

Surface and intracardiac ECG for discriminating conduction disorders after CoreValve implantation

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Received: 25 March 2011 / Accepted: 7 December 2011 / Published online: 17 December 2011
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Abstract

Background Transcatheter aortic valve implantation (TAVI) has been developed to minimize operative morbidity and mortality in high-risk symptomatic patients unfit for open surgery. With the proximity of the aortic valve annulus to the conduction system there is, however, an unknown risk of conduction disturbances necessitating monitoring and often cardiac pacing.

Materials and methods We enrolled 50 consecutive patients from January 2007 to 2008 in our prospective evaluation of conduction disturbances measured by surface and intracardiac ECG recordings. Baseline parameters, procedural characteristics as well as twelve-lead surface ECG and intracardiac conduction times were revealed pre-interventionally, after TAVI and at 7-day follow-up.

Results TAVI was performed successfully in all patients. During 7 days of follow-up the rate for first-degree AV block raised from 14% at baseline to 44% at day 7 ($p < 0.001$), while rates for type II second- and third-degree were 0 versus 8% ($p < 0.001$) and 0 versus 12% ($p < 0.001$), respectively. Similarly, the prevalence of new left bundle branch block (LBBB) rose from 2 to 54% ($p < 0.001$). Intracardiac measurements revealed a prolongation of both AH and HV interval from 123.7 ± 41.6 to 136.6 ± 40.5 ms ($p < 0.001$) and from 54.8 ± 11.7 to 71.4 ± 20.0 ms ($p < 0.001$), respectively. Pacemaker implantation at a mean follow-up of 4.8 ± 1.2 days was subsequently performed in 23 patients (46%) due to complete AV block (12%) and type II second-degree AV block (8%) while another 13 patients (26%) received a pacemaker for the combination of new LBBB with marked HV prolongation. The high rate of first-degree AV block was primarily driven by an increase in HV interval.

Conclusion Cardiac conduction disturbances were common in the early experience with CoreValve implantation necessitating close surveillance for at least 1 week.

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Dr. Ince is an accredited proctor to Medtronic CoreValve system.

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Keywords Conduction disorders · CoreValve · AV block ·
Pacemaker · Left bundle branch block · His bundle

Introduction

Rising life expectancy results in an increase in degenerative and neoplastic diseases. Population-based observational studies have revealed that 1–2% of patients over 65 years have moderate to severe aortic stenosis [1]. Current guidelines consider aortic valve replacement as a class I indication for symptomatic patients [2, 3], facing,

however, the fact that one-third of patients are considered to have an unacceptably high risk for open surgery [4]. Current treatment options for those patients include medical treatment and percutaneous balloon aortic valvuloplasty, although neither has been shown to reduce long-term mortality of medically treated patients with symptomatic aortic stenosis with a 1- and 5-year survival of 60 and 32%, respectively, and only minor short-term benefits were reported after balloon aortic valvuloplasty [5–7]. Transcatheter aortic valve implantation (TAVI) has recently been developed to minimize surgical risk in high-risk patients with severe symptomatic aortic stenosis who are refused for conventional open aortic valve replacement. With the anatomical proximity of the conduction system to the aortic annulus there is potential to develop conduction disorders in up to 6% even after conventional surgical aortic valve replacement [8, 9]. Initial experience with TAVI reported complete AV block and pacemaker requirement in 5.7–42.5% [10–17]. Better prediction of pacemaker requirement would be of considerable benefit in patients undergoing TAVI with respect to potential need and duration of postoperative monitoring. We examined both incidence and characteristics of conduction disorders periinterventionally and during in-hospital follow-up period after TAVI measured by surface and intracardiac ECG recordings.

Methods

Patients

Between January 2007 and 2008, 50 consecutive patients who underwent TAVI using the third-generation percutaneous self-expanding CoreValve prosthesis (Medtronic, Minneapolis, MN, USA) were identified for this study. The criteria for inclusion and exclusion to the TAVI procedure have been described elsewhere [10, 11]. In brief, patients were included with echocardiographic measurements demonstrating severe native valvular aortic stenosis with an area $<1\text{ cm}^2$, or $<0.6\text{ cm}^2/\text{m}^2$ regardless of adjunct regurgitation; a diameter of the basal orifice of the stenosed valve between 20 and 27 mm; and a diameter at the sinotubular junction $\leq 43\text{ mm}$. Most importantly, all patients were considered unfit for open surgery with a EuroSCORE $\geq 20\%$ [10, 11, 18]. TAVI was suggested in agreement between a cardiac surgeon and both, a clinical and interventional cardiologist; patient's or referring physician's preference was not relevant. Pacemaker implantation at follow-up was considered as indicated in case of complete AV block, type II second-degree AV block, and in presence of new LBBB in combination with HV prolongation to $\geq 75\text{ ms}$.

Procedure

Details of the implantation procedures have been described elsewhere [10–17]. In brief, all patients were operated in a hybrid interventional suite under general anesthesia to assure stable hemodynamics and minimize patient movement during valve implantation. TAVI was performed via femoral access under fluoroscopic imaging. The aortic valve was initially dilated using a standard valvuloplasty balloon with a nominal diameter similar to the aortic valve and followed by CoreValve insertion [10, 11].

In each patient, prior to TAVI and aside a right ventricular bipolar pacing lead (PacelTM, St. Jude Medical, St Paul, MN, USA), a 6F quadripolar electrode catheter with ring electrodes (5-mm interpolar distance) (Webster DTM, Biosense Webster, Diamond, USA) was introduced and advanced to the His bundle. A 6F quadripolar electrode catheter (SoloistTM, Medtronic, Minneapolis, MN, USA) was advanced to the right atrium and another to the right ventricle to record a bipolar electrogram and for programmed atrial and ventricular stimulation. The access sites for all electrophysiologic electrode catheters were the femoral veins. With such instrumentation the sinus node recovery time (SNRT), corrected sinus node recovery time (c-SNRT), antegrade and retrograde effective refractory period (ERP) of the AV node, as well as intracardiac conduction times (atrium to His and His to ventricle time; AH and HV interval) were assessed. The rationale to measure SNRT was the observations of sinus node arrest in a single patient receiving a CoreValve prior this study. Thus, we wanted to avoid overseeing sinus node pathology in this elderly patient suffering from a high comorbidity index. All measurements were done on an Axiom SensisTM (Siemens, Erlangen, Germany) electrophysiology workstation. The AV nodal ERP was measured by introducing a single extrastimulus (S2) after a drive train of 8 stimuli at a fixed rate (S1) (600 ms), at which time the S1–S2 interval is decreased until the S2 impulse does not conduct to the His bundle. To assess conduction disorders, patients were attached to uninterrupted ECG monitoring using the Philips monitoring system (IntelliVueTM, Best, The Netherlands) that is installed at our ICU/IMC unit. All patients were prophylactically given a temporary pacemaker via the existing femoral venous access; with VVI mode the active pacing was 60 bpm for at least 24 h.

Statistical methods

All data were processed using the SPSS statistical package for windows, release 16.0 (Chicago, IL, USA). The descriptive statistical characteristics for quantitative parameters are listed as numbers (*n*), arithmetic mean (mean), median (med), minimum (min), maximum (max),

and relative frequency (%). The Fisher exact test and χ^2 -test were used to compare proportions. A normal distribution of differences was confirmed by the Kolmogorov–Smirnov test; in presence of normally distributed data paired-sample *t* testing was used while with non-normal distribution the Wilcoxon rank test was required. Differences were considered significant at a probability value of $p < 0.05$.

Results

The analysis included 22 men and 28 women with a mean age of 81.5 ± 6.8 years. All patients had qualified for TAVI according to recent recommendations [10, 11]. Clinical symptoms included dyspnoea (56%), angina (42%), syncope (22%) as well as heart failure (38%) (Table 1). The logistic EuroSCORE operative mortality estimate was $23.0 \pm 17.5\%$ while 4 patients (8%) were classified inoperable because of porcelain aorta. Echocardiographic mean pressure across the aortic valve was 55 ± 15.4 mmHg with an aortic valve area of 0.7 ± 0.2 cm² measured by planimetry during transesophageal echocardiography.

TAVI required a mean procedural and fluoroscopy time of 109.6 ± 36.4 min and 14.1 ± 1.6 min, respectively, and was successfully performed in all patients followed by an intensive care and hospital stay of 2.2 ± 2.8 and 13.8 ± 9.3 days. The placement of electrode catheters throughout the procedure resulted in an additional fluoroscopy time of 2.5 min. Six patients suffered from intra-procedural circulatory depression and required intermittent intravenous catecholamines; one patient required 1 DC shock for ventricular fibrillation induced by wire irritation. Postinterventional aortography revealed a mean aortic insufficiency grade of 1.2 ± 0.58 (Table 2).

Sinus rhythm was documented at baseline in 39 (78%) and atrial fibrillation in 9 (18%); five patients (10%) had previously implanted pacemakers due to bradyarrhythmia ($n = 3$; 6%) and sino-atrial block ($n = 2$; 4%). Seven patients (14%) had first-degree AV block before TAVI, which increased to 22 (44%) ($p < 0.001$) at 7-day follow-up. Similarly, newly developed second-degree AV block (all of them being type II blocks) was present in 4 (8%) at follow-up ($p < 0.001$). LBBB, present in 1 patient (2%) prior to TAVI, was documented at the time of post-procedural electrogram in 20 patients (40%) eventually rising to 27 (54%) at 7-day follow-up ($p < 0.001$). The two patients with pre-existing left anterior hemiblock developed complete left bundle branch block and the two patients with pre-existing right bundle branch block emerged with complete AV block after placement of the CoreValve prosthesis. All four patients received permanent

Table 1 Baseline characteristics of the study population ($n = 50$)

Variable	
Clinical parameters	
Male, <i>n</i> (%)	22 (44)
Age (years)	81.5 ± 6.8
BMI (kg/m ²)	26.8 ± 3.8
Hypertension, <i>n</i> (%)	46 (92)
Smoker, <i>n</i> (%)	15 (30)
Diabetes mellitus, <i>n</i> (%)	19 (38)
Creatinine (μ mol/l)	133.6 ± 114.5
Renal insufficiency (creatinine level >1.5 mg/dl), <i>n</i> (%)	28 (56)
Chronic obstructive pulmonary disease, <i>n</i> (%)	10 (20)
New York Heart Association functional class (grade)	3.2 ± 0.6
Logistic EuroSCORE (%)	23.0 ± 17.5
Dyspnoea, <i>n</i> (%)	28 (56)
Angina, <i>n</i> (%)	21 (42)
Syncope, <i>n</i> (%)	11 (22)
Pulmonary artery pressure (mmHg)	41.2 ± 18.2
Porcelain aorta, <i>n</i> (%)	4 (8)
Cardiac decompensation, <i>n</i> (%)	19 (38)
Ischemic heart disease, <i>n</i> (%)	38 (76)
Previous coronary artery by pass graft surgery, <i>n</i> (%)	6 (12)
Peripheral vessel disease, <i>n</i> (%)	6 (12)
Cerebral vascular disease, <i>n</i> (%)	16 (32)
Echocardiographic parameters	
Aortic valve area (cm ²)	0.7 ± 0.2
Left ventricular ejection fraction (%)	47.6 ± 11.4
Peak pressure gradient (mmHg)	86.9 ± 25.9
Mean pressure gradient (mmHg)	55.4 ± 15.4
Aortic annulus dimension (mm)	22.8 ± 3.6
Aortic bulbus dimension (mm)	29.6 ± 3.4
Interventricular septal dimension (mm)	14.1 ± 1.6
Aortic regurgitation grade \geq I, <i>n</i> (%)	19 (38)
Mitral insufficiency \geq grade II, <i>n</i> (%)	43 (86)

pacemaker due to either complete AV block or markedly prolonged HV conduction.

Of the 22 patients suffering from first-degree AV block, intracardiac measurements revealed 18 cases of HV prolongation (13 patients with a prolongation to ≥ 75 ms and 5 patients with a prolongation up to 75 ms) while 8 had AH prolongation without progression to complete heart block and thus not necessitating a permanent pacemaker. Similarly, five patients with HV prolongation to values lower than 75 ms (2 patients with additional new LBBB) received no pacemaker and had no higher degree conduction abnormality during observation. Baseline AH and HV intervals increased from 123.7 ± 41.6 and 54.8 ± 11.7 ms

Table 2 Intraoperative data

Parameter	
Procedural success, <i>n</i> (%)	50 (100)
Conversion to surgical AVR, <i>n</i> (%)	0 (0)
Intraprocedural circulatory depression, <i>n</i> (%)	6 (12)
Catecholamine therapy, <i>n</i> (%)	6 (12)
Resuscitation, <i>n</i> (%)	2 (4)
Defibrillation, <i>n</i> (%)	1 (2)
Vascular access site complication, <i>n</i> (%)	9 (18)
Contrast agent (ml)	117.2 ± 50.2
Procedure time (min)	109.6 ± 36.4
Fluoroscopy time (min)	14.1 ± 1.6
CoreValve size (mm)	
26	23 (46)
29	27 (54)
Pre-TAVI valvuloplasty, <i>n</i> (%)	50 (100)
Post-TAVI valvuloplasty, <i>n</i> (%)	21 (42)
Number of inflations after TAVI (<i>n</i>)	1.1 ± 0.2
Balloon diameter (mm)	21.7 ± 2.1
Balloon length (mm)	53.8 ± 12.6
Angiographic aortic insufficiency (grade)	1.2 ± 0.58
ICU stay (days)	2.2 ± 2.8
Hospital stay (days)	13.8 ± 9.3

to 136.6 ± 40.5 and 71.4 ± 20.0 ms at 7-day follow-up without any significant change in SNRT, c-SNRT (Table 3). Any increasing intracardiac conduction time was irreversible (Figs. 1, 2).

At 7 days, complete heart block with pacing was present in 6 cases (12%), while another 4 patients (8%) received a pacemaker for type II second-degree AV block and further 13 patients (26%) for the combination of new LBBB with an increase in AV conduction time, especially the HV intervals ≥ 75 ms (dual chamber pacing in 15 and single chamber pacing in 8 patients). All conduction abnormalities in patients receiving a pacemaker were due to delay or block in infra-His region. Pacemakers were implanted at 4.8 ± 1.2 days of follow-up. None of the five patients with previously implanted pacemakers experienced additional procedure-related pacemaker indication after TAVI.

Discussion

Aortic valve disease has been associated with cardiac conduction system disease as aortic stenosis and insufficiency have been associated with both prolonged AV conduction times and higher degrees of AV block [19–21]. Due to the vicinity of aortic valve and AV node as well as His bundle, AV block is a common complication of conventional surgical aortic valve replacement and has been

described in up to 6% [8, 9]. New LBBB after surgical valve replacement is even more common and has been reported in 18% [8, 9]. Furthermore, development of new LBBB after surgical aortic valve replacement is associated with higher rates of complete AV block, syncope, and sudden cardiac arrest at long term [8, 9, 22]. Such conduction disturbances are presumed to result from surgical trauma to the cardiac conduction tissue during debridement of the calcified annulus [8, 9, 22].

TAVI is a relatively new alternative to conventional surgical valve replacement in high-risk patients not eligible for open surgery [10, 11]. There are only few data regarding the incidence of early conduction disorders after TAVI. The incidence of permanent pacemaker implantation after TAVI with the CoreValve system has been reported in 20–42.5%, and that of a new LBBB in 50–70% [12–15, 23]. In the study by Marcheix et al. [23] 30% of patients required pacemaker implantation due to persistent AV block [23], whereas Zahn et al. [12] reported a permanent pacemaker rate of 42.5% in the German Transcatheter Aortic Valve Intervention Registry [12]. Different rates of pacemaker implantation might be due to different indications for pacing (e.g. complete AV block, new LBBB, prolonged AV conduction). A comparison of hard endpoints like high-grade AV block would be more convincing. Other reasons for different pacemaker implantation rates might be the learning curve with high implantation techniques resulting in less compromise of the compact AV node [23–27].

Although several reports describe changes in surface ECG, our study is the first to note intracardiac conduction abnormalities for better discriminating new ECG changes on surface ECG. Interestingly, the evolution to complete AV block and to LBBB took place over an observation period of 7 days. Similarly, PQ interval and QRS duration, as well as AH and HV intervals prolonged and resulted in a rate of permanent pacemakers of 46%. The AH interval is considerably affected by patient's autonomic state when TAVI procedure is performed under general anesthesia. However, the main changes during TAVI results in HV conduction. Scheinman et al. [24] have shown that patients with an HV interval greater than 100 ms are at high risk to develop complete AV block. Therefore, the possibility of progression of LBBB to complete AV block should always be considered [22, 24, 25] and may explain the liberal use of pacemakers for conduction disorders observed in our series of TAVI patients. This liberal approach may be debatable, but in elderly patients with several comorbidities preventive pacemaker insertion is justified by guideline recommendation [25]. Piazza et al. [26, 27] showed that some of the initial conduction delay after TAVI was partially reversible at 1-month follow-up and presumably related to inflammation and edema around the conduction

Table 3 Electrocardiographic characteristics during follow-up

Variable	Before TAVI	After TAVI	7 days after TAVI	<i>p</i> Value before TAVI versus after TAVI	<i>p</i> Value after TAVI versus 7 days after TAVI	<i>p</i> Value before TAVI versus 7 days after TAVI
Rhythm						
Sinus, <i>n</i> (%)	39 (78)	39 (78)	38 (76)	0.999	0.873	0.766
Atrial fibrillation, <i>n</i> (%)	9 (18)	9 (18)	9 (18)	0.999	0.999	0.999
Pacemaker, <i>n</i> (%)	2 (4)	2 (4)	3 (6)	0.999	0.647	0.835
Heart rate (beats/min)	69.8 ± 11.4	69.6 ± 13.4	66.1 ± 16.2	0.835	0.694	0.372
Surface ECG						
PQ interval (ms)	179.4 ± 48.5	203.5 ± 51.2	210.6 ± 49.5	0.001	0.001	0.03
QRS width (ms)	98.8 ± 16.8	125.6 ± 29.4	142.0 ± 36.0	0.001	0.001	0.001
QT interval (ms)	395.0 ± 31.0	410.0 ± 31.5	407.5 ± 27.9	0.714	0.682	0.477
Hemiblock, <i>n</i> (%)						
Anterior	4 (8)	1 (2)	2 (4)	0.009	0.055	0.012
Posterior	0 (0)	0 (0)	1 (2)	0.999	0.456	0.348
Bundle branch block, <i>n</i> (%)						
Left	1 (2)	20 (40)	27 (54)	0.004	0.001	0.001
Right ^a	2 (4)	0 (0)	0 (0)	0.006	0.999	0.001
Atrioventricular block, <i>n</i> (%)						
First degree	7 (14)	11 (22)	22 (44)	0.001	0.384	0.001
Second degree ^b	0 (0)	4 (8)	4 (8)	0.001	0.994	0.001
Complete	0 (0)	4 (8)	6 (12)	0.001	0.001	0.001
Intracardiac measurement						
c-SNRT (ms)	484.4 ± 68.1	492.8 ± 73.5	478.1 ± 56.7	0.280	0.638	0.612
SNRT (ms)	1070.5 ± 171.0	1078.7 ± 165.4	1103.9 ± 160.9	0.736	0.882	0.824
AH interval (ms)	123.7 ± 41.6	129.7 ± 38.8	136.6 ± 40.5	0.263	0.459	0.001
HV interval (ms)	54.8 ± 11.7	66.8 ± 16.9	71.4 ± 20.0	0.001	0.003	0.001
Antegrade AVN ERP	408.8 ± 45.1	446.7 ± 91.8	451.4 ± 55.6	0.001	0.638	0.001
Retrograde AVN ERP	439.3 ± 47.1	464.3 ± 56.4	479.4 ± 66.1	0.046	0.378	0.033

^a Both patients suffered from complete AV block during follow-up

^b All second-degree AV blocks were type II blocks

pathways [26, 27]; in our series we could not identify a single case of conduction recovery.

Notably, we demonstrated a higher pacemaker requirement rate than seen after open surgical technique. A critical issue, however, is that, with surgical replacement, the native valve is explanted, whereas with TAVI, the native aortic valve remains in situ and is compressed by stent frame against the surrounding structures. Other potential sources of local damage can include degeneration and

calcification of the conduction system, the mechanical or ischemic effects of pre-implantation balloon valvuloplasty, or the direct contact and trauma by catheters and guide-wires with components of the conduction system; however, trauma from percutaneous balloon aortic valvuloplasty is often reversible. The close anatomic vicinity of the His bundle to the non-coronary and right-coronary cusp results in a mechanical damage of the compact AV node and bundle of His, predominantly (but not exclusively) of the

Fig. 1 Intracardiac measurements during follow-up

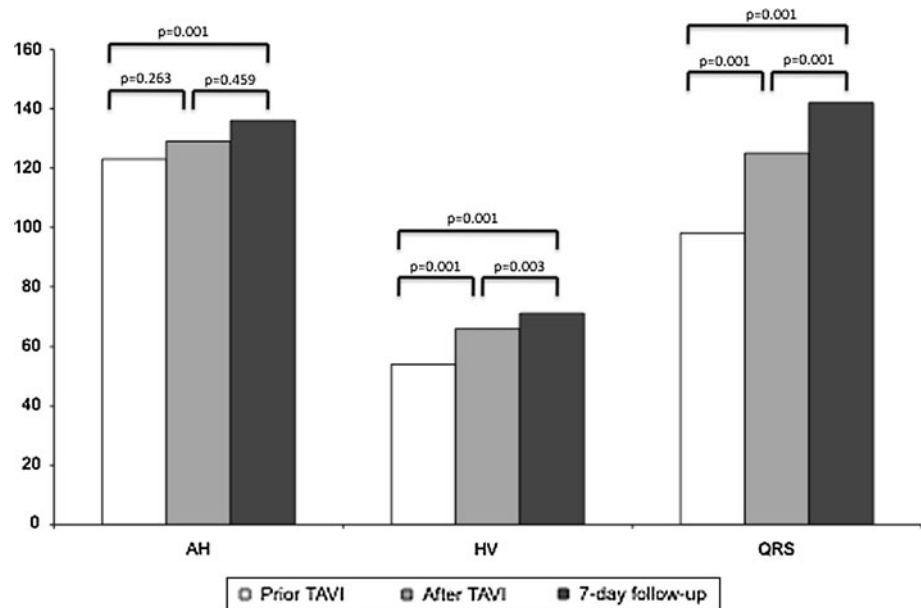
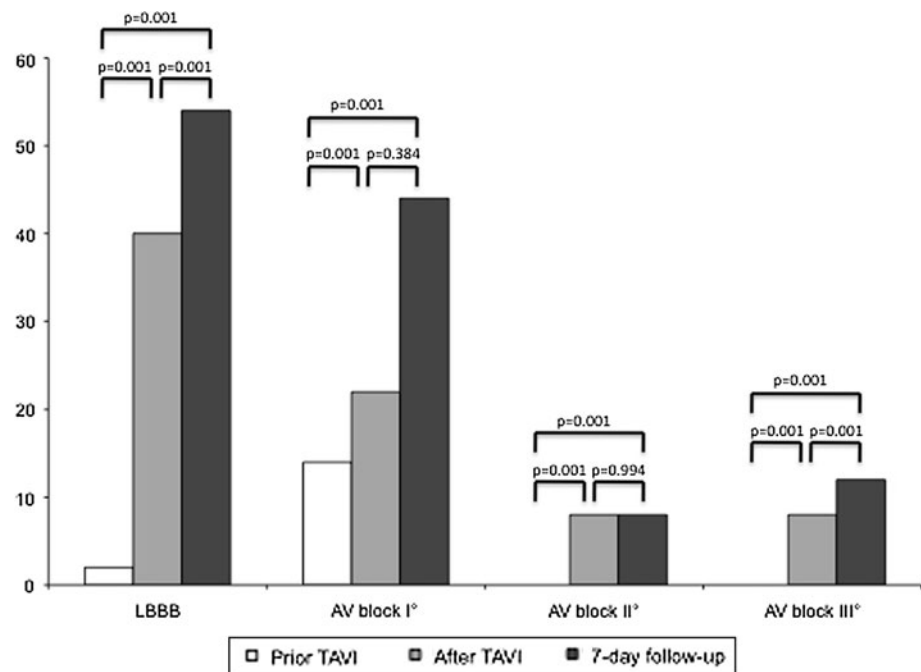


Fig. 2 Electrocardiographic characteristics during follow-up



infra-His region during TAVI. Additionally, compression from nitinol expansion (over hours and days) explains further mechanical trauma and “late” onset of conduction disturbances. Actually we have no data according to the time course of prosthesis expansion. Our experience showed that most of the conduction disturbances emerged within the first 7 days.

Nevertheless, with the balloon-expandable shorter Edwards SAPIEN prosthesis, which is placed in the aortic annulus without direct impact on left ventricular outflow tract (LVOT), the incidence of AV conduction block

requiring pacemaker was reported between 0 and 6% and new onset LBBB of 3.3% [28, 29].

Although yet to be investigated, technical strategies to diminish trauma to the conduction system by TAVI using the CoreValve revalving system may reduce the risk of conduction abnormalities. Such strategies may include limiting the depth of the valve within the LVOT and keeping the number of pre- and post-valve implantation balloon valvuloplasties to a minimum. Additionally, operators should deploy the device only a few millimeters below the annulus and avoid impacting the septum. A

modified implantation technique, however, may also require technical modifications to avoid malalignment of valve. Such new challenging technical approach was, however, not utilized in our early implantation experience.

Conclusion

Cardiac conduction disturbances were common after TAVI and need close surveillance at least during the first week after implantation. The indication for pacemakers in our patient population was liberal and somewhat prophylactic due to the combination of new LBBB with an increase in AV conduction time, especially HV interval. Further evaluation with long-term follow-up is required to analyze a potential temporal evolution of these conduction disturbances as well as progression of the combination of new LBBB with an increase of AV conduction time to complete heart block.

Conflict of interest No conflict of interest for IA, SK, HS, AL, JO, DB, TCR, OT, RS, GK, HK, TC, CAN.

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