available at the time of surgery.

INTRODUCTION

Operative mortality is high in patients with symptomatic aortic valvular disease and significant comorbidities. Therefore, surgery is often declined in these high-risk patients [Iung 2005]. 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 performed the first human implantation of a balloon-expandable aortic valve prosthesis [Cribier 2002]. Others have shown the feasibility of percutaneous implantation of the self-expanding CoreValve aortic valve prosthesis (CoreValve, Irvine, CA, USA) in high-risk patients and have produced marked hemodynamic and clinical improvement with this method [Grube 2007]. However, there are cases in which no adequate "access" exists in the groin vessels because of peripheral vascular disease. Transapical access has been shown to be feasible in these cases [Lange 2006]. Because of a redesign, a transapical delivery system was not available at the time of surgery. Therefore, the patient we describe was scheduled for right subclavian artery access.

CASE REPORT

The 66-year-old female patient with an aortic valvular orifice area of 0.7 cm^2 and a peak gradient of 110 mm Hg was assigned to New York Heart Association functional class IV. In addition, her additive EuroSCORE [Nashef 1999] was 13, which is equivalent to a logistic EuroSCORE of 35%. The patient's medical history included an impaired left ventricular function with an ejection fraction of 35% to 40%, coronary artery bypass grafting, femoro-popliteal artery bypass grafting, severe left subclavian artery stenosis, chronic renal failure, atrial fibrillation, recurrent cardiac decompensation, and mitral and tricuspid regurgitation. We obtained informed consent within the criteria of 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). The operation was performed in a hybrid operation theater.

The procedure was performed with the patient under general anesthesia and a single-lumen endotracheal tube. A pacing catheter was placed in the right ventricle, and a 5-cm incision was made below the right clavicula. A purse-string suture was placed at the right subclavian artery. An aortic root pigtail catheter inserted through the left femoral artery allowed angiographic visualization throughout the procedure. Low-dose heparin (5000 IU) was used for the procedure with a target activated clotting time of >160 seconds. Using a Terumo wire, we were able to traverse the unfavorable angle between the right subclavian artery and the ascending aorta. An 18F femoral arterial sheath was inserted. An Amplatz Super Stiff 0.035-inch wire was used to cross the native valve. Balloon valvuloplasty with a NuMED Nucleus 22/4 balloon (NuMED, Hopkinton, NY, USA) was performed during

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a brief episode of rapid ventricular pacing. The balloon catheter was then withdrawn, and the delivery sheath was inserted. Positioning of the prosthesis was visualized by fluoroscopic and echocardiographic imaging. A 26-mm CoreValve prosthesis was delivered, and valve function was immediately assessed (Video 1 online). No transvalvular gradient was present, and echocardiography showed minimal paravalvular regurgitation. The sheath was removed, and the right subclavian artery was closed securely. Postoperative medical therapy consisted of 75 mg clopidogrel daily and Marcumar (phenprocoumon), because the patient experienced atrial fibrillation. The postoperative course was uneventful. At discharge on postoperative day 10, an echocardiographic evaluation showed trivial paravalvular leakage.

DISCUSSION

Percutaneous aortic valve implantation via transfemoral or transapical access has become an alternative treatment in patients for whom open heart surgery is out of the question. For the severe peripheral vascular disease present in our patient, transfemoral access was unfavorable, and a transapical-delivery device was not available at the time of surgery. Furthermore, the left subclavian artery, which has been used as an alternative access in cases of unfavorable anatomy of the groin vessels, showed severe stenosis in our patient. We therefore chose an access through the right subclavian artery. We demonstrated that the CoreValve delivery device can be advanced through the right subclavian artery despite the unfavorable angle between the right subclavian artery and the ascending aorta. When evaluating patients presenting for transcatheter aortic valve implantation, surgeons should keep this access in mind as an alternative to transfemoral and transapical access.

DISCLOSURES

The authors 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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