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Factors Predicting and Having an Impact on the Need for a Permanent Pacemaker After CoreValve Prosthesis Implantation Using the New Accutrak Delivery Catheter System

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Objectives The purpose of this study was to evaluate the need for a permanent pacemaker after transcatheter aortic valve implantation with the CoreValve prosthesis (Medtronic, Inc., Minneapolis, Minnesota) using the new Accutrak delivery system (Medtronic, Inc.).

Background The need for a permanent pacemaker is a recognized complication after transcatheter aortic valve implantation with the CoreValve prosthesis.

Methods Between April 23, 2008 and May 31, 2011, 195 consecutive patients with symptomatic aortic valve stenosis underwent transcatheter aortic valve implantation using the self-expanding CoreValve prosthesis. In 124 patients, the traditional delivery system was used, and in 71 patients, the Accutrak delivery system was used.

Results There were no significant differences in baseline electrocardiographic characteristics between the traditional system and the Accutrak patients: PR interval: 153 ± 46 mm versus 165 ± 30 mm, $p = 0.12$; left bundle branch block: 22 (20.2%) versus 8 (12.7%), $p = 0.21$; right bundle branch block: 21 (19.3%) versus 8 (12.7%), $p = 0.26$. The depth of the prosthesis in the left ventricular outflow tract was greater with the traditional system than with the Accutrak system (9.6 ± 3.2 mm vs. 6.4 ± 3 mm, $p < 0.001$) and the need for a permanent pacemaker was higher with traditional system than with Accutrak (35.1% vs. 14.3%, $p = 0.003$). The predictors of the need for a pacemaker were the depth of the prosthesis in the left ventricular outflow tract (hazard ratio [HR]: 1.2, 95% confidence interval [CI]: 1.08 to 1.34, $p < 0.001$), pre-existing right bundle branch block (HR: 3.5, 95% CI: 1.68 to 7.29, $p = 0.001$), and use of the traditional system (HR: 27, 95% CI: 2.81 to 257, $p = 0.004$).

Conclusions The new Accutrak delivery system was associated with less deep prosthesis implantation in the left ventricular outflow tract, which could be related to the lower rate of permanent pacemaker requirement. (J Am Coll Cardiol Intv 2012;5:533–9) © 2012 by the American College of Cardiology Foundation

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Transcatheter aortic valve implantation (TAVI) is becoming an established alternative therapy in the treatment of symptomatic aortic stenosis in patients with a high surgical risk in Europe and Canada. TAVI is associated with 30-day mortality below 10% (1–4) and a similar 1-year survival compared with that seen with surgical aortic valve replacement (5). One of the limitations of TAVI with the CoreValve prosthesis (Medtronic, Inc., Minneapolis, Minnesota) is the need for a definitive pacemaker after the implantation due to disturbances in atrioventricular (AV) conduction. The need for a post-operative permanent pacemaker varies greatly (6) and reaches over 30% in some series (2,4). These results are far higher than those found after using the Edwards-Sapien prosthesis (Edwards Lifesciences, Irvine, California) (1) or after surgical aortic valve replacement, which range from 5% to 8% (7). These variations may be partly explained by differences in prosthesis design and implantation technique.

The aim of this study was to analyze the factors predicting and affecting the need for a pacemaker after TAVI with the CoreValve aortic valve prosthesis using the new Accutrak release system (Medtronic, Inc.).

Abbreviations and Acronyms

AV = atrioventricular
ECG = electrocardiogram
LBBB = left bundle branch block
LVOT = left ventricular outflow tract
RBBB = right bundle branch block
TAVI = transcatheter aortic valve implantation
TS = traditional system

Methods

Between April 23, 2008 and May 31, 2011, 195 patients with severe aortic valve stenosis and a high surgical risk were treated with the CoreValve aortic valve prosthesis. In 124 patients (63.6%), the traditional system (TS) was used. The remaining 71 patients (36.4%) underwent the procedure with the new Accutrak release system. All the patients were evaluated by a multidisciplinary team composed of surgeons and clinical and interventional cardiologists. The process for patient selection and evaluation of the complications followed the joint consensus recommendations of the various scientific societies (8), and the Valve Academic Research Consortium criteria (9), as well as complying with the necessary anatomical criteria for percutaneous implantation with the CoreValve aortic valve prosthesis (2,4).

Of the 195 patients, 18 were excluded from the analysis as they had a definitive pacemaker due to advanced AV block before the TAVI and 3 due to failure in the implantation of the CoreValve prosthesis. Thus, the final analysis involved 111 patients with TS and 63 patients with Accutrak.

Description of the prosthesis and release system. The CoreValve prosthesis consists of a trileaflet bioprosthetic porcine pericardial tissue valve, which is mounted and sutured in a self-expanding nitinol stent frame. There are 2 different valve sizes currently available for different annulus dimensions: the 26-mm prosthesis (small prosthesis) for aortic valve annulus sizes from 20 to 23 mm and the 29-mm prosthesis (large prosthesis) for aortic valve annulus sizes from 23 to 27 mm. The small prosthesis is 55 mm long and the large prosthesis 53 mm.

Release system. The traditional release system for the CoreValve aortic valve prosthesis is a 12-F catheter for the first 108 cm and 18-F (6 mm) for the distal portion (7 cm long), introduced via a 0.035-inch guidewire. The distal portion of the catheter, which transports the prosthesis folded in a sheath, is characterized by being flexible and directable, as well as possessing the necessary stiffness to navigate through the aortic annulus. The proximal end consists of a precise release system composed of 2 adjustment knobs, 1 for rotation, called micro, and the other for sliding, called macro. After positioning the catheter at the level of the aortic annulus, the micro knob is used to withdraw the sleeve slowly, thereby releasing the prosthesis, which recovers its original position in contact with the blood.

The first 90.9 cm of the new Accutrak release system has a 15-F additional layer isolating the retractable sheath, permitting greater stability when introducing the catheter into the aortic annulus and starting release of the prosthesis, making the transmission of the release strength imparted with the micro knob more proportionate, thus preventing uncontrolled displacement of the prosthesis toward the interior of the left ventricle during the release process.

Procedure. Before the procedure, the patients took acetylsalicylic acid 100 mg, which they then continued indefinitely. They also received a loading dose of clopidogrel 300 mg, later continuing with 75 mg for at least 6 months. During the procedure, intravenous sodium heparin was given, adjusted for weight (70 IU/kg). Antibiotic prophylaxis was given with cephalosporin or vancomycin if the patient was allergic to beta-lactams.

Almost all (92.3%) of the procedures were performed under local anesthesia with superficial sedation. Access was via the femoral artery in most cases, with an 18-F introducer, closing the femoral puncture with the Prostar XL 10-F percutaneous closure device (Abbott Vascular Devices, Redwood City, California). In 18 patients, the left subclavian artery was used as the access route, in collaboration with the cardiac surgeon who performed the opening and closure of the artery.

After positioning a transitory pacemaker catheter via the transjugular route, the femoral artery was punctured for the implantation of the valve, leaving the closure device fitted. Aortic valvuloplasty was then performed with cardiac overstimulation at a frequency of 150 to 180 beats/min to prevent balloon displacement. The aortic prosthesis was then released under fluoroscopy-guided angiographic control. After the procedure, the patients were monitored by telemetry for 4 days and echocardiographic control at 72 h.

Electrocardiographic study. All the patients had an electrocardiogram (ECG) before and after the percutaneous im-