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Conduction disorders using the Evolut R prosthesis compared with the CoreValve: has anything changed?

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ABSTRACT

Aim We compared early postprocedural and midterm evolution of atrioventricular and intraventricular conduction disorders following implantation of the new generation Evolut R (ER) prosthesis in comparison with the previous generation CoreValve (CV) system using routinely recorded ECG up to 6-month follow-up.

Methods All consecutive patients treated by transcathether aortic valve implantation (TAVI) using the Medtronic self-expanding devices for symptomatic severe aortic stenosis in a single centre between October 2011 and February 2016 were considered for inclusion. ECGs recorded at baseline, day 1 after TAVI, discharge and 6 months were retrospectively analysed. At each time-point, intrinsic rhythm, PR interval, QRS axis and duration, and atrioventricular and intraventricular conduction were analysed. Atrioventricular and intraventricular conduction following TAVI at discharge and at 6 months were compared intrasubject at the different time intervals and between patients receiving the ER versus the CV prosthesis.

Results Among the 113 patients included in the analysis (51% female, 83.3±6.2 years), 60 (53%) patients received the CV and 53 (47%) patients received the ER. Compared with patients in the CV group, those in the ER group had a lower Society of Thoracic Surgeons score (6.3±3.1vs 4.8±3.6, P=0.02). Patients in the ER group in comparison with those in the CV group more frequently had postprocedural PR interval (57%vs23%, respectively, P=0.004) and QRS prolongation (76%vs50%, P=0.03) at discharge. Incidence of complete atrioventricular block was similar between both groups (9%vs18%, P=0.3) up to 6-month follow-up. No difference in term of new left bundle branch block (LBBB) (34%vs28%, P=0.8) or permanent pacemaker implantation rates (32.1%vs31.7%, P=1.0) was reported.

Conclusions Patients with the ER had greater postprocedural atrioventricular and intraventricular conduction delays than those with the CV at discharge, with however similar incidence of high-degree atrioventricular block, new LBBB and permanent pacemaker implantation up to 6-month follow-up.

Key questions

What is already known about this subject?

- Postprocedural conduction disorders following transcatheter aortic valve implantation remain frequent and their management challenging. With respect to the Medtronic self-expanding prostheses, there was no significant decrease in the new pacemaker implantation rate when implanting the Evolut R compared with the CoreValve in our experience.

What does this study add?

- Whether the new generation Evolut R prosthesis performs better in terms of atrioventricular and intraventricular conduction recovery than the CoreValve prosthesis has not yet been reported.

How might this impact on clinical practice?

- Despite the new design of the Evolut R prosthesis including repositionable properties, incidence of postprocedural conduction disturbances has not improved significantly in comparison with patients receiving the previous generation CoreValve prosthesis.

INTRODUCTION

Over the past years, transcathether aortic valve implantation (TAVI) has become a routine procedure with broadening indications. However, despite significant improvements in design of valvular prostheses leading to better clinical outcomes in recent trials,[1 2] postprocedural conduction disorders remain frequent and their management challenging. A new generation of self-expandable transcatheter heart valves, the Medtronic Evolut R system (Medtronic, Minneapolis, Minnesota, USA, henceforth referred to as ER), has recently been developed with improved valve deployment accuracy and recapturing/repositioning properties. Optimised radial expansion forces have also been improved. Impact of this new valve on cardiac conduction disorders has not been described in detail yet.

We aim to compare early postprocedural and midterm evolution of atrioventricular and intraventricular conduction properties

following implantation of the new generation ER prosthesis to the previous generation CoreValve (CV) system.

METHODS

Study and data collection

All consecutive patients treated by TAVI using the Medtronic self-expanding devices for symptomatic severe aortic stenosis in our tertiary referral centre between October 2011 and February 2016 were considered for inclusion. Patients for whom no follow-up ECGs were available were excluded from the analysis. Patients with a ventricular paced rhythm at baseline were also excluded, as conduction delays could not be assessed.

Before the procedure, all patients had an assessment of medical history, physical examination, frailty assessment, ECG, transthoracic echocardiography and blood tests as previously described.[3–5] In addition, multislice CT (MSCT)—MRI and/or transoesophageal echocardiography in cases of severe renal insufficiency—was performed to measure aortic annulus and root dimensions as well as to assess minimal iliofemoral or subclavian vascular diameter, tortuosity and calcifications. Finally, each case was discussed at our Heart Team meeting.

All patients gave written informed consent to the TAVI procedure and use of related anonymous data for research and publication and were also included in the Swiss TAVI registry.

Procedure

Procedural steps have been described previously in detail for both devices.[4 5] Importantly, a temporary right jugular transvenous pacemaker with a screw-in lead was systematically implanted at the beginning of procedures and kept for at least 48 hours and up to 5 days.[6]

Medtronic self-expanding devices were used in all procedures. The CV prosthesis was used until the launch of the ER system in Switzerland in February 2015. Thereafter, patients with a large aortic annulus (perimeter between 81.7 mm and 91.1 mm) continued to receive the 31 mm CV prosthesis, whereas those with a smaller annulus received the new generation ER prosthesis. The ER 34 became available in Switzerland after the end of patient recruitment for this analysis.

Sizing was based on MSCT measurements and device sizing charts. Oversizing ratio was calculated as *(prosthesis size–aortic annulus diameter)/prosthesis size*, whereas aortic annulus diameter was defined as the mean of the diameters estimated by measuring aortic annulus perimeter and area on gated MSCT: $perimeter/\varpi$ and $2\times\sqrt{(area/\varpi)}$, respectively. Depth of prosthesis implantation was measured on the final aortography and defined as the distance between the non-coronary cusp and the most proximal end of the deployed prosthesis stent frame in the left ventricle. Implantation was considered as low, optimal or high for measured distances <2 mm, 2–8 mm or >8 mm, respectively.

ECG analysis and criteria for permanent pacemaker implantation

Twelve-lead ECG recordings were done repetitively for all patients during hospitalisation and follow-up, with a paper speed of 25 mm/s and amplitude of 1 mV/10 mm. ECGs recorded at baseline defined as the last ECG recorded before TAVI, day 1 after TAVI, discharge and 6 months were retrospectively analysed by the same investigator (NP) blinded to the patient's name and clinical condition. A random control assessment of 80 ECGs was performed by a second investigator (TP) in order to control interobserver variability. Discharge ECG was considered as either the last ECG before patient's discharge or any ECG available between day 2 and day 10 following the index procedure.

At each time-point, intrinsic rhythm, PR interval, QRS axis and duration, and atrioventricular and intraventricular conduction were analysed. Intervals were measured using a manual calliper to the nearest 10 ms. Types of intraventricular conduction delays were defined according to the AHA/ACCF/HRS recommendations for the standardisation and interpretation of the ECG, with division into left and right bundle branch block (LBBB and RBBB, respectively) and unspecified interventricular conduction disorders.[7] Postprocedural PR interval and QRS prolongation were defined as a difference between the postprocedural ECG measurements and baseline >0. Indication for permanent pacemaker implantation was in adherence with the 2013 ESC (European Society of Cardiology) Guidelines on cardiac pacing and cardiac resynchronisation therapy.[8] Ventricular pacing rates at 6 months were reported for patients with a new permanent pacemaker. As pacemaker control was not systematically performed at the 6-month follow-up visit, the closest control was used.

Outcomes

Atrioventricular and intraventricular conduction following TAVI at discharge and at 6 months were compared intrasubject at the different time intervals and between patients receiving the ER versus the CV prosthesis. We assessed other clinical outcomes—all adjudicated according to the revised Valve Academic Research Consortium criteria[9]—including 30-day and 6-month all-cause mortality, strokes, life-threatening bleeding, major vascular complications and AKIN (Acute Kidney Injury Network) 2 or 3 renal failure. New permanent pacemaker implantation was also reported.

Statistical analysis

Categorical data are presented as numbers and percentages, whereas continuous data are expressed as mean±SD or median (IQR) according to their distribution. Data were compared using the χ^2 and Student's t-test as appropriate. Inter-rater reliability for ECG measurements was explored by intraclass correlation coefficient (ICC). All statistical analyses were performed using IBM SPSS Statistics V.23 (IBM, Armonk, New York, USA).

Table 1 Baseline characteristics

	Overall (n=113)	CoreValve (n=60)	Evolut R (n=53)	P values
Sex				
Female	58 (51)	33 (55)	25 (47)	0.4
Age, years	84.0 (80.0–88.0)	85.0 (81.0–88.0)	83.0 (80.0–87.0)	0.2
BMI, kg/m^2	25.6 (22.7–28.6)	25.0 (22.3–27.4)	26.1 (23.2–31.9)	0.2
NYHA				0.5
0–2	33 (29)	16 (27)	17 (32)	
3-4	80 (71)	44 (73)	36 (68)	
STS score, %	5.6±3.4	6.3±3.1	4.8±3.6	0.02
Comorbidities				
Dyslipidaemia	82 (73)	44 (73)	38 (72)	0.9
Diabetes mellitus	33 (29)	16 (27)	17 (33)	0.6
Hypertension	88 (78)	47 (78)	41 (77)	0.9
COPD	23 (20)	11 (18)	12 (23)	0.8
PVD	10 (9)	8 (13)	2 (4)	0.07
Ischaemic heart disease	47 (42)	29 (48)	18 (34)	0.09
Previous stroke	11 (10)	4 (7)	7 (13)	0.1
Echocardiographic characteristics				
Aortic valve area, cm^2	0.7±0.2	0.7±0.2	0.7±0.2	0.9
Aortic peak velocity, m/s	4.2±0.7	4.2±0.8	4.2±0.7	0.8
Mean aortic gradient, mm Hg	44.0±14.5	44.4±14.4	43.6±14.7	0.8
LVEF, %	57.9±10.9	58.5±9.6	57.3±11.9	0.6

Values are number (%), mean±SD or median (IQR).
BMI, body mass index; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PVD, peripheral vascular disease; STS, Society of Thoracic Surgeons.

RESULTS

Baseline and procedural characteristics

Baseline and procedural characteristics are presented in tables 1 and 2. Between October 2011 and February 2016, 168 patients underwent TAVI with a Medtronic self-expanding device at our centre. Nine patients with a ventricular paced rhythm at baseline and 46 patients with missing ECG at day 1 or discharge were excluded. Among the 113 remaining patients included in the analysis (51% female, 83.3±6.2 years), 60 (53%) received the CV and 53 (47%) received the ER. Compared with patients in the CV group, those in the ER group had a lower Society of Thoracic Surgeons score (6.3±3.1 vs 4.8±3.6, P=0.02). Main comorbidities were similarly distributed. Predilatation was used more often in patients in the CV groups, whereas postdilatation was needed more often in patients in the ER group. Oversizing ratio was similar between both groups (17.3%±4.3 vs 16.7%±4.7, P=0.5, respectively, for the ER or CV). Finally, the ER device was more frequently implanted at an optimal depth in the left ventricle outflow track in comparison with the CV (94% vs 77%, respectively, of the cases, P=0.01).

Electrocardiographic characteristics

Follow-up ECGs were available at day 1, discharge and 6 months in 98 (87%), 101 (89%) and 100 (89%), respectively, of the included patients. Discharge ECGs were recorded at 5.3±1.8 days following TAVI (5.3±1.6 vs 5.3±2.0, P=0.9, respectively, for the ER and CV groups). The interobserver reliability was good (ICC=0.89 for PR measurements and 0.85 for QRS measurements, P<0.001).

Baseline and postprocedural ECG characteristics are displayed in table 3. *At baseline,* the ER patients presented less first-degree atrioventricular block (AVB) than those in the CV group (28% vs 43%, P=0.03) but had similar QRS duration.

Among patients with postprocedural QRS prolongation *at discharge,* the rate of new LBBB was similar between ER and CV patients (34% vs 28%, P=0.8). However, there were more patients in the ER group compared with the CV group who presented both postprocedural PR interval and QRS prolongation (45% vs 17%, respectively, P=0.002).

Among patients undergoing predilatation, rate of high-degree AVB at discharge was similar in the ER and

Table 2 Procedural characteristics

	CoreValve (n=60)	Evolut R (n=53)	P values
Vascular access			0.3
Transfemoral	58 (97)	50 (94)	
Subclavian	1 (2)	3 (6)	
Direct aortic	1 (2)	0	
Predilatation	51 (86)	31 (60)	<0.01
Postdilatation	6 (10)	16 (30)	<0.01
Valve size used, mm			–
23	0	2 (4)	
26	28 (47)	22 (42)	
29	20 (33)	29 (55)	
31	12 (20)	–	
Valve position			0.01
High (<2 mm)	7 (12)	0	
Optimal (2–8 mm)	46 (77)	50 (94)	
Low (>8 mm)	7 (12)	3 (6)	
Valve oversizing, %	16.7±4.7	17.3±4.3	0.5

Values are number (%) or mean±SD.

CV groups (13% vs 20%, P=0.3), and only one patient with postdilatation (ER group) presented high-degree AVB.

At 6 months, a similar proportion of patients in both groups with first-degree AVB at discharge presented a PR interval <200 ms at 6 months (28% vs 20%, P=0.8, respectively, for the ER and CV group).

Permanent pacemaker implantation

Permanent pacemaker implantation rate was similar in patients implanted with ER or CV devices (32.1% vs 31.7%, P=1.0). Indications for permanent pacemaker implantation are reported in table 4. All but five patients had their permanent pacemaker implanted during the same index-hospitalisation. The five remaining patients underwent pacemaker implantation between the 30-day and 6-month follow-up for high-degree AVB (one patient in each group) and atrial fibrillation with slow ventricular conduction or sinus bradycardia (two patients in the CV group). One patient of the ER group, still in functional class NYHA III at 5-month post-TAVI, had a cardiac resynchronisation device implanted for LBBB and left ventricular ejection fraction <35%.

Ventricular pacing rates among patients with new permanent pacemaker for all indications (median of 5% (2–92) vs 21% (1–99), P=0.7, respectively, for the ER and CV group) and those implanted for third-degree AVB (51% (1–100) vs 52% (3–100), P=0.9) were similar between both groups (median time of control since TAVI of 12 months (6–13) vs 12 months (12–12), P=0.4).

Finally, rate of permanent pacemaker implantation were similar between the ER and CV group, both among

Table 3 Baseline and postprocedural ECG characteristics

	CoreValve (n=60)	Evolut R (n=53)	P values
Baseline ECG characteristics			
Atrial fibrillation/flutter	15 (25)	9 (17)	0.5
PR interval, ms	197.8±50.2	181.6±48.6	0.1
Atrioventricular block			
First degree	26 (43)	15 (28)	0.03
Mobitz I	0	0	
Mobitz II	0	0	
Third degree	0	0	
Ventricular conduction delay			0.2
LBBB	2 (3)	3 (6)	
RBBB	7 (12)	1 (2)	
RBBB+LAFB	0	2 (4)	
NIVCD	0	1 (2)	
QRS width, ms	92.2±25.4	88.3±28.0	0.4
QRS axis, °	8.4±54.8	6.7±50.9	0.9
Postprocedural ECG characteristics			
Atrial fibrillation/flutter			
Day 1	8 (13)	5 (9)	0.4
Discharge	13 (22)	7 (13)	0.3
6 months	7 (12)	7 (13)	0.4
PR interval, ms			
Day 1	212.0±51.3	192.1±37.8	0.06
Discharge	217.6±55.6	211.9±39.2	0.6
6 months	185±47.0	197.3±61.1	0.3
Δ PR interval, ms			
Δ day 1 to baseline	13.3±44.0	28.6±53.7	0.6
Δ discharge to baseline	17.6±37.1	41.9±63.6	0.06
Δ 6 months to baseline	−14.4±42.4	22.4±46.0	0.001
Δ 6 months to discharge	−33.9±46.2	−19.6±48.7	0.3
Δ PR interval >0, %			
Δ discharge to baseline	14 (23)	30 (57)	0.004
Δ 6 months to baseline	8 (27)	21 (40)	0.007
New atrioventricular block, at discharge			
First degree	22 (37)	28 (53)	0.09
Mobitz I	0	0	–
Mobitz II	0	1 (2)	–
Third degree	11 (18)	5 (9)	0.3
QRS width, ms			
Day 1	103.5±25.4	106.6±25.9	0.6
Discharge	109.8±27.0	117.4±27.8	0.2
6 months	103.2±27.1	112.7±27.1	0.1
Δ QRS width, ms			

Continued

Table 3 Continued

	CoreValve (n=60)	Evolut R (n=53)	P values
Δ day 1 to baseline	15.5±23.1	23.2±28.6	0.2
Δ discharge to baseline	21.5±21.8	32.6±27.0	0.03
Δ 6 months to baseline	13.2±29.9	26.8±27.6	0.03
Δ 6 months to discharge	−5.8±29.6	−1.0±21.1	0.4
Δ QRS width >0, %			
Δ discharge to baseline	30 (50)	40 (76)	0.03
Δ 6 months to baseline	26 (43)	36 (68)	0.09
Δ QRS axis, °			
Δ day 1 to baseline	8.0±33.1	−6.1±38.2	0.07
Δ discharge to baseline	−10.2±32.9	−15.8±50.7	0.5
Δ 6 months to baseline	4.1±45.2	−0.6±37.3	0.6
New permanent pacemaker, at 6 months	19 (32)	17 (32)	1

Values are number (%) or mean±SD.
LAFB, left anterior fascicular block; LBBB, left bundle branch block; NIVCD, non-specific intraventricular conduction disorder; RBBB, right bundle branch block.

patients with predilatation (26% vs 31%, respectively, P=0.6) and postdilatation (13% vs 33%, P=0.3).

Clinical outcomes

Clinical outcomes related to TAVI procedure were not significantly different between the ER and CV groups and are presented in table 5. No patient died from atrioventricular (AV) conduction disorders. At 6 months, five patients presented cardiovascular death. Two patients died during the indexed hospitalisation. The first one had a massive ischaemic cerebrovascular accident during the procedure and died at day 4. The second patient, even though he underwent permanent pacemaker implantation, was found deceased in bed at day 6 post-TAVI without pacemaker dysfunction. Fatal arrhythmia was assumed due to cardiac amyloidosis revealed by autopsy. The three remaining patients were rehospitalised for acute heart failure without prosthesis dysfunction, and therapeutic withdrawal was finally decided in the context of advanced multiple organ failure.

Table 4 Indication for permanent pacemaker implantation

	CoreValve (n=19/60)	Evolut R (n=17/53)
2:1 or greater AVB	12 (63)	5 (29)
Alternating LBBB and RBBB	0	1 (6)
First-degree AVB+either RBBB or LBBB	4 (21)	8 (47)
AF with slow ventricular conduction	2 (11)	2 (12)
Sinus bradycardia	1 (5)	0
Cardiac resynchronisation therapy	0	1 (6)

Values are number (%).
AF, atrial fibrillation; AVB, atrioventricular block; LBBB, left bundle branch block; RBBB, right bundle branch block.

Table 5 VARC-2 30-day clinical outcomes

	Overall (n=113)	CoreValve (n=60)	Evolut R (n=53)	P values
All-cause mortality				
30 days	7 (6)	5 (8)	2 (4)	0.4
6 months	9 (8)	7 (12)	2 (4)	0.2
Cardiovascular mortality				
30 days	3 (3)	2 (3)	1 (2)	0.6
6 months	5 (4)	4 (7)	1 (2)	0.2
All strokes	7 (6)	4 (7)	3 (6)	1
Disabling, % of strokes	4 (57)	3 (75)	1 (33)	
Life-threatening bleeding	5 (4)	2 (3)	3 (6)	0.7
Major vascular complications	6 (5)	2 (3)	4 (7)	0.4
AKIN 2 or 3	6 (5)	4 (7)	2 (4)	0.7

Values are number (%). AKIN, acute kidney injury network; VARC, valve academic research consortium.

DISCUSSION

We hereby present detailed analyses of atrioventricular and intra-ventricular conduction disorders over 6-month follow-up among patients receiving the new generation ER prosthesis compared with the CV. The main findings of this study are the following:

1. Patients in the ER group more frequently had postprocedural PR interval and QRS prolongation at discharge in comparison with those in the CV group.
2. Incidence of 2:1 or greater AVB was similar between both groups.
3. New LBBB and permanent pacemaker implantation rates were similar between both groups.
4. Patients in the ER group had more questionable indications for pacemaker implantation than those in the CV group.

Technical improvements of new generation transcatheter heart valve devices have resulted in a decrease in most of the periprocedural complications. However, significant impact on cardiac conduction disorders is lacking with most available devices. Nowadays, atrioventricular and intraventricular conduction disorders are still the most frequent adverse events following TAVI with new LBBB remaining on top of the list (varying from 4%–57% depending on the type of valve used).[10] Close proximity between the calcified aortic valve and cardiac conduction system plays a role in the risk of conduction disorders following TAVI. QRS prolongation results from conduction disorders below the atrioventricular node, whereas PR prolongation rarely results from infranodal conduction delay but frequently from slow conduction

through the atrioventricular node (eg, in case of damage to the fast pathway that lies superiorly and at proximity to the aortic root). Indeed, trauma by the delivery system advanced on a stiff guidewire or significant compression of the conduction tissue by the stent frame of the prosthesis may be responsible for conduction delay. In addition, local inflammation and fibrosis in reaction to the presence of foreign body material may enhance conduction disorders at follow-up.

With respect to the Medtronic self-expandable prostheses, there was no significant decrease in the pacemaker rate among new generation devices in the different series reported.[5 11–14] In the recent SWISS TAVI registry analysis comparing clinical outcomes among patients receiving the ER or CV prosthesis, rates of conduction disorders leading to permanent pacemaker implantation were similar between both groups (22.1% vs 23.4%, respectively, P=0.72).[14] Whether the new generation ER prosthesis performs better in term of atrioventricular and intraventricular conduction recovery than the CV prosthesis has not been reported yet.

Deeper prosthesis implantation is considered to be predictive for the development of conduction disorders (in particular LBBB) due to more interaction of the stent frame with the left bundle branch.[15] Recapturable and repositionable properties of the new generation ER prosthesis was thus thought to improve valve deployment accuracy and limit cases of deep valve implantation. This was verified in our study by reporting a rate of deep valve implantation among the ER group about half that of patients in the CV group (6% vs 12%, P=0.01) and the need of, respectively, 2% versus 7% of valve-in-series. However, patients in the ER group presented more frequently PR interval or QRS prolongation at discharge in comparison with the CV group. Of note, we considered a distance of 2–8 mm between the base of the coronary sinus and the lower part of the device as a good implantation height, which differs from the recommendation of the company. The good clinical practice from Medtronic considers an optimal implantation depth between 4 mm and 6 mm for the CV and 3 mm and 5 mm for the ER.

Among patients presenting QRS prolongation, looking for concomitant postprocedural atrioventricular conduction delay is important as these patients are at increased risk for developing complete AVB.[16] However, based solely on external ECGs, atrioventricular conduction analysis remains difficult and sometimes insufficient to diagnose conduction disorders (eg, in case of paroxystic AVB or intra-Hissian conduction delays with a narrow QRS and relatively normal PR intervals). With the exception of prior RBBB, there is no strong ECG predictor of postprocedural conduction abnormalities. The latter remain quite unpredictable as patients with a normal QRS complex and AV interval might develop complete AVB, whereas patients with LBBB and prolonged atrioventricular interval do not necessarily show any additional AV conduction alteration. Indeed, in our study, only 9% (3/34) of patients with postprocedural PR interval and QRS prolongation developed ECG-proven high-degree AVB (one in the ER group and two in the CV). Occurrence of complete AVB is random and related to the location of conduction pathways that cannot be predicted by non-invasive methods. Periprocedural monitoring with use of telemetry until discharge remains thus primordial. In that respect, Auffret *et al*[17] suggested a management strategy of conduction disorders in the periprocedural period. Whereas implantation of a permanent pacemaker is recommended in patients with persistent high-degree AVB at 24–48 hours post-TAVI, temporary pacemakers may be already removed during the same time period among those who present conduction recovery.

With time, total or partial atrioventricular and intraventricular conduction recovery has been reported.[15] Current literature remains contradictory, and the proportion of patients showing pacemaker-dependency at midterm to long term widely varies among the different published series.[18 19] In our analysis, both groups presented similar atrioventricular and intraventricular conduction recovery with time since PR intervals and QRS complexes continued to lengthen between day 1 and discharge, whereas at 6 months, a reduction in these intervals in comparison with discharge was observed (with no statistically significant difference between both groups). Similarly, patient in both groups had similar ventricular pacing rates at 6 months with <50% of patients presenting ventricular pacing rates >80% of the time (39% vs 43%, P=0.5, respectively, in the ER and CV group). This confirms the actual difficulty of predicting persistence of conduction disorders and to identify patients who should benefit of early permanent pacemaker implantation. Even though not statistically significant, one should note a trend towards reduction of ventricular pacing rate among the ER group. That be, this might suggest greater conduction recovery with the redesigned stent frame of the ER and can also be at least partially explained by more debatable indications of pacemaker implantation in the ER group in comparison with the CV group (table 4). Indeed, identifying patients who benefit from early pacemaker implantation remains challenging. In the current era where length of stay is shortening, standardised indications for pacemaker implantation need to be specifically addressed.

Even though the new generation of self-expanding prosthesis does not seem to reduce conduction disorders in comparison with the previous generation, patients with the ER device might tolerate a greater oversizing ratio. Indeed, the patients who developed third-degree AVB in the ER group had a greater oversizing ratio than those in the CV group (20.0%±2.1 vs 16.2%±4.1, respectively, P=0.05). The possibility of a more permissive oversizing ratio with no significant increase in the risk of conduction disorders is

interesting, since oversizing is associated with decrease in paravalvular leak rates.[20]

Finally, native valve predilation and prosthesis postdilation may also play a role in the occurrence of conduction disorders following TAVI. In the report of Nuis *et al*[21], more than 50% of new conduction disorders already occurred after native valve predilatation, and a higher balloon size/annulus ratio was predictive of postprocedural conduction disorders. Similarly, Franzoni *et al*[22] found that postdilatation was associated with a higher incidence of new LBBB. In the present report, significantly more patients in the CV group underwent predilatation, whereas patients in the ER group had more postdilatation. More patients undergoing predilatation (18%) in comparison with postdilatation (5%) developed high-degree AVB, independently of the type of valve implanted.

Limitations

The main limitation concerns the limited number of patients included, which does not permit definitive conclusions. Also, electrophysiological studies were not performed, and intra-Hissian conduction delay or HV intervals could not be evaluated. Nevertheless, careful analysis of the surface ECG is able to yield much information, and we believe that most conduction disorders can thus be diagnosed. Accuracy of the ECG measurements was limited by the fact that they were performed manually using 25 mm/s paper speed. However, this limitation applies equally to both groups, thereby limiting the impact on comparisons between the groups, and a good inter-rater reliability was observed. Finally, our acceptable depth of valve implantation was more permissive than the best clinical practice provided by Medtronic.

CONCLUSIONS

Despite the new design of the ER prosthesis including repositionable properties, incidence of postprocedural conduction disturbances has not significantly improved in comparison with patients receiving the previous generation CV prosthesis in our experience. Patients with the ER had greater postprocedural atrioventricular and intraventricular conduction delays than those with the CV at discharge, with however similar incidence of high-degree AVB, new LBBB and permanent pacemaker implantation up to 6-month follow-up.

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Ethics approval All patients were prospectively included in our local registry, which was approved by the institutional ethics committee.

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