JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 5, NO. 5, 2012

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
DOI: 10.1016/j.jcin.2012.03.011

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

Antonio J. Muñoz-García, MD, PHD, José M. Hernández-García, MD, PHD, Manuel F. Jiménez-Navarro, MD, PHD, Juan H. Alonso-Briales, MD, Antonio J. Domínguez-Franco, MD, Julia Fernández-Pastor, MD, Jose Peña Hernández, MD, Alberto Barrera Cordero, MD, Javier Alzueta Rodríguez, MD, PHD, Eduardo de Teresa-Galván, MD, PHD

Malaga, Spain

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

From the Department of Cardiology, Virgen de la Victoria Clinical University Hospital, Malaga, Spain. Drs. Hernández-García and Alonso-Briales are physician proctors for Medtronic, Inc. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received December 16, 2011; revised manuscript received March 19, 2012, accepted March 26, 2012.

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-

plant. Analyses were made of the rhythm; heart rate; and PR, QRS, and QT intervals (measured in milliseconds at a speed of 25 mm/s), as well as the presence of bundle branch block or advanced AV block according to the criteria recommended by the World Health Organization and the International Society and Federation for Cardiology Task Force to define hemiblock and right bundle branch block (RBBB) and left bundle branch block (LBBB) (10). The implantation of a definitive pacemaker was indicated by the cardiology care team in the presence of third- and second-degree AV block (Mobitz type 2), following the recommendations of the European Society of Cardiology for patients with acquired AV block in special situations, such as valve surgery (11).

Quantitative angiography, done by 2 independent observers, was used to measure the depth of the prosthetic structure in the outflow tract by the distance (in millimeters) from the noncoronary cusp to the distal extreme of the prosthesis situated in the left ventricle, as described by Piazza et al. (12).

The implantation was considered normal when the depth of the prosthesis in the left ventricular outflow tract (LVOT) was 4 to 8 mm, high when it was below 4 mm, and low when it was more than 8 mm (13). The number of primary operators that were involved in this study was 2 in all patients.

Severe calcification was defined as the presence of heavy calcification of all cusps or bulky calcification detected on the aortic angiogram (14).

Statistical analysis. The continuous variables are expressed as the mean ± SD and the qualitative variables as percentages. The chi-square test was used for the qualitative variables and the Student *t* test for paired data for continuous variables, as all the variables had a normal distribution. A multivariate analysis was performed with a backward stepwise Cox regression analysis to identify independent variables predicting the need for a pacemaker due to AV block. This model included those variables with probability value <0.05 in the univariate analysis. Results are presented as hazard ratios with 95% confidence intervals. Significance was set at $p < 0.05$. The data were analyzed with SPSS (version 15.0, SPSS, Inc., Chicago, Illinois).

Results

The success rate for the procedure was 97.5% for the TS and 100% for Accutrak. After the implantation, 48 patients (27.6%) required a definitive pacemaker due to AV conduction disturbances. Table 1 shows the baseline characteristics and the procedure data according to the release system used.

No significant differences were found in the baseline electrocardiographic characteristics between the TS patients and the Accutrak patients (Table 2).

Table 1. Baseline Characteristics and Procedure Data According to the Release System Used

	Traditional System (n = 111)	Accutrak (n = 63)	p Value
Age, yrs	79.4 ± 6.7	78.3 ± 6.5	0.273
Male	40 (36)	25 (39.7)	0.633
EuroSCORE, %	20 ± 13	17 ± 9	0.154
STS score, %	7.4 ± 5	6 ± 3.5	0.295
Frailty	15 (13.5)	7 (11.1)	0.647
Karnofsky	58 ± 20	59 ± 19	0.503
Charlson	3.4 ± 1.8	3.6 ± 1.9	0.503
Risk factors			
Hypertension	84 (75.7)	49 (77.8)	0.754
Diabetes mellitus	38 (34.2)	27 (42.9)	0.258
Dyslipidemia	52 (46.8)	37 (58.7)	0.132
Coronary disease	33 (29.7)	24 (38.1)	0.258
Acute renal failure	19 (17.1)	11 (19.6)	0.333
Prior stroke	13 (11.7)	15 (23.8)	0.037
Syncope	7 (6.3)	4 (6.3)	0.991
Beta-blockers	45 (40.5)	29 (46)	0.481
Chronotropic therapy	64 (57.6)	34 (54)	0.5
Cessation of chronotropic therapy	44 (62.9)	2 (5.4)	0.001
Ejection fraction, %	64 ± 13	59 ± 11	0.512
Severe calcification	53 (58.9)	29 (47.5)	0.104
Severe hypertrophy	50 (46.3)	28 (45.2)	0.735
LVOT, mm	19.9 ± 1.6	20 ± 1.6	0.931
Septal thickness, mm	13.9 ± 1.4	13.7 ± 1.6	0.737
Procedure			
Total time, min	100 ± 35	101 ± 29	0.749
Release time, min	5.9 ± 3	6 ± 2.7	0.756
AV block intraprocedural	26 (26.5)	8 (12.7)	0.036
Pre-dilation	103 (92.8)	59 (93.7)	0.83
Valvuloplasty balloon size, mm	22.9 ± 1.8	22.6 ± 1.9	0.477
Post-dilation	27 (24.3)	16 (25.4)	0.875
AR ≥2+	28 (25.2)	6 (19.5)	0.047
Prosthesis			
Small	63 (56.8)	34 (54)	0.722
Large	48 (43.2)	29 (46)	
Valve in valve	5 (4.5)	2 (3.7)	0.668
CoreValve/annulus ratio	1.21 ± 0.07	1.22 ± 0.06	0.668
New-onset LBBB after implantation*	37 (41.5)	31 (56.3)	0.21
New pacemaker placement	39 (35.1)	9 (14.3)	0.003
Time procedure-pacemaker placement, h	38 ± 19	60 ± 36	0.005
Stroke	1 (0.9)	5 (7.9)	0.015
Vascular complications	3 (2.5)	5 (7.9)	0.113
30-day mortality	2 (1.8)	3 (4.8)	0.261

Values are mean ± SD or n (%). *In the analysis of new-onset LBBB after implantation, the patients with LBBB on baseline ECG were excluded.

AR = aortic regurgitation; AV = atrioventricular; ECG = electrocardiogram; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LBBB = left bundle branch block; LVOT = left ventricular outflow tract; STS = Society of Thoracic Surgeons.

The depth of the prosthesis in the LVOT was greater in the TS patients than in the Accutrak patients (9.6 ± 3.2 mm vs. 6.4 ± 3 mm, $p < 0.001$). Only 36.3% of the TS

Table 2. Baseline ECG Characteristics According to the Release System Used

	Traditional System (n = 111)	Accutrak (n = 63)	p Value
Heart rate, beats/min	71 ± 14	73 ± 12	0.297
Atrial fibrillation	36 (32.4)	20 (31.7)	0.926
PR interval, ms	153 ± 46	165 ± 30	0.127
QRS duration, ms	90 ± 30	92 ± 24	0.624
QT interval, ms	392 ± 33	413 ± 23	0.001
LBBB	22 (20.2)	8 (12.7)	0.213
RBBB	21 (19.3)	8 (12.7)	0.268
Hemiblock			0.342
Anterior	21 (19.4)	9 (14.3)	
Posterior	7 (6.5)	3 (4.8)	
RBBB + hemiblock	16 (14.7)	4 (6.3)	0.101

Values are mean ± SD or n (%).
RBBB = right bundle branch block; other abbreviations as in Table 1.

patients had a depth <8 mm compared with 74.6% of the Accutrak patients (p < 0.001) (Fig. 1). The need for a pacemaker was greater in the TS patients than in the Accutrak patients (35.1% vs. 14.3%, p = 0.003). New-onset LBBB occurred in 41.5% of patients with TS and 56.3% of patients with Accutrak system (p = 0.210) after excluding the patients with LBBB on baseline ECG.

In 18 patients, the subclavian route was used, 9 patients with TS and the other 9 patients with the Accutrak system. There were not significant differences between the TS patients and the Accutrak patients in the need for a pacemaker (44.4% vs. 22.2%, p = 0.317), depth in the LVOT (10.2 ± 3.2 mm vs. 7.6 ± 3.3 mm, p = 0.112), and low implantation (55.6% vs. 44.4%, p = 0.444) in this subgroup.

In our series, we found that 34 patients (21.1%) experienced AV block during the procedure and 22 (64.7%) of these patients required a definite pacemaker. There was a higher rate of intraprocedural AV block for the TS than the Accutrak group (Table 1). Of the 26 patients who required pacemaker by conduction disturbances after procedure and without AV block during the procedure, there were not significant differences between TS patients compared with Accutrak patients (58.3% vs. 55.6%, p = 0.880), but we found differences in the occurrence AV block in the time, with a median of 48 h (24 to 72 h) for the TS group and 72 h (48 to 148 h) for Accutrak group (p < 0.005).

In the analysis of the first one-half of the TS patients compared with the second one-half showed no significant differences in the need for a pacemaker (34.5% in the first one-half vs. 35.7% in the second one-half, p = 0.974) nor in the depth of the prosthesis (10 ± 3.2 mm vs. 9.2 ± 3.2 mm, p = 0.226). In the same analysis of the Accutrak patients, no significant differences were found (12.9% in the first one-half vs. 15.6% in the second one-half, p = 0.758) nor in the depth of the prosthesis (6.13 ± 2.7 mm vs. 6.8 ± 3.4 mm, p = 0.401).

The factors associated with the need for a pacemaker are shown in Table 3. Of note among these were baseline electrocardiographic disturbances, mainly the presence of RBBB and the presence of hemiblock, and the parameters related with the procedure, such as the position of the prosthesis.

The multivariate analysis showed that the predictors of the need for a definitive pacemaker due to ventricular conduction disorders were the depth of the prosthesis in LVOT, the prior presence of RBBB, and use of the TS (Table 4).

Discussion

With the introduction of the new Accutrak release system, we noted a significant reduction in the need for a pacemaker after the percutaneous implant with the CoreValve aortic valve prosthesis, falling from 35.1% to 14.3%. The main reasons for this decline were the simplicity to position the CoreValve prosthesis higher and because of fewer manipulations and less trauma to the LVOT during the procedure with the Accutrak release system. The membrane stabilizing the Accutrak system balances the transmission of the forces at the moment of release better, thus avoiding sudden displacement toward the interior of the left ventricle, minimizing mechanical trauma against the left bundle branch, and enabling the prosthesis to be adequately placed in the valvular plane.

The incidence of AV conduction disturbances with the need to implant a definitive pacemaker after TAVI with the CoreValve aortic valve prosthesis is high (15,16). This is easily explained if we recall the anatomic relation between the AV conduction system and the aortic valve. Rubín et al. (17) recently reported that after implantation with the CoreValve aortic valve prosthesis there is worsening of AV

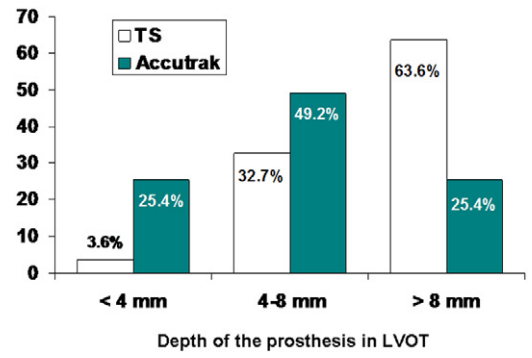

Figure 1. Position of the Prosthesis, High, Low, or Normal, According to the Release System Used

LVOT = left ventricular outflow tract; TS = traditional system.

Table 3. Factors Associated With the Need to Implant a Pacemaker

	No Pacemaker (n = 126)	Pacemaker (n = 48)	p Value
Clinical parameters			
Age, yrs	78 ± 7.4	79 ± 4.6	0.561
Male	44 (34.9)	21 (43.8)	0.282
Syncope	7 (5.6)	4 (8.3)	0.501
Beta-blockers	53 (42.1)	21 (43.8)	0.841
Chronotropic therapy	67 (54.5)	31 (64.6)	0.23
Cessation of chronotropic therapy	26 (36.1)	20 (57.1)	0.039
ECG parameters			
Atrial fibrillation	42 (33.3)	14 (29.2)	0.599
PR interval, ms	156 ± 42	161 ± 40	0.55
QRS width, ms	88 ± 26	99 ± 33	0.039
LBBB	23 (18.4)	7 (14.9)	0.589
RBBB	9 (7.2)	20 (42.6)	<0.001
Hemiblock	22 (17.7)	18 (38.3)	0.013
Echocardiographic parameters			
Ejection fraction, %	62 ± 13	61 ± 14	0.616
LVEF <40%	15 (11.9)	8 (16.7)	0.407
LVOT, mm	20 ± 1.6	20.1 ± 1.2	0.883
Septal thickness, mm	13.7 ± 1.3	13.9 ± 1.1	0.693
Severe hypertrophy	54 (43.9)	24 (51.1)	0.798
Pulmonary hypertension, >60 mm Hg	23 (50)	16 (66.7)	0.188
Annulus diameter, mm	22.1 ± 1.7	22.6 ± 1.9	0.1
Sinus of Valsalva width, mm	28.6 ± 3.6	30 ± 4	0.017
Sinotubular junction, mm	26.3 ± 3.1	27 ± 4.1	0.046
Procedure			
Severe calcification	57 (52.3)	25 (59.5)	0.389
Accutrak release system	54 (42.9)	9 (18.8)	0.003
Prosthesis			
26 mm	73 (57.9)	24 (50)	0.346
29 mm	53 (42.1)	24 (50)	
P/R ratio	1.21 ± 0.06	1.2 ± 0.7	0.208
Depth, mm	7.4 ± 2.9	11.2 ± 3.5	<0.001
AV block during procedure	12 (10.2)	22 (51.2)	<0.001
Post-dilation	32 (25.4)	11 (22.9)	0.731
AR ≥2+	23 (18.9)	11 (23.9)	0.687
Valve in valve	4 (3.2)	3 (6.3)	0.356

Values are mean ± SD or n (%).
LVEF = left ventricular ejection fraction; P/R ratio = prosthesis/annulus diameter ratio; other abbreviations as in Tables 1 and 2.

conduction, due to the direct damage of the bundle of His or the AV node. In an autopsy, Moreno et al. (18) demonstrated the histopathologic presence of a hematoma of the interventricular septum that compromised the bundle of His after implanting an Edwards-Sapien prosthesis, which could explain the AV conduction disturbances. In our series, we found that of the 48 patients who required a permanent pacemaker, 22 patients experienced AV block during the procedure. The possible mechanisms involved include inflammation, edema, ischemia, and mechanical trauma over the interventricular septum, with the resulting consequences in the conduction system, which may be transitory as occurs with the balloon used to predilate the native valve (19). Gutiérrez et al. (20) reported transitory ECG changes after implanting the Edwards-Sapien prosthesis, with the incidence of LBBB increasing from 9% at baseline to 27% after the procedure, and then falling at 1 month to 13%.

The greater prosthetic surface area in contact with the LVOT and the particular characteristics of nitinol, which provide a continued self-expansion, might account for the differences in the percentage of pacemaker implants due to persistent AV conduction disorders between the CoreValve aortic valve prosthesis and the Edwards-Sapien prosthesis,

Table 4. Multivariate Analysis: Cox Regression for Predictors of the Need for a Definitive Pacemaker

	HR (95% CI)	p Value
AV block during procedure	2.14 (0.95–4.83)	0.066
Depth of implantation	1.20 (1.08–1.34)	<0.001
RBBB	3.50 (1.68–7.29)	0.001
QRS	1.01 (0.99–1.02)	0.248
TS	27.0 (2.81–257)	0.004
Hemiblock	1.41 (0.75–2.63)	0.279
Cessation of chronotropic therapy	0.25 (0.01–0.67)	0.053

CI = confidence interval; HR = hazard ratio; TS = traditional system; other abbreviations as in Tables 1 and 2.

which is mounted over a balloon and is shorter (14 mm) and therefore has less contact with the LVOT.

Our study also confirms other previously described factors regarding the need for pacemaker implantation: the depth of the prosthesis in the LVOT (14,15) and the previous presence of RBBB (14,21). The improvements incorporated into the release system of the prosthesis thus allow greater stability during the implantation and a higher position, resulting in a reduction in AV conduction disorders. In our study, cessation of chronotropic therapy is a potential independent negative predictor of pacemaker placements. Because chronotropic therapy before implantation has been suggested to increase the need for pacing (22), in this scenario, it is reasonable that this may favor a strategy of that cessation of chronotropic therapy before the procedure.

We found that there were more incidences of stroke in the Accutrak group than in the TS group (7.9% vs. 0.9%, $p = 0.015$) after TAVI in according to Valve Academic Research Consortium criteria, likely because there were more previous strokes in the Accutrak group than in the TS group (23.8% vs. 11.7%, $p = 0.037$) before the procedure. We also found a trend toward more vascular complications with the Accutrak group, which could be related to poor femoral vascular access in the Accutrak group (mean diameter femoral vascular 6.8 ± 1.4 mm vs. 7.2 ± 1.2 mm, $p = 0.053$).

Study limitations. A possible limitation of this study concerns operator experience, attempting to position the prosthesis at <8-mm depth from the aortic annulus. Nevertheless, analysis of the first one-half compared with the second one-half of the TS patients and Accutrak patients showed no significant differences in the need for a pacemaker or in the depth of the prosthesis. Also, the operators that were involved in this study were the same in all patients. The cardiology care team had the same criteria for placing permanent pacemakers for AV block as those indicated in the Methods section. Another possible limitation concerns the method used to measure the depth of the CoreValve aortic valve prosthesis. We used quantitative angiography, as have other series, though different imaging techniques, such as computerized tomography or magnetic resonance, could provide more accurate quantification of the depth of the prosthesis in the LVOT. There was a numerical, but statistically nonsignificant, trend toward less LBBB, RBBB, and hemiblock in the Accutrak patients than in the TS patients, and it could to be associated with reduced pacemaker need. Although there were significant differences in the univariate analysis between the no pacemaker group and the pacemaker group in relation to RBBB and hemiblock, furthermore, it seems these differences may have contributed to the magnitude of the difference in pacemaker needs between the TS group and the Accutrak group, although they probably do not take away from the fact that traditional system is an independent predictor of the need for pacemaker. In addition, the ratio of endpoint count to predictors evaluated is low and that replication in a larger sample is indicated.

Conclusions

The new Accutrak release system was associated with less deep prosthesis implantation in the LVOT, which could be related to the lower rate of permanent pacemaker requirement.

Reprint requests and correspondence: Dr. Antonio J. Muñoz-García, Department of Cardiology, Virgen de la Victoria Clinical University Hospital, Campus de Teatinos s/n, 29010 Málaga, Spain. E-mail: ajmunozgarcia@secardiologia.es.

REFERENCES

1. Rodés-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of multicenter Canadian experience. J Am Coll Cardiol 2010;55:1080–90.
2. Avanzas P, Muñoz-García AJ, Segura J, et al. Implante percutáneo de la prótesis aórtica autoexpandible CoreValve en patients con estenosis aórtica severa: experiencia inicial en España [Percutaneous implantation of the CoreValve self-expanding aortic valve prosthesis in patients with severe aortic stenosis: early experience in Spain]. Rev Esp Cardiol 2010;63:141–8.
3. Zahn R, Gerkens U, Grube E, et al., for the German Transcatheter Aortic Valve Interventions Registry Investigators. Transcatheter aortic valve implantation: first results from a multicentre real-world registry. Eur Heart J 2011;32:198–204.
4. Grube E, Buellesfeld L, Mueller R, et al. Progress and current status of percutaneous aortic valve replacement: results of three device generations of the CoreValve Revalving system. Cir Cardiovasc Interv 2008;1:167–75.
5. Smith CR, Leon MB, Mack MJ, et al., for the PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med 2011;364:2187–98.
6. Bates MG, Matthews LG, Fazal IA, Turley AJ. Postoperative permanent pacemaker implantation in patients undergoing trans-catheter aortic valve implantation: what is the incidence and are there any predicting factors? Interact Cardiovasc Thorac Surg 2011;12:243–53.
7. Nardi P, Pellegrino A, Scafuri A, et al. Permanent pacemaker implantation after isolated aortic valve replacement: incidence, risk factors and surgical technical aspects. J Cardiovasc Med (Hagerstown) 2010;11:14–9.
8. Vahanian A, Alfieri O, Al-Attar N, et al. Transcatheter valve implantation for patients with aortic stenosis: a position statement from the

European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC). Eur Heart J 2008;29:1463–70.
9. Leon MB, Piazza N, Nikolsky E, et al. Standardized endpoint definitions for Transcatheter Aortic Valve Implantation clinical trials: a consensus report from the Valve Academic Research Consortium. J Am Coll Cardiol 2010;57:253–69.
10. Willems JL, Robles de Medina EO, Bernard R, et al., for the World Health Organization/International Society and Federation for Cardiology Task Force Ad Hoc. Criteria for intraventricular conduction disturbances and pre-excitation. J Am Coll Cardiol 1985;5:1261–75.
11. Vardas PE, Auricchio A, Blanc JJ, et al. Guidelines for cardiac pacing and cardiac resynchronization therapy: the Task Force for Cardiac Pacing and Cardiac Resynchronization Therapy of the European Society of Cardiology. Eur Heart J 2007;28:2256–95.
12. Piazza N, Onuma Y, Jesserun E, et al. Early and persistent intraventricular conduction abnormalities and requirements for pacemaking after percutaneous replacement of the aortic valve. J Am Coll Cardiol Intv 2008;1:310–6.
13. De Jaegere P, Piazza N, Tzikas A, et al. Implantation of the CoreValve Revalving system7. In: Serruys PW, Piazza N, editors. Transcatheter Aortic Valve Implantation. Tips and Tricks to Avoid Failure. New York, NY: Informa Healthcare, 2010:183–9.
14. Fraccaro C, Buja G, Tarantini G, et al. Incidence, predictors, and outcome of conduction disorders after transcatheter self-expandable aortic valve implantation. Am J Cardiol 2011;107:747–54.
15. Muñoz-García AJ, Hernández-García JM, Jiménez-Navarro MF, et al. Alteraciones de la conducción auriculoventricular y predictores de la necesidad de marcapasos tras el implante percutáneo de la prótesis aórtica de CoreValve® [Changes in atrioventricular conduction and predictors of pacemaker need after percutaneous implantation of the CoreValve® aortic valve prosthesis]. Rev Esp Cardiol 2010;63:1444–51.
16. Khawaja MZ, Rajani R, Cook A, et al. Permanent pacemaker insertion after CoreValve transcatheter aortic valve implantation: incidence and contributing factors (the UK CoreValve Collaborative). Circulation 2011;123:951–60.
17. Rubín JM, Avanzas P, Del Valle R, et al. Atrioventricular conduction disturbance characterization in transcatheter aortic valve implantation with the CoreValve prosthesis. Circ Cardiovasc Interv 2011;4:280–6.
18. Moreno R, Dobarro D, López de Sá E, et al. Cause of complete atrioventricular block after percutaneous aortic valve implantation: insights from a necropsy study. Circulation 2009;120:e29–30.
19. Serruys PW, Luijten HE, Beatt KJ, et al. Percutaneous balloon valvuloplasty for calcific aortic stenosis. A treatment "sine cure"? Eur Heart J 1988;9:782–94.
20. Gutiérrez M, Rodés-Cabau J, Bagur R, et al. Electrocardiographic changes and clinical outcomes after transapical aortic valve implantation. Am Heart J 2009;158:302–8.
21. Haworth P, Behan M, Khawaja M, et al. Predictors for permanent pacing after transcatheter aortic valve implantation. Catheter Cardiovasc Interv 2010;76:751–6.
22. Jilaihawi H, Chin D, Vasa-Nicotera M, et al. Predictors for permanent pacemaker requirement after transcatheter aortic valve implantation with the CoreValve bioprosthesis. Am Heart J 2009;157:860–6.

Key Words: aortic stenosis ■ pacemakers ■ prosthesis ■ transcatheter aortic valve implantation.