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Relevance of New Conduction Disorders after Implantation of the ACURATE neo Transcatheter Heart Valve in the Aortic Valve Position

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Abstract:

The ACURATE neo transcatheter heart valve has been associated with very low rates of new conduction disorders (CDs). We assessed the clinical relevance of new CDs in patients undergoing transcatheter aortic valve replacement (TAVR) with this valve. Data of consecutive patients without a pre-existing left bundle branch block (LBBB) or a permanent pacemaker (PPM) undergoing TAVR with the ACURATE neo were analyzed from the prospective SwissTAVI registry. Patients with new CDs were compared to patients with an unchanged electrocardiogram (ECG). ACURATE neo was implanted in 203 patients (mean age 82 ± 6 years, 63% women), CDs occurred in 28 patients (22 (11%) developed a LBBB, 6 (3%) required a PPM). New CDs resulted in a longer median duration of hospitalization (7 vs. 5 days, IQR 4-13 vs. 3-8 days, p=0.04). At 1-year follow-up, left ventricular ejection fraction (LV-EF) was significantly lower in patients with new CDs compared to patients with an unchanged ECG (54±13% vs. 61±9%, p<0.01). Kaplan Meier estimates of survival at 1-year were 89% in patients with new CDs and 95% in patients with an unchanged ECG (HR 2.0, 95% CI 0.7 – 6.2, p = 0.22). After TAVR with the self-expanding ACURATE neo valve, the rate of new CDs, including complete LBBB was low and very few patients required a new PPM. However, new CDs prolonged initial hospitalization and increased the risk for LV-dysfunction at 1-year follow-up. Patients without new CDs had excellent outcomes with a very high survival rate at 1-year follow-up.

Key words. Aortic stenosis; transcatheter aortic valve replacement; conduction disorders; permanent pacemaker implantation

Introduction

The long-term impact of conduction disorders (CDs) such as occurrence of a new persistent left-bundle branch block (LBBB) or need for a new permanent pacemaker (PPM) after transcatheter aortic valve replacement (TAVR) is still an ongoing debate. Previous studies have yielded conflicting results. Latest data from the PARTNER II trial indicated that a new LBBB was associated with a lower left ventricular ejection fraction (LV-EF) and an increased risk for mortality at 2- year follow-up. Moreover, implantation of a new PPM in this study cohort was related to a higher rate of the combination of mortality or repeat hospitalizations at 1 year, but there was no difference in LV-EF [1]. With respect to studies evaluating self-expanding TAVR valves, the results showed inconsistent long-term outcomes following postprocedural occurrence of new LBBB or necessity of a PPM[2 3 4 5]. The self-expanding ACURATE neo (Boston Scientific, Marlborough, USA) transcatheter heart valve (THV) is a second-generation device with design features to minimize trauma to the conduction system[6]. It has been associated with a very low rate of new CDs [6 7], but data to evaluate the clinical relevance of this potentially beneficial feature are lacking. We therefore assessed the clinical relevance of new CDs in patients undergoing TAVR with ACURATE neo THV.

Methods

Between June 2015 and June 2019, consecutive patients undergoing TAVR with the ACURATE neo or ACURATE neo 2 THV at the Heart Center Lucerne were enrolled in the prospective SwissTAVI registry. Data were collected throughout the initial hospital stay and follow-ups were conducted at 30 days and 1 year. The study complies with the declaration of Helsinki. Prospective data acquisition was approved by the local ethic committee. All patients provided written informed consent for the TAVR procedure, prospective data acquisition, and follow-up examinations. Events were adjudicated by an independent clinical

event committee. The ACURATE neo was the most frequently implanted valve in our center. In particular, we selected patients with pre-existing conduction disorders and patients with narrow sinuses/heavily calcified anatomy at risk for annular rupture with a balloon-expandable valve or patients with a horizontal aorta. The ACURATE neo is a supra-annular aortic bioprosthesis consisting of a self-expanding nitinol frame and porcine pericardial leaflets. Due to the relatively low radial force of the inflow portion of the ACURATE neo THV, predilatation is recommended in almost all patients. In this series, the valve size was chosen according to the perimeter of the annulus. The degree of oversizing was calculated as the nominal diameter of the valve (23, 25 and 27mm for the S, M, and L valves) minus the perimeter-derived annular diameter from CT [8]. Device landing zone calcifications were semi-quantitatively assessed [9]. To minimize trauma to the annulus and the underlying conduction system, the diameter of the balloon for predilatation was chosen 1-2 mm smaller than the perimeter-derived annular diameter. Post-dilatation was only performed in case of relevant aortic regurgitation or relevant transvalvular gradient (>15 mmHg) with a balloon 1-2 mm smaller than the perimeter- derived annular diameter. Following TAVR, patients with new CDs were monitored until the electrocardiogram (ECG) remained unchanged for at least 48 hours. Patients without CDs were not monitored with telemetry. In all patients a 12-lead ECG was obtained daily until discharge. Any negative dromotropic medications were omitted one day before TAVI. The decision to implant a PPM was left to the discretion of the operator. All clinical endpoints were prespecified and defined according to the updated definitions of the Valve Academic Research Consortium (VARC-2). Clinical endpoints were duration of hospital stay, new PPM implantation, LV-EF and mortality at 1-year follow-up. Patients with new CDs including new LBBB or new PPM implantation were compared to patients with an unchanged ECG before discharge. Data are presented as mean ± standard

deviation (SD) for continuous and as numbers and frequencies for categorical variables. Continuous variables with normal distribution were compared using the student's t-test. Continuous variables without normal distribution are presented as median (interquartile range, IQR) and compared using the Wilcoxon rank sum test. Categorical variables were compared using the Fisher's exact test. Survival curves were graphed using the Kaplan-Meier method and compared using the log-rank test. Cox regression was used to analyze the association of CDs with all-cause mortality rates. Statistical analyses were conducted with STATA´s statistical software package (Version 13, StataCorp, College Station, Texas, USA). A p-value < 0.05 was considered as statistically significant.

Results

A total of 229 consecutive patients undergoing TAVR with ACURATE neo were enrolled. Of those, 26 patients with a preexisting LBBB or PPM were excluded from the current analyses. Mean age of the study cohort was 82±6 years and 128 (63%) were women. ECG at discharge showed a new LBBB in 22 (11%) patients and 6 (3%) patients had received a new PPM. These patients were compared to the remaining 175 (86%) patients with an unchanged ECG. Baseline characteristics and procedural details of the study groups were similar, as displayed in *Table 1*. However, in patients with new CDs was a trend with more RBBB at baseline and post-dilatation was more commonly used (*Table 1*). In-hospital and 30-day outcomes of both groups are listed in *Table 2*. Following TAVR, the mean gradient was low in both groups before discharge (7±4 mmHg vs 7±4 mmHg, p= 0.85). Paravalvular regurgitation was none/mild in 28 (100%) patients with new CDs and in 170 (97%) patients with an unchanged ECG (p= 1.00). LV-EF before discharge was 58±14 vs 62±9 (p=0.06). Median duration of hospitalization was longer in patients with new CDs than in those with an unchanged ECG (7 vs. 5 days, IQR 4-13 vs. 3-8 days, p=0.04). Echocardiographic follow-up at

1- year revealed similar mean gradients in both groups (8 ± 4 mmHg vs 7 ± 4 mmHg, p= 0.50). LV-EF was significantly lower in patients with new CDs compared to patients with an unchanged ECG (56 ± 10 vs 61 ± 9, p< 0.04) (*Figure 1*). The median difference of LV-EF at baseline compared with LV-EF after 1- year was a reduction of 5% LV-EF in patients with new CDs as compared to an increase of 1% LV-EF in patients with an unchanged ECG (-5 vs. 1%, IQR -12 - 5 vs -5 -6%, p= 0.10). NYHA functional class at 1-year follow-up did not differ between both groups. NYHA functional class 3 or 4 occurred in 1 patient (6%) with new CD and in 6 patients (5%) with an unchanged ECG, p= 0.83 respectively. At 1-year follow-up, ventricular stimulation rate in patients with a new PPM was >90% in 4, ~40% in 1 and 0% in 1 patient. Only one patient received a new PPM between discharge and 1-year follow-up. Prior to TAVR, this patient was in sinus rhythm with a first-degree atrioventricular block, but received amiodarone for symptomatic paroxysmal atrial fibrillation. During the TAVR procedure, she developed atrial fibrillation an a new LBBB ultimately resulting in PPM implantation for symptomatic sick sinus syndrome 77 days after hospital discharge. Kaplan Meier estimates of survival at 1-year were 89% in patients with new CDs and 95% in patients with an unchanged ECG (HR 2.0, 95% CI 0.7 – 6.2, p = 0.22, *Figure 2*).

Discussion

Evaluating data from a prospective registry, we assessed the impact of TAVR with the ACURATE neo valve on occurrence of CDs. We found: (1) Implantation of the ACURATE neo resulted in remarkably low rates of new CDs; (2) new CDs prolonged the median duration of hospitalization by 2 days; (3) Patients with new CDs had a significantly lower LV-EF at 1-year follow-up; and (4) patients without new CDs had excellent short- and mid-term outcomes with a remarkably high 1-year survival rate of 95%. Notably, this study showed one of the highest 1-year survival rates in an intermediate to low-risk TAVR population of unselected,

consecutive patients with an STS score of 4.3 ± 3.2 and a mean age of 82 ± 6 years that has ever been reported. Indeed, 1-year survival rate of the overall collective was 94%. For comparison, the SAVI- TF registry reported a 1-year survival rate of 92% in a population with a mean age of 81 ± 5 years and an STS score of 6.0 ± 5.6 %. [7]. New CDs may likely become increasingly important in lower risk patients without multiple comorbidities as they may negatively affect prognosis. Despite improvements in TAVR technology, the incidence of CDs has failed to decrease over the last years. Notably, there are reports suggesting an increased number of new CDs associated with the use of some newer-generation THVs[10,11]. With respect to the expansion of TAVR to patients at low surgical risk, procedure-related CDs, in particular occurrence of new LBBB or need for a new PPM, can be expected to increase and potentially also influence long-term outcomes of afflicted patients. Therefore, strategies and valve technologies mitigating the risks for novel CDs are clinically highly relevant. In the present study, the rate of new LBBB and need for new PPM were among the lowest ever reported after TAVR (11% and 3%, respectively)[12]. Possible mechanism explaining the low rate of CDs in our study may include the low radial force of the ACURATE neo, careful selection of the balloon size for pre- and post-dilatation as well as periprocedural withholding of any negative dromotropic medications (e.g. beta-blockers or calcium-antagonists). With regards to low rates of PPM implantation after contemporary surgical AVR, we show that with the ACURATE neo, it seems possible to achieve similar PPM rates[13] [14]. Two recent large randomized trials showed that in low risk patients undergoing surgical aortic valve replacement, PPM rates after one year were 5.5% and 6.7% [13] [14]. Our results underline that TAVR with self-expanding THVs may not per se be associated with high rates of PPM. With current prices for THVs, TAVR remains an expensive treatment. Implementation of the so called “minimalistic approach” with mainly transfemoral access

and the use of local anesthesia and conscious sedation has reduced costs significantly over the last decade[15]. However, early discharge has also been proposed to increase cost effectiveness of TAVR procedure and patient comfort[16]. Our data show that occurrence of novel CDs significantly prolonged duration of hospitalization, which in turn can be explained by prolonged need for rhythm-monitoring and possible PPM implantation. [17] It is plausible that omission of new CDs facilitates early ambulation and discharge, which in addition may directly reduce in-hospital costs. Furthermore, patients requiring PPM implantation are at risk for periprocedural complications and necessitate life-long PPM check-ups, both of which is associated with healthcare costs. Thus, minimizing the incidence of new CDs using a THV like the ACURATE neo may help to increase cost-effectiveness of TAVR procedure. We are well aware of certain limitations, which apply to our study. Although data were analyzed from a prospective registry including an all-comer TAVR-cohort, this is a single center study and our results need to be confirmed by others. Moreover, long-term follow-up beyond one year is probably required to better comprehend the relevance of TAVR-related CDs and related ventricular dysfunction. In conclusion, patients without new CDs had excellent short- and mid-term outcomes with a remarkably high 1-year survival rate of 95%. TAVR with ACURATE neo resulted in very low rates of new LBBB and new PPM implantations, comparable to current surgical data. Nevertheless, new CDs resulted in a longer duration of hospitalization and a lower LV-EF at 1-year follow-up, highlighting the clinical relevance of TAVR associated CDs.

Authorship contribution: 1) conception and design or analysis and interpretation of data, or both: MB, ST. 2) drafting of the manuscript or revising it critically for important intellectual content: MB, MW, FM, MBo, BB, FC, RK, ST. 3) final approval of the manuscript submitted: all authors.

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Figure Legends

Figure 1. LV-EF (mean) at baseline, 1 month and 1 year.

LV-EF; left ventricular ejection fraction, ECG; electrocardiogram, LBBB; left bundle branch block, no CDs; no conduction disorders, RBBB; right bundle branch block, PPM; permanent pacemaker

Figure 2. Probability of survival

ECG; electrocardiogram, CDs; conduction disorders, HR; hazard ratio, CI; confidence interval

Table 1 Baseline and procedural characteristics

	All patients (n=203)	Patients with new CDs (n= 28)	Patient with unchanged ECG (n=175)	p= value
Age (years)	82 ± 6	83 ± 4	82 ± 6	0.20
Women	128 (63%)	14 (50%)	114 (65%)	0.14
Hypertension	169 (83%)	24 (86%)	145 (83%)	1.00
Diabetes Mellitus	42 (21%)	9 (32%)	33 (19%)	0.13
Coronary artery disease	99 (49%)	17 (61%)	81 (46%)	0.33
Prior stroke	28 (14%)	5 (18%)	23 (13%)	0.55
Betablocker at admission	74 (37%)	13 (48%)	61 (36%)	0.28
Right bundle branch block	17 (8%)	5 (18%)	12 (7%)	0.07
Atrial fibrillation	40 (20%)	5 (19%)	35 (20%)	1.00
STS PROM (%)	4.3 ± 3.2	5.4 ± 4.0	4.1 ± 3.0	0.07
NYHA functional class				0.37
1	3 (2%)	1 (4%)	2 (1%)	
2	86 (43%)	9 (32%)	77 (45%)	
3	93 (47%)	15 (54%)	78 (45%)	
4	18 (9%)	3 (11%)	15 (9%)	
Mean gradient (mmHg)	49 ± 22	50 ± 22	49 ± 16	0.65
Aortic valve area (cm2)	0.7 ± 0.2	0.8 ± 0.2	0.7 ± 0.2	0.48
LVEF (%)	59 ± 11	57 ± 16	60 ± 10	0.32
Bicuspid aortic valves	1 (0.5%)	0 (0%)	1 (0.6%)	1.00
Annulus size (mm, IQR)	23.9 (22.6-25.2)	23.9 (22.6- 25.5)	23.9 (22.6-25.2)	0.66

Device landing zone calcification				0.10
Mild	62 (31%)	8 (29%)	54 (31%)	
Moderate	68 (34%)	5 (18%)	63 (37%)	
Severe	54 (27%)	12 (43%)	42 (24%)	
Massive	16 (8%)	3 (11%)	13 (8%)	
Valve size				0.38
S	45 (22%)	5 (18%)	40 (23%)	
M	88 (43%)	10 (36%)	78 (45%)	
L	70 (34%)	13 (46%)	57 (33%)	
Degree of valve oversizing (mm)	0.8 (-2.2- 1.45)	0.9 (0.4- 1.6)	0.8 (-2.2-1.45)	0.29
Cover index (%)	5.7 (3.2- 8.0)	6.3 (3.3- 8.3)	5.7 (3.2-7.7)	0.39
Predilatation	194 (96%)	27 (96%)	167 (95%)	1.00
Postdilatation	63 (32%)	13 (46%)	50 (29%)	0.08
Implantation depth (mm, IQR)	4 (3- 5)	4 (4-5)	4 (3-5)	0.09
Conscious sedation (%)	197 (97%)	28 (100%)	169 (97%)	1.00
Transapical access	5 (2%)	0 (0%)	5 (3%)	0.62
Procedure duration (min, IQR)	45 (35-567)	55 (36-66)	44 (35-56)	0.06
Conversion to surgery	0 (0%)	0 (0%)	0 (0%)	N/A

Data are displayed as n(%) or mean ± SD or median (IQR), STS PROM, Society of Thoracic Surgeons Predicted Risk of Mortality. CDs; conduction disorders, ECG; electrocardiogram, IQR; interquartile range, LV-EF; left ventricular ejection fraction, Cover index defined as 100 x ((prosthesis diameter – CT annulus diameter)/prosthesis diameter).

Table 2. In-hospital and 30 days outcomes

	All patients n=203	Patients with new CDs n= 28	Patients with unchanged ECG n=175	p= value
In-hospital outcomes				
Duration of hospitalization (d, IQR)	5 (3-8)	7 (4-13)	5 (3-8)	0.04
Mean transvalvular gradient (mmHg)	7 ± 4	8 ± 4	7 ± 4	0.33
Aortic valve area (cm2)	2.1 ± 0.5	2.2 ± 0.5	2.1 ± 0.5	0.22
> than mild PVL	5 (3%)	0 (0%)	5 (3%)	1.00
LV-EF (%)	62 ± 10	58 ± 14	62 ± 9	0.06
Outcomes at 30 days				
Major vascular complication	12 (6%)	3 (11%)	9 (5%)	0.22
Major or life-threatening bleeding	12 (6%)	3 (11%)	9 (5%)	0.22
Any stroke	5 (2%)	1 (4%)	4 (2%)	0.53
New PPM implantation	6 (3%)	6 (21%)	0 (0%)	< 0.01
All-cause mortality	1 (0.5%)	0 (0%)	1 (0.6%)	1.00

Data are displayed as n (%) or mean ± SD or median (IQR), IQR; interquartile range, LV-EF; left ventricular ejection fraction, PVL; paravalvular leakage, PPM; permanent pacemaker

Figure 1

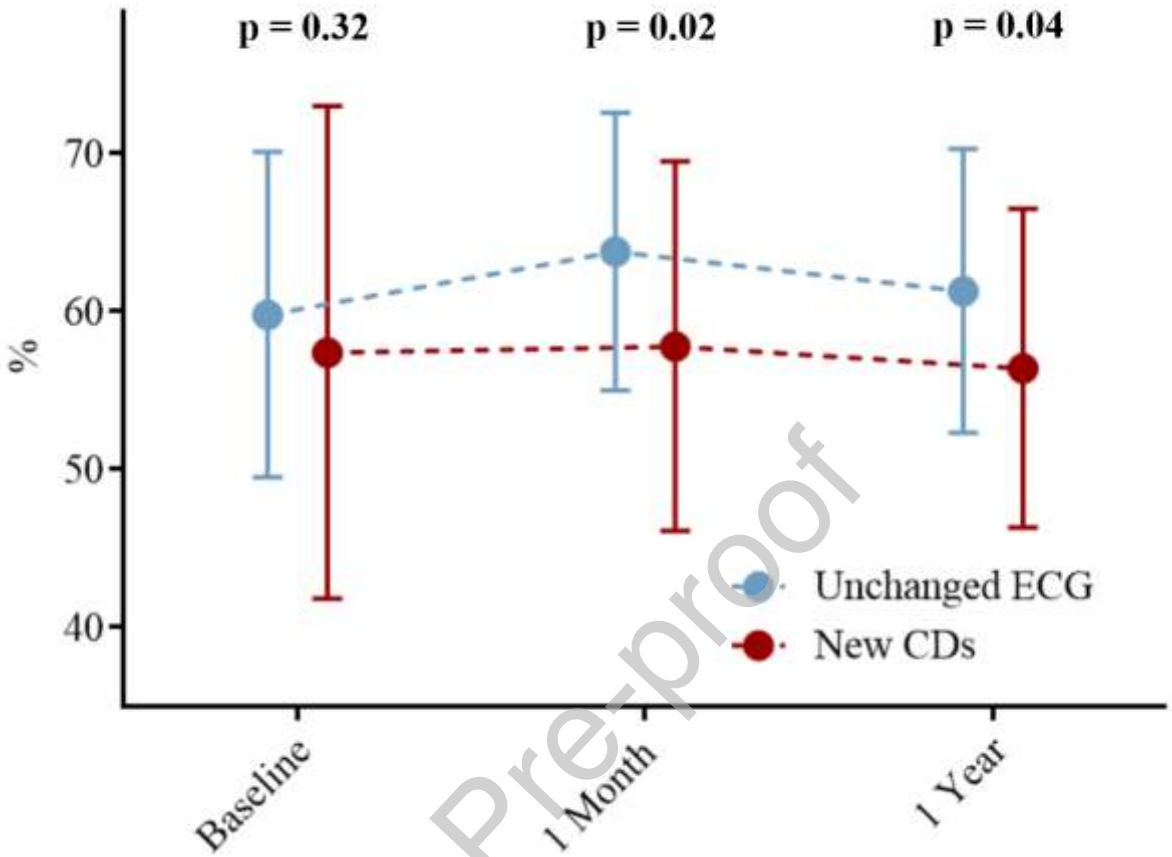

Figure 2