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Update on the need for a permanent pacemaker after transcatheter aortic valve implantation using the CoreValve® Accutrak™ system

Didier Tchetche[1]*, MD; Thomas Modine[2], MD; Bruno Farah[1], MD; Olivier Vahdat[1], MD; Arnaud Sudre[2], MD; Mohamad Koussa[2], MD; Corinne Lereun[3], MSE, BA; Mohammed Nejjari[1], MD; Michael Choby[1], MD; Julien Rosencher[1], MD; Emmanuel Sorbets[1], MD; Jean Fajadet[1], MD

1. Clinique Pasteur, Toulouse, France; 2. Hôpital Cardiologique, Lille, France; 3. Independent Biostatistician, Carrigaline, Cork, Ireland

KEYWORDS

- CoreValve®
- Accutrak™
- pacemaker

Abstract

Aims: High rates of permanent pacemaker (PPM) implantation are reported after transcatheter aortic valve implantation (TAVI) using the Medtronic CoreValve® system. The Accutrak™ catheter is designed to allow a more predictable landing zone. Little is known about the real clinical impact of this catheter. The aims of this paper were to describe the potential impact of the Accutrak™ catheter on the accuracy of positioning a 26 or 29 mm CoreValve® across the aortic annulus and its impact on the need for a pacemaker.

Methods and results: A total of 134 patients were treated with the CoreValve® Accutrak™ system at two French centres (Lille and Toulouse). Mean age was 82.4±4.7 years; logistic EuroSCORE was 24.3±9.5%. Procedural success rate was 99.2%; mean depth of implantation was 4.9 mm. A final position between 0 and 6 mm was achieved in 85.8% of the patients. All-cause mortality at 30 days was 6%. The PPM implantation rate was 10.6%. Due to a limited number of events, we could not identify any predictor of need for a PPM: pre-existing right bundle branch block (RBBB) (OR 2.72 [0.63-11.87], p=ns), use of a 29 mm prosthesis (OR 2.73 [0.33-22.90], p=ns) and left ventricular septal hypertrophy (OR 2.63 [0.08-83.32], p=ns).

Conclusions: In this cohort of patients treated with the CoreValve® Accutrak™ system, the incidence of permanent pacemaker implantation was low, which may be a consequence of an average small implantation depth. The Accutrak™ catheter seems to be helpful in achieving higher and more predictable implants. Operators could standardise their technique to place the CoreValve® prostheses less than 6 mm below the aortic annulus.

**Corresponding author: Groupe CardioVasculaire Interventionnel, Clinique Pasteur, 45, avenue de Lombez, FR-31300 Toulouse, France. E-mail: d.tchetche@clinique-pasteur.com*

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Abbreviations

AV	atrioventricular
ECG	electrocardiogram
ES	Edwards SAPIEN®
ESXT	Edwards SAPIEN XT®
LBBB	left bundle branch block
MCV	Medtronic CoreValve®
MCVA	Medtronic CoreValve® Accutrak™
MSCT	multislice computed tomography
NYHA	New York Heart Association
PPM	permanent pacemaker
PVL	paravalvular leakage
RBBB	right bundle branch block
TAVI	transcatheter aortic valve implantation

Introduction

Transcatheter aortic valve implantation (TAVI) has emerged as a therapeutic option for patients deemed inoperable or at high risk for surgery, suffering from symptomatic aortic stenosis[1]. Its superiority over medical therapy has been demonstrated in a cohort of inoperable patients and it appears to be a valid alternative to surgery for high-risk patients[2,3]. Two bioprostheses received the CE mark in 2007 and are routinely used worldwide for TAVI: the Edwards SAPIEN®(ES) (Edwards Lifesciences, Irvine, CA, USA), and the Medtronic CoreValve® (MCV) (Medtronic Inc., Minneapolis, MN, USA). In Europe, the currently used versions of these catheters are the Edwards SAPIEN XT® (ESXT) and the Medtronic CoreValve® Accutrak™ (MCVA). No clear difference in clinical outcome between both devices has been demonstrated in various registries, except for the need of a permanent pacemaker following TAVI. Indeed, rates of pacemaker implantation range from 4 to 7% for the ES[4-6] and from 16 to 40% after treatment with the MCV[7-9].

Several risk factors for conduction disturbances after TAVI have been identified, including low implantation of the MCV as regards the aortic annulus. The vast majority of low implantations result from technical difficulties in maintaining the prosthesis in the correct location during its flaring phase. The delivery catheter of the MCV has been recently modified by the adjunction of an additional layer: the Accutrak™ stability layer. This catheter is made up of three layers: an inner shaft to which the prosthesis is attached; a retractable sheath containing the prosthesis; and an external layer, designed to isolate the retractable delivery sheath from the 18 Fr introducer sheath and the patient's arterial anatomy, thus reducing frictions **(Figure 1)**. By securing the MCV delivery through increased stability during deployment, the Accutrak™ catheter induces, in theory, more predictable implantations. Little is known about the actual performances of this new catheter in a real-world setting and its impact on clinical outcome, particularly the need for a permanent pacemaker.

We report on a series of patients treated with the MCVA at two French centres, which have a large experience of MCV implantation. The accuracy of positioning the valve across the aortic annulus and the potential for permanent pacemaker implantation are analysed.

Methods

From 20 September 2010 to 30 June 2011, 134 patients were treated with the Medtronic CoreValve Accutrak™ bioprosthesis at two French centres: the Clinique Pasteur (Toulouse) and the Hôpital Cardiologique (Lille). Teams in both centres had already regularly used both CE-marked TAVI devices and had an experience of at least 50 CoreValve® implantations prior to the treatment of their first patient with the Accutrak™ catheter. Patients were eligible for TAVI if they had a combination of a symptomatic aortic stenosis,

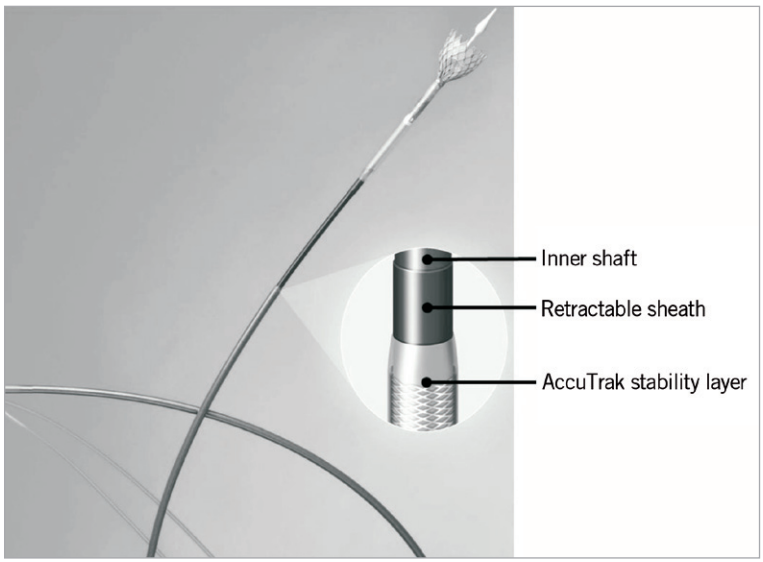

Figure 1. *Structure of the Accutrak™ catheter with its 3 layers: inner shaft, retractable sheath and external stability layer. (Courtesy of Medtronic)*

a EuroSCORE ≥20% and a suitable aortic anatomy and peripheral vasculature (common femoral artery or subclavian arteries) for TAVI using MCVA. However, patients with a EuroSCORE <20% were also eligible if they had comorbidities contraindicating surgery; e.g., porcelain aorta, chest deformation or liver cirrhosis. The final decision for intervention was taken at a multidisciplinary heart team meeting including a cardiac surgeon, an interventional cardiologist and an anaesthesiologist.

Prior to procedure, the aortic annulus measurement was obtained by transoesophageal echocardiography. The aortic annulus diameter had to range between 20 and 27 mm for implantation of a 26 or 29 mm MCVA. None of the patients in this series was treated with a 31 mm bioprosthesis.

Twelve-lead electrocardiogram (ECG) analysis was performed for each patient. The following items were notified: sinus rhythm, atrial fibrillation, left bundle branch block (LBBB), right bundle branch block (RBBB) and previous pacemaker. The analysis was performed at baseline, one day after valve implantation and at 30 days.

Procedures were performed under general anaesthesia as it has been previously described. Transoesophageal echocardiography guidance was used during the procedure according to local practice. The sizes of the predilatation balloon and CoreValve and the need for post-dilatation were left to the discretion of the operators.

Depth of implantation was defined as the maximal distance between the intraventricular end of the bioprosthesis and the aortic annulus at the level of the non-coronary cusp and the left anterior coronary cusp **(Figure 2)**. At the start of the procedure, the predetermined target depth of implantation was 4-6 mm below the plane of the aortic annulus. The final depth of implantation was measured by using on-site quantitative angiography. The height of an inflow cell (8 mm) was the reference for measurement at the level of the non-coronary sinus and the left anterior sinus. The maximal value found at any of these locations was retained. To minimise the influence of inter-observer differences in measurement, the final valve position was classified into three categories: correct final position (depth between 4-6 mm), high final position (depth between 0-3 mm) and low final position (depth greater than 6 mm).

After TAVI, the patients were kept in an intensive care unit with a right ventricular pacing lead for at least two days, which was removed in the absence of severe conduction anomalies. The patients were afterwards monitored by telemetry until discharge. The decision for permanent pacemaker implantation was left to the discretion of the local teams.

Clinical follow-up was obtained at 30 days. Primary endpoints were all-cause mortality, cardiovascular mortality, rate and timing of permanent pacemaker implantation. CoreValve function was also assessed by transthoracic echocardiography at 30 days. Clinical events were adjudicated according to the Valve Academic Research Consortium.

Statistical analysis

All analyses were performed in Stata® SE version 8.2. (StataCorp LP, College Station, TX, USA).

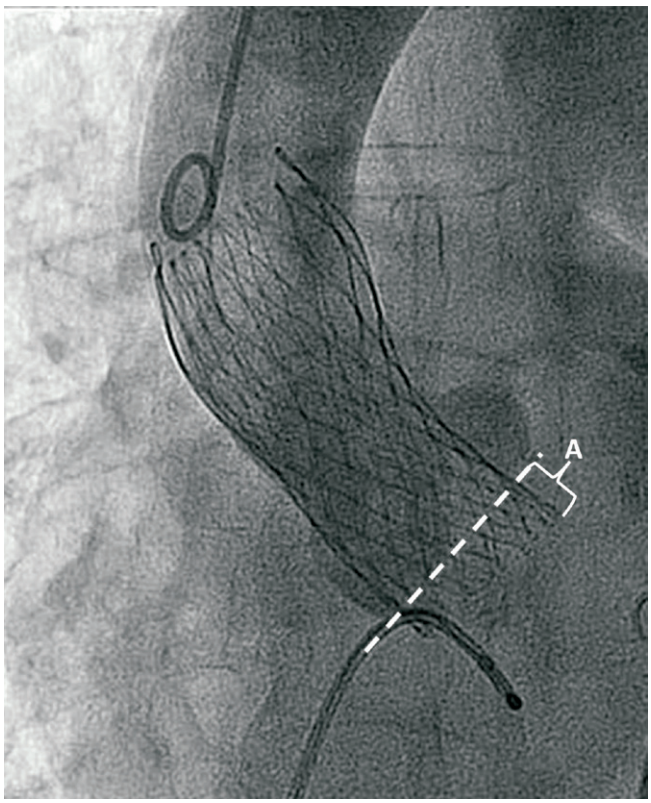

Figure 2. *Depth of implantation as measured by quantitative angiography. A: number of mm below the plane of the aortic annulus*

All the variables in the database are described using summary statistics. Continuous variables are expressed as mean±standard deviation. Frequencies and percentages in each category are reported for categorical variables.

Patients' characteristics and details of the procedure are explored as potential predictors of the need for a pacemaker. The impact of dichotomous predictors on the rate of need for a new pacemaker is described using cross-tabulation and Fisher's exact tests, as well as univariate logistic regression models. The results of these models are reported as odds ratios (OR).

The impact of continuous predictors is first assessed in a continuous manner using a univariate logistic regression model that evaluates the need for a new pacemaker in function of the value of the continuous variable, as it is and following a logarithmic transformation. Further explorations are conducted by transforming each continuous predictor into a categorical variable based on the percentiles of its distribution on the global population. Variables corresponding to a split into two, three and four groups are created and their impact on the need for a new pacemaker is tested following the same methodology as the one described for the dichotomous predictors.

Survival at 30 days is analysed using standard time-to-event analysis techniques, and the following are reported:

– Information on the time-to-event data: number of subjects; number of events; minimum, maximum and median exit times

– Information on the distribution: mean and median times to response and associated 95% confidence interval (CI), time at which 25% and 75% of the cohort reach response (if applicable)
– Kaplan-Meier curve

Results

STUDY POPULATION

The baseline characteristics of the study population are described in **Table 1**. The current recommendations for TAVI were respected as the mean patient age was 82±4.7 years and the mean logistic EuroSCORE was 24.3±9.5%. A high proportion of patients had a history of coronary artery disease treated with either bypass grafts or percutaneous intervention (41.8%). The high-risk profile of the cohort is furthermore highlighted by a significant proportion of patients with diabetes mellitus, chronic pulmonary disease or creatinine clearance below 60 ml/min. The analysis of baseline ECG was notable, as 77.6% of the patients were in sinus rhythm, 27.6% had a left bundle branch block (LBBB), 14.2% had a right bundle branch block (RBBB) and 15.7% already had a permanent pacemaker. As regards the echocardiographic findings, despite a high frequency of coronary artery disease associated with aortic stenosis, the mean left ventricle ejection fraction (LVEF) was only mildly decreased prior to TAVI: 49.5%±13.3%.

Table 1. Baseline characteristics of the study population.

	Patients n=134
Age (years), mean±SD	82.4±4.7
Male, n (%)	81 (60.5)
Logistic EuroSCORE (%), mean±SD	24.3±9.5
NYHA Class II, n (%)	23 (17.2)
NYHA Class III, n (%)	100 (74.6)
NYHA Class IV, n (%)	11 (8.2)
Coronary artery disease, n (%)	56 (41.8)
Previous PCI, n (%)	40 (29.8)
Previous coronary bypass grafting	16 (11.9)
Degenerated aortic bioprosthesis, n (%)	4 (3)
Diabetes mellitus, n (%)	30 (22.4)
Chronic lung disease, n (%)	34 (25.4)
Liver cirrhosis, n (%)	2 (1.5)
Porcelain aorta, n (%)	6 (4.5)
Cerebrovascular disease, n (%)	16 (11.9)
Glomerular filtration rate <60 ml/min, n (%)	37 (27.6)
Sinus rhythm, n (%)	104 (77.6)
Previous pacemaker	21 (15.7)
1st degree atrioventricular block, n (%)	15 (11.2)
Left bundle branch block, n (%)	37 (27.6)
Right bundle branch block, n (%)	19 (14.2)
Aortic valve area (cm^2), mean±SD	0.73±0.19
Aortic annulus (mm), mean±SD	24.5±2.2
Mean transaortic gradient (mmHg), mean±SD	48.4±15
Left ventricle ejection fraction, (%), mean±SD	46.5±13.3 (35)
Mitral regurgitation grade 0-2/4, n (%)	27 (20.2)
Mitral regurgitation >grade 2/4, n (%)	0 (0)

NYHA: New York Heart Association

PROCEDURAL OUTCOME

Table 2 summarises the main procedural outcome. All procedures were performed under general anaesthesia, except two implantations done under conscious sedation because of severely impaired lung function. The vast majority of TAVI was achieved through transfemoral access (93.3%), while 6.7% were performed through the subclavian route. The overall success rate was 99.2%: one patient had two valves implanted due to the embolisation of a first prosthesis in the aortic root during final release. This case of valve embolisation occurred in patient 5, at an early stage of our experience with the MCVA.

Table 2. Procedural outcome.

	Patients n=134
Transfemoral, n (%)	125 (93.3)
Transaxillary, n (%)	9 (6.7)
Procedural success, n (%)	133 (99.2)
General anaesthesia, n (%)	132 (98.5)
Balloon aortic valvuloplasty, n (%)	129 (96.3)
Balloon-annulus ratio	0.95±0.09
26 mm CoreValve®, n (%)	27 (20.2)
29 mm CoreValve®, n (%)	107 (79.8)
Prosthesis-annulus ratio	1.17±0.09
Depth of implantation (mm), mean±SD	4.9±2
Correct final position, n (%)	93 (69.4)
High final position, n (%)	22 (16.4)
Low final position, n (%)	19 (14.2)
Paravalvular leakage grade 0-1/4, n (%)	106 (81.3)
Paravalvular leakage grade 2/4, n (%)	25 (18.7)
Paravalvular leakage > grade 2/4, n (%)	0 (0)
New left bundle branch block, n (%)	18 (13.4)
Transient or sustained complete atrioventricular block, n (%)	17 (12.7)

The mean aortic annulus in this cohort was 24.5±2.2 mm. There was a trend to use undersized balloons during valvuloplasty prior to valve implantation: mean balloon size was 23.2±1.7 mm and mean balloon-annulus ratio was 0.95±0.09. For example, among the 107 patients treated with the 29 mm MCVA, 47 (43.9%) had predilatation with a 22 mm Nucleus™ (NuMED Inc., Hopkinton, NY, USA) with a balloon-annulus ratio close to 0.85.

THE MEAN PROSTHESIS-ANNULUS RATIO OF 1.17±0.09

The mean depth of implantation was 4.9±2 mm. A low final position was observed in 19 patients (14.2%). In this latter subgroup of patients, mean depth of implantation was 8.1 mm.

After valve implantation, 18.7% of the patients had a paravalvular leakage (PVL) grade 2/4. Subsequently, post-dilatation was performed in 12.7% patients. The rest of the cohort had no PVL or less than 2/4. No patients had grade 3 or 4/4 regurgitation. No central leakage was noticed.

A new LBBB appeared in 18 patients (13.4%), while 12.7% experienced transient or sustained complete atroventricular (AV) block during the procedure. The exact timing of these periprocedural events was not sufficiently collected to be part of this analysis.

OUTCOME DURING FOLLOW-UP

At 30 days, the survival rate was 94% **(Table 3)**. Eight patients died; seven from a cardiovascular cause. The 134 patients who underwent the procedure were followed up for a mean time of 150±98 days. The shortest follow-up time was 12 days, the longest one was 380 days. Over that period, 16 out of the 134 patients died (11.9%). The Kaplan-Meier survival curve is presented in **Figure 3**.

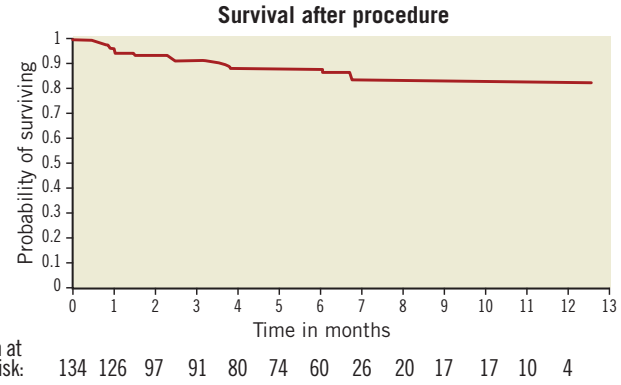

Figure 3. *Kaplan-Meier survival curve. n: number of patients at risk at each time interval*

New York Heart Association (NYHA) functional class significantly improved at 30 days. The vast majority of the patients who were in NYHA Class III-IV at baseline moved to NYHA Class I-II at 30 days (88.6%). There was a significant change between the two time-points ($p<0.001$).

Table 3 summarises the principal echocardiographic findings. Aortic valve area, mean transvalvular gradient and left ventricle ejection fraction significantly improved at 30 days. Mean mitral regurgitation grade did not significantly differ from baseline to 30 days.

A new permanent pacemaker (PPM) was implanted in 10.6% of the patients without a previous PPM (12/113) between 0 and 21 days after the procedure (mean of 4.4±5.9 days and median of two days). Eighty percent of the patients requiring a new pacemaker had one implanted within five days. The main indications for PPM were persistent complete atrioventricular block (5/12; 41.7%), transient high degree atrioventricular block (3/12; 25%), persistent prolonged PR interval with large LBBB (2/12; 16.7%) and slow atrial fibrillation (2/12; 16.7%) during telemetry monitoring. Patients with transient conduction abnormalities during the procedure, e.g., subsequent to balloon valvuloplasty, did not systematically receive a PPM if the previously described indications were not noticed during intensive care monitoring.

Table 3. Thirty-day outcome according to the definition of the Valve Academic Research Consortium.

	Patients n=134
Overall death, n (%)	8 (6)
Cardiovascular death, n (%)	7 (5.3)
NYHA Class I-II, n (%)	112 (88.9)
NYHA Class III, n (%)	12 (9.5)
NYHA Class IV, n (%)	2 (1.5)
New permanent pacemaker, n (%)	12/113 (10.6)
Days until new pacemaker, mean±SD	4.4±5.9
Vascular complication, n (%)	16 (11.9)
Major vascular complication, n (%)	7 (5.3)
Bleeding complication, n (%)	23 (17.2)
Life-threatening bleeding, n (%)	8 (6)
Major bleeding, n (%)	9 (6.7)
Stroke, n (%)	4 (3)
Acute kidney injury, n (%)	16 (11.9)
Myocardial infarction, n (%)	0 (0)
Effective orifice area (mm^2), mean±SD	1.91±0.67
Mean gradient (mmHg), mean±SD	8.2±3.5
Left ventricle ejection fraction (%), mean±SD	53±10.8
Paravalvular leakage grade 0-1/4, n (%)	109 (81.3)
Paravalvular leakage grade 2/4, n (%)	17 (12.7)
Paravalvular leakage >grade 2/4, n (%)	0 (0)
Mitral regurgitation grade 0-1/4, n (%)	3 (2.2)
Mitral regurgitation grade >1/4, n (%)	0 (0)

PREDICTORS OF THE NEED FOR A NEW PACEMAKER

Several potential predictors of need for a pacemaker after TAVI were investigated. No significant parameter was identified due to the relatively small number of patients needing a pacemaker in this cohort. We did not succeed in identifying similar RBBB (OR 2.72 [0.63-11.87], p=ns), use of a 29 mm prosthesis (OR 2.73 [0.33-22.90], p=ns) or left ventricular septal hypertrophy (OR 2.63 [0.08-83.32], p=ns) as predictors of need for a new pacemaker. Combining several predictors into a single model was not possible due to the limited sample size.

Discussion

This paper is one of the first to describe the potential impact of the Accutrak™ catheter on the accuracy of positioning a 26 or 29 mm CoreValve® across the aortic annulus and its impact on the need for a pacemaker.

The target depth of implantation was 4-6 mm below the plane of the aortic annulus. This objective was achieved in 69.4% of the patients, while 16.4% of the prostheses were implanted between 0 and 4 mm and 14.2% of the procedures ended with a prosthesis deeper than 6 mm. This finding is consistent with a real life setting in which the properties of the Accutrak™ catheter can be impeded by some frictions created by a tortuous peripheral vasculature or a horizontal aorta in a certain number of patients. Reports from the Rotterdam team, using the previous generation of CoreValve delivery catheter and the same method for measurement, showed that the mean depth of implantation was 8-9 mm[10]. In our series, the mean depth of implantation was 4.9 mm whilst it was limited to 8.1 mm in the subgroup of patients with a "low final position". Thus it appears that the main use of the Accutrak™ catheter is to help physicians in achieving a high final position. Implants higher than 4 mm were explained by the tendency of this catheter to generate an upward movement of the prosthesis during the last phase of the deployment. This phenomenon seems to be amplified by the presence of a septal bulge that pushes the inflow frame of the valve towards the ascending aorta. As a consequence, one embolisation in the aorta occurred and therefore a second valve had to be inserted in the correct location in patient 5. With increased experience in the use of this catheter, this late upward movement can be anticipated and minimised by applying a gentle push on the catheter shaft and pull on the intraventricular stiff wire, prior to final detachment of the CoreValve. One has to be aware of the difficulties in decoupling the hooks of the CoreValve from the inner catheter.

Piazza et al reported a pacemaker implantation rate of 9.3% following CoreValve implantation in 646 patients. In this registry, 83 patients were excluded from the final analysis because they had been treated without the presence of a physician proctor or a clinical specialist, which constituted a bias that could potentially impact on the real final pacemaker rate[11]. Following this encouraging initial report, several studies reported pacemaker rates ranging from 16 to 40%[7-9]. In a previous study using CoreValve, we noticed that a pacemaker was implanted in 27% of the patients[4]. The main finding of this paper is a dramatic decrease in the need for a pacemaker after CoreValve Accutrak™ implantation: 10.6% at 30 days. One explanation for this low event rate seems to be that we have been able regularly to achieve implants less than 6 mm below the plane of the aortic annulus. This is consistent with reports identifying a low final position of the CoreValve as a predictor for further need of a pacemaker[12]. Similarly, Gutierrez et al observed that a low positioning of the Edwards SAPIEN valve, through transapical access, was associated with a higher rate of LBBB, highlighting the importance of a correct final position of any TAVI prosthesis to minimise conduction disturbances[13]. We could not identify statistically significant predictors of need for a pacemaker nor demonstrate that a low final position was associated with a greater risk of need of a pacemaker because only a few deep implantations and few events occurred in this series. In a recent meta-analysis of 5,258 patients, Erkapic et al identified RBBB and CoreValve implantation as the only predictors of pacemaker requirement following TAVI, with 90% of the events occurring within the first week[14]. Pre-existing RBBB could, for centres using both Edwards SAPIEN XT® and CoreValve®, be an indication for use of the balloon-expandable device in order to decrease the global risk of need for a permanent pacemaker.

Grube et al also recently reported a decreased need for a pacemaker (11.7%) after CoreValve in a series of 60 patients treated without balloon predilation[15]. The multifactorial aspects of conduction disturbances occurring after TAVI have recently been highlighted by Nuis et al in a series of 65 patients treated with the Medtronic CoreValve system. New conduction anomalies occurred at different steps of the procedure, principally after balloon valvuloplasty (46% of the patients), prosthesis expansion (29%) and positioning of the prosthesis (12%). Patients who developed a new conduction anomaly during balloon valvuloplasty had a significantly higher balloon/annulus ratio than those who did not (1.10±0.10 vs. 1.03±0.11, p=0.030[16]). In our cohort we tended to downsize balloons for valvuloplasty in a significant number of patients. This could also have an impact on the decreased rate of need for a pacemaker, besides achieving high implantations. The optimal balloon-artery and valve-artery ratios remain to be determined. We could not achieve this in this report because of the low number of pacemaker implantations. Larger registries are needed.

No clear guidelines exist for pacemaker implantation for TAVI. The variety in indications from one centre to another largely explains divergences in reported pacemaker rates. In this report, we did not consider a new LBBB alone as an indication for the need for a pacemaker, without any subsequent event during follow-up. This policy may have had an impact on the final low rate of the need for a pacemaker. Standardisation of the indication for the need for pacemaker implantation and monitoring post TAVI will be helpful to improve our practice. For healthcare costs, it is important to reduce the rate of need for pacemaker implantation post TAVI, but little is known about the real impact on the overall outcome, in terms of morbidity and mortality.

Our study has several limitations. It is an observational study. We included a limited number of patients at two centres. More precise measurement of the final depth of implantation would have been obtained by performing MSCT post TAVI, which was not the case in this cohort. Although MSCT is also becoming a technique of choice for measuring the aortic annulus, assessing the aortic root and planning the procedure, a significant proportion of our study population did not undergo this technique. Therefore, we decided not to integrate MSCT in our analysis. Recently in our experience, MSCT is being systematically performed during the screening phase.

We did not directly compare cohorts of patients treated with the third generation CoreValve® and the CoreValve Accutrak™ because some important data regarding baseline ECG and final position were missing for the first cohort. Both centres are also Edwards

SAPIEN XT® users and this could have created a bias in the selection of the patients receiving the Medtronic CoreValve Accutrak™ although we tried to include consecutive patients suitable for CoreValve.

Conclusion

It appears that implanting 26 or 29 mm CoreValve® in a high position, in regard to the aortic annulus, may result in a decreased need for a pacemaker. The Accutrak™ catheter seems to be helpful in achieving higher and more predictable implants. Operators could standardise their technique to place the CoreValve prosthesis less than 6 mm below the aortic annulus.

Conflict of interest statement

D. Tchetche is proctor for Edwards Lifesciences and Medtronic. T. Modine is a proctor for Medtronic. The other co-authors have no conflicts of interest to declare.

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