Midterm clinical outcome following Edwards SAPIEN or Medtronic Corevalve transcatheter aortic valve implantation (TAVI) : results of the Belgian TAVI registry

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Original Studies

Midterm Clinical Outcome Following Edwards Sapien or Medtronic CoreValve Transcatheter Aortic Valve Implantation (TAVI): Results of the Belgian TAVI Registry

AQ4

Valérie M. Collas,[1,2*] Christophe Dubois,[3] Victor Legrand,[4] Joëlle Kefer,[5] Bernard De Bruyne,[6] Jo Dens,[7] Inez Rodrigus,[2] Paul Herijgers,[3] and Johan M. Bosmans,[1,2] for the Belgian TAVI Registry Participants

AQ1 AQ2

Objective: To assess midterm (3 years) clinical outcomes of transcatheter aortic valve implantation (TAVI) in Belgium using the Edwards SAPIEN valve or the Medtronic CoreValve transcatheter heart valve (THV). Background: Medium and long term follow-up data of both THVs are still relatively scarce, although of great clinical relevance for a relatively new but rapidly expanding treatment modality. Therefore, reporting mid- and long term clinical outcome data, coming from large "real world" national registries, remains contributive. Methods: Between December 2007 and March 2012, 861 "real world" patients who were not candidates for surgical aortic valve replacement as decided by the local heart teams, underwent TAVI at 23 sites. Eleven sites exclusively used SAPIEN THV ($n = 460$), while 12 exclusively used CoreValve THV ($n = 401$). Differences in clinical outcomes by valve system were assessed, according to access route and baseline EuroSCORE risk profile (<10%: low, 10–20%: intermediate and >20%: high risk). Results: Overall cumulative survival at 3 years was 51% for SAPIEN vs. 60% for CoreValve ($P = 0.021$). In transfemorally treated patients, SAPIEN and CoreValve had similar survival at 3 years for each of the baseline EuroSCORE cohorts (low risk: 72% vs. 76%, $P = 0.45$; intermediate risk: 62% vs. 59%, $P = 0.94$; high risk: 48% vs. 53%, $P = 0.65$). Conclusion: Cumulative midterm 3 year survival after transfemoral TAVI in "real world" patients refused for surgery with similar baseline EuroSCORE risk profile is not different between SAPIEN or CoreValve. © 2015 Wiley Periodicals, Inc.

Key words: valvular heart disease; aortic stenosis; transcatheter aortic valve implantation (TAVI); registry

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Conflicts of interest: Prof. Dr. Christophe Dubois, Prof. Dr. Johan Bosmans, Prof. Dr. Victor Legrand and Prof. Dr. Joëlle Kefer are part-time clinical proctors for Edwards LifeSciences SAPIEN or Medtronic CoreValve. The other authors have no conflicts of interest to declare.

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INTRODUCTION

Aortic valve stenosis is the most common acquired valvular heart disorder in the elderly. Despite advances in cardiac surgery and low mortality rates after surgical aortic valve replacement (SAVR), up to one third of patients with symptomatic aortic stenosis are not considered for SAVR, often due to frailty or comorbidities [1].

Transcatheter aortic valve implantation (TAVI) enables treatment of aortic stenosis without open heart surgery. Recently, TAVI using the balloon-expandable SAPIEN valve (Edwards LifeSciences, Irvine, CA) or the self-expanding CoreValve bioprosthesis (Medtronic, Inc., Minneapolis, MN) has been shown to be superior to standard medical therapy for inoperable patients and to be at least non-inferior to SAVR in (very) high-risk patients with severe symptomatic aortic stenosis [2–5]. However, medium and long term follow-up data of both transcatheter heart valves (THVs) are still relatively scarce [6], although of great clinical relevance for a relatively new but rapidly expanding treatment modality. Therefore, reporting mid- and long term clinical outcome data, coming from large "real world" national registries, remains contributive.

The Belgian TAVI Registry is a prospective multicenter national Registry, the details of which have been previously reported [7]. During the inclusion period, all patients in this registry were treated at centers exclusively using the SAPIEN valve or alternatively the CoreValve bioprosthesis. No site used both devices simultaneously. This unique feature allows, in the absence of randomized trials evaluating both valves simultaneously, some comparisons of outcomes between SAPIEN and CoreValve treated patients. The primary aim of this Registry was to monitor early and midterm clinical outcomes and safety of TAVI with both devices.

METHODS

The Belgian TAVI Registry

All 23 Belgian TAVI sites participated in this national TAVI Registry. Eleven sites exclusively used the SAPIEN valve and 12 other sites exclusively used the CoreValve bioprosthesis for all TAVI procedures. The choice for TAVI was decided by the local Heart Teams in symptomatic patients with significant aortic valve stenosis who were no candidates for SAVR. Collection of patient data for the registry was approved by the institutional ethics committee of the different participating centers.

Sizing of the CoreValve or Edwards SAPIEN prosthesis was always based on multi-slice computed tomography or transoesophaegal echocardiograpghy of the aortic annulus and root and in agreement with the sizing instructions provided by the manufacturer.

Patient outcome was assessed during and immediately after valve implantation (procedural success), at 30 days (early), and 1, 2, and 3 (medium) years after TAVI. Clinical outcomes were assessed overall, as well as according to access route (transfemoral vs. non-transfemoral) and logistic EuroSCORE (<10%: low, 10–20%: intermediate and >20%: high risk), based on the classification of Linke et al. [5]. At the time of starting the Belgian TAVI Registry (2007), the Valve Academic Research Consortium (VARC) definitions were not yet in use. However, based on the description of the cause of death, events were assessed post-hoc according to the actual VARC-2 definitions [8] and defined as cardiovascular (including unknown cause of mortality) or non-cardiovascular death. Major adverse cardiac and cerebrovascular events (MACCE) included new myocardial infarction, new pacemaker implantation and new clinically relevant stroke or transient ischemic attack (TIA) within 30 days after TAVI.

All values and adverse events collected were site recorded and there was no central clinical events committee. Statistical analysis was performed at the University of Antwerp.

Statistical Analysis

Continuous variables are presented as mean (± standard deviation) or as median (Q1–Q3), depending on the distribution of data. Two groups are compared using unpaired Student t test or Mann–Whitney U-test. Categorical variables are presented as frequencies and were compared using Chi Square tests (Pearson Chi-Square). The Fisher's exact test was used when one or more of the cells had an expected frequency of five or less.

The Kaplan–Meier method was used to show differences between groups for survival, and these were tested by the log rank test. Cox regression was used to determine predictors of mortality. Variables with a $P < 0.05$ in the univariable analysis were included in the multivariable analysis. Results are presented as hazard ratio with 95% confidence intervals. Collinearity of the parameters was determined by variance inflation factor. All data were processed using the Statistical Package for Social Science, version 20.0 (IBM Corporation, New York, NY). A $P < 0.05$ was considered statistically significant.

RESULTS

Between December 2007 and March 2012, 861 consecutive patients undergoing TAVI in Belgium were

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TABLE I. Baseline Clinical Characteristics and Associated Comorbidities of all Patients, Treated With TAVI

Baseline characteristics	SAPIEN ($N = 460$)	CoreValve ($N = 401$)	Total ($N = 861$)	P
Age (years)	84 (80–87)	83 (79–87)	83 (79–87)	0.055
Logistic EuroSCORE (%)	26.0 (18.0–36.5)	18.0 (12.0–29.0)	22.8 (14.4–33.7)	<0.001
Aortic valve area (cm^2)	0.60 (0.50–0.70)	0.64 (0.55–0.73)	0.60 (0.50–0.70)	0.001
Peak gradient (mm Hg)	75.0 ± 24.8	71.1 ± 25.1	73.2 ± 24.9	0.030
Mean gradient (mm Hg)	45.8 ± 15.4	46.5 ± 15.7	46.1 ± 15.6	0.515
LVEF (%)	55 (40–60)	59 (50–65)	55 (44-62)	<0.001
	~~N (%)~~	~~N (%)~~	~~N (%)~~	
Male	213 (47)	190 (47)	403 (47)	0.844
NYHA III, IV	372 (82)	305 (79)	677 (81)	0.256
Comorbidities				
Carotid artery disease	111 (24)	54 (15)	165 (20)	<0.001
Coronary artery disease	285 (63)	225 (58)	510 (61)	0.230
COPD	143 (31)	100 (26)	243 (29)	0.078
Diabetes	123 (27)	88 (23)	211 (25)	0.164
Hyperlipidemia	324 (71)	202 (52)	526 (62)	<0.001
Hypertension	360 (79)	270 (70)	630 (75)	0.003
Previous myocardial infarction	122 (27)	67 (17)	189 (23)	0.001
Peripheral arterial disease	153 (36)	97 (26)	250 (31)	0.003
Porcelain aorta	38 (8)	35 (9)	73 (9)	0.706
Previous stroke or TIA	83 (18)	45 (12)	128 (15)	0.009
Previous pacemaker	56 (12)	57 (14)	113 (13)	0.372
Previous CABG	123 (27)	98 (26)	221 (26)	0.620
Previous PCI	152 (33)	109 (28)	261 (31)	0.117

Data are presented as mean (~~±~~ standard deviation~~)~~, median (Q1–Q3) or N (%).
CABG = coronary artery bypass grafting, COPD = chronic obstructive pulmonary disease, LVEF = left ventricle ejection fraction, NYHA = New York Heart Association classification, PCI = percutaneous coronary intervention, TIA = transient ischemic attack.

TABLE II. Procedural Characteristics and 30-day Clinical Events

Procedure	SAPIEN ($N = 460$) N (%)	CoreValve ($N = 401$) N (%)	Total ($N = 861$) N (%)	P
Access route				
Transfemoral	280 (61)	356 (89)	636 (74)	
Transapical	164 (36)	0 (0)	164 (19)	
Subclavian	0 (0)	33 (8)	33 (4)	
Direct aortic	12 (3)	11 (3)	23 (3)	
Valve size				
23 mm	186 (42)	0 (0)	186 (22)	
26 mm	256 (58)	183 (46)	439 (52)	
29 mm	0 (0)	205 (51)	205 (24)	
31 mm	0 (0)	12 (3)	12 (1)	
Procedural succes	451 (98)	391 (98)	842 (98)	0.959
Valve migration	6 (2)	4 (1)	10 (1)	0.755
Valve-in-valve	4 (1)	11 (3)	15 (2)	0.036
MACCE				
Survival after 30 days	416 (90)	365 (91)	781 (91)	0.767
New myocardial infarction	10 (3)	3 (1)	13 (2)	0.057
New permanent pacemaker[a]	25 (7)	88 (29)	113 (17)	<0.001
New clinically relevant stroke or TIA	19 (5)	25 (7)	44 (6)	0.365

[a]New pacemaker implantation: exclusion of patients with previous pacemaker.
MACCE = major adverse cardiac and cerebrovascular events within 30 days after procedure, TIA = transient ischemic attack.

enrolled in this registry. The total number of implants per year progressively increased from 10 in 2007 to 100 in 2008, 163 in 2009, 257 in 2010 and 289 in 2011.

The completeness of follow up for the Sapien THV at 30 days was 98%, for 1 year 85% for 2 years 64% and for 3 years 52%. For the CoreValve, this was 98% at 30 days, 82% for 1 year, 69% for 2 years and 48% for 3 years. In total, the completeness of follow up was 98% at 30 days, 83% for 1 year, 66% for 2 years and 50% for 3 years.

Baseline clinical characteristics and comorbidities are summarized in Table I. Median age was 83 (79– T1

TABLE III. Acute and Early Outcomes in Patients Undergoing Transfemoral TAVI

	EuroSCORE < 10%			EuroSCORE 10–20%			EuroSCORE >20%		
	SAPIEN (*N* = 18)	CoreValve (*N* = 56)	*P*	SAPIEN (*N* = 59)	CoreValve (*N* = 121)	*P*	SAPIEN (*N* = 203)	CoreValve (*N* = 134)	*P*
Procedure	*N* (%)	*N* (%)		*N* (%)	*N* (%)		*N* (%)	*N* (%)	
Procedural succes	18 (100)	56 (100)	–	58 (98)	118 (98)	1.000	200 (99)	131 (98)	0.685
Valve migration	0 (0)	3 (5)	1.000	0 (0)	0 (0)	–	3 (2)	1 (1)	0.646
MACCE									
Survival after 30 days	16 (89)	54 (96)	0.247	55 (93)	111 (92)	1.000	190 (94)	121 (90)	0.267
New myocardial infarction	0 (0)	0 (0)	–	2 (4)	2 (2)	0.584	1 (1)	0 (0)	1.000
New permanent pacemaker[a]	2 (14)	9 (17)	1.000	2 (4)	28 (27)	0.001	8 (6)	33 (34)	<0.001
New clinically relevant stroke or TIA	0 (0)	5 (9)	0.575	1 (2)	5 (4)	0.672	5 (3)	6 (5)	0.547

[a]New pacemaker implantation: exclusion of patients with previous pacemaker.
MACCE = major adverse cardiac and cerebrovascular events within 30 days after procedure, TIA = transient ischemic attack.

87) years, and 47% were male. Baseline peak and mean aortic valve gradients were 73 ± 25 and 46 ± 16 mm Hg, respectively, and aortic valve area was 0.60 (0.50–0.70) cm^2. Patients receiving the SAPIEN THV had a significantly higher logistic EuroSCORE (26% vs.18%; $P < 0.001$), smaller aortic valve area (0.60 cm^2 vs. 0.64 cm^2; $P = 0.001$), lower left ventricular ejection fraction (LVEF; 55% vs. 59%; $P < 0.001$) and more comorbidities compared to the patients treated with the CoreValve bioprosthesis. The presence of aortic aneurysm (7% vs. 4%, $P = 0.14$), atrial fibrillation (30% vs. 30%, $P = 0.97$), mediastinal radiation (4% vs. 5%, $P = 0.39$), defibrillator (0% vs. 1%, $P = 0.60$) and previous valve surgery (4% vs. 2%, $P = 0.16$) was not different between the SAPIEN THV and the CoreValve THV cohort, respectively.

Procedural and Early Clinical Outcome

Procedural success (Table II) was high in both treatment groups (98%). After CoreValve implantation, there was a significantly higher need of new pacemaker implantation within 30 days after TAVI (29% vs. 7% for SAPIEN, $P < 0.001$). T2

One month survival was 90% for SAPIEN and 91% for CoreValve treated patients ($P = 0.77$). Causes of early death (<30 days) were all cardiovascular (100%, $n = 80$), including 24% of patients with death of unclear origin (SAPIEN 27% vs. CoreValve 19%, $P = 0.41$).

When stratifying patients according to access route transfemoral (Table III) vs. alternative access (Table IV), no significant differences other than the need for pacemaker implantation were detected in terms of early mortality or MACCE between SAPIEN and CoreValve THVs. The number of patients undergoing a transfemoral procedure allowed ~~for~~ additional stratification according to EuroSCORE. Within these risk subgroups, no differences in early clinical outcomes were seen between the SAPIEN and CoreValve THVs. T3 T4

Medium Term Clinical Outcome

Kaplan–Meier survival curves for all patients are presented in Fig. 1 up to 3 year follow-up. Overall survival was 77% at 1 year (SAPIEN: 75% vs. CoreValve: 80%, $P = 0.14$), 66% at 2 years (SAPIEN: 61% vs. CoreValve: 71%, $P = 0.021$) and 55% at 3 years (SAPIEN: 51% vs. CoreValve: 60%, $P = 0.021$). Causes of death between 30 days and 3 years after TAVI were cardiovascular in 58% ($n = 118$) of cases (SAPIEN 59% vs. CoreValve 56%, $P = 0.68$), including 34% of patients with death of unclear origin (SAPIEN 34% vs. CoreValve 34%, $P = 0.97$). Causes of death between 30 days and 3 years after TAVI were F1

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TABLE IV. Acute and Early Outcomes in Patients Treated Through an Alternative Access-site

	SAPIEN[a] ($N=176$)	CoreValve[b] ($N=44$)	P
Procedural characteristics	*N* (%)	*N* (%)	
Procedural success	171 (97)	43 (98)	1.000
Valve migration	3 (2)	0 (0)	1.000
MACCE	N (%)	N (%)	
Survival after 30 days	151 (86)	40 (91)	0.370
New myocardial infarction	7 (4)	0 (0)	0.349
New pacemaker implantation[c]	13 (9)	10 (32)	0.001
New clinically relevant stroke or TIA	13 (8)	3 (8)	1.000

[a]Edwards SAPIEN: transapical and direct aortic.
[b]CoreValve: transsubclavian, truncus brachiocephalicus and direct aortic.
[c]New pacemaker implantation: exclusion of patients with previous pacemaker.
MACCE = major adverse cardiac and cerebrovascular events within 30 days after procedure, TIA = transient ischemic attack.

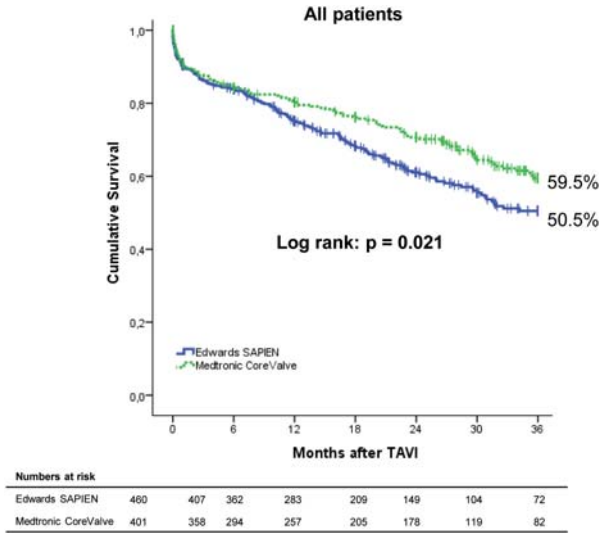

Fig. 1. Kaplan Meier survival curve of all patients.

C O L O R

non-cardiovascular in 42% ($n=86$) of cases (SAPIEN 41% vs. CoreValve 44%, $P=0.68$).

Three years after valve implantation, cumulative survival in transfemorally treated patients was similar for SAPIEN (72, 62, and 48%, $P=0.26$), but borderline significantly different for CoreValve (76, 59, and 53%, $P=0.047$) for the low, intermediate and high risk EuroSCORE cohorts, respectively (Fig. 2). No differences in survival could be demonstrated when comparing survival within each EuroSCORE risk profile cohort between SAPIEN and CoreValve treated patients (low risk: $P=0.45$; intermediate risk: $P=0.94$; high risk: $P=0.65$).

For patients undergoing TAVI through non-transfemoral routes, no further comparative medium term clinical outcome analysis was performed based on the limited number of patients in the CoreValve cohort.

Predictors for Early and Medium Term Mortality After TAVI

Early mortality (30 day) was predicted by peak gradient (hazard ratio: 0.989 (0.979–0.998), $P=0.023$), mean gradient (hazard ratio: 0.981 (0.966–0.997), $P=0.023$), coronary artery disease (hazard ratio: 0.640 (0.411–0.998), $P=0.049$), non transfemoral approach (hazard ratio: 1.667 (1.056–2.632), $P=0.028$), valve in valve (hazard ratio: 3.182 (1.164–8.698), $P=0.024$), new myocardial infarction (hazard ratio: 7.309 (3.162–16.895), $P<0.001$) and new clinically relevant stroke or TIA (hazard ratio: 3.103 (1.583–6.028), $P=0.001$) in the univariable analysis. Of these, low mean gradient (hazard ratio: 0.976 (0.958–0.994), $P=0.011$), coronary artery disease (hazard ratio: 0.508 (0.293–0.884), $P=0.016$), valve-in-valve (hazard ratio: 5.273 (1.202–23.137), $P=0.028$), new myocardial infarction (hazard ratio: 5.397 (1.875–15.531), $P=0.001$) and new clinically relevant stroke or TIA (hazard ratio: 3.808 (1.707–8.496), $P=0.001$) remained significant predictors for early mortality after multivariable analysis. Gender, logistic EuroSCORE, carotid disease, chronic obstructive pulmonary disease, previous stroke or TIA, new myocardial infarction and new clinically relevant stroke or TIA were significant predictors for medium term mortality after multivariable analysis (Table V).

DISCUSSION

The Belgian TAVI Registry is one of few mixed national registries, together with the UK TAVI Registry [6], the FRANCE [9], the PRAGMATIC Plus Initiative [10] and the German TAVI Registry [11], containing data of both SAPIEN and CoreValve THVs. However, a unique feature of the Belgian TAVI Registry is that all TAVI sites were exclusively using the SAPIEN THV or the CoreValve THV for all patients, allowing in absence of randomized trials evaluating both valves simultaneously, some comparison of outcome between devices.

Early and 1 year outcome data in a smaller Belgian TAVI patient population have been published previously [7]. However, reporting of mid- and long term clinical outcome data, coming from relatively large "real world" national registries are of particular clinical relevance, especially for relatively new and rapidly expanding treatment modalities like TAVI.

The Belgian TAVI Registry confirms excellent early and midterm clinical outcomes after TAVI in a "real world" patient cohort. Moreover, similar early and midterm outcomes were seen after transfemoral

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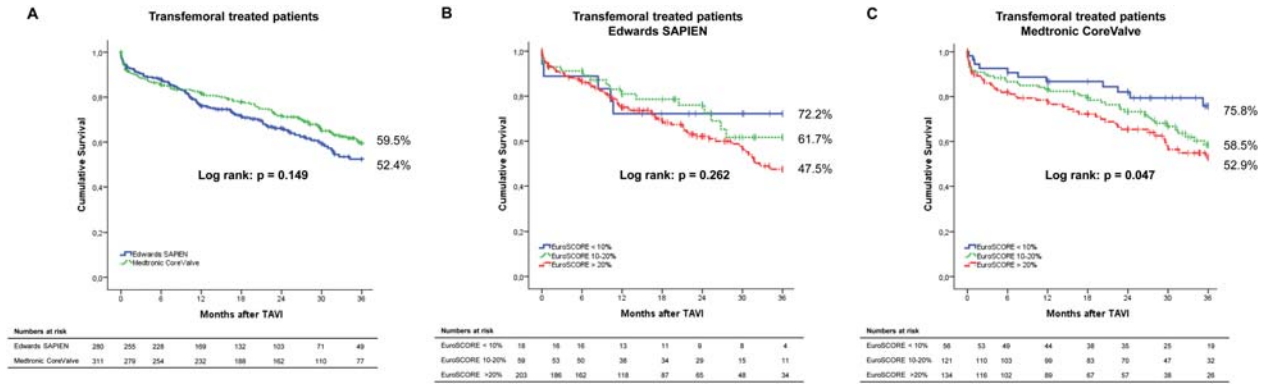

Fig. 2. Kaplan Meier survival curve of transfemorally treated patients (A), according to logistic EuroSCORE for SAPIEN (B) and CoreValve (C).

TABLE V. Predictors of Mortality After TAVI

	Univariable analysis				Multivariable analysis			
			95% CI				95% CI	
	P	Hazard ratio	Lower limit	Upper limit	*P*	Hazard ratio	Lower limit	Upper limit
Predictors 3-year mortality								
Female	0.001	0.670	0.530	0.847	0.042	0.753	0.573	0.990
EuroSCORE	0.009	1.010	1.002	1.017	0.008	1.011	1.003	1.019
NYHA III–IV	0.033	1.418	1.028	1.957				
Mean gradient	0.009	0.990	0.982	0.997				
LVEF	0.048	0.992	0.985	1.000				
Atrial fibrillation	0.003	1.444	1.131	1.844				
Carotid artery disease	0.024	0.685	0.494	0.951	0.014	0.633	0.439	0.913
COPD	0.000	1.586	1.244	2.023	0.003	1.525	1.156	2.012
Previous stroke or TIA	0.002	1.590	1.188	2.127	0.003	1.622	1.175	2.240
Type of valve (CoreValve)	0.022	0.757	0.597	0.960				
Non- transfemoral approach	0.038	1.314	1.015	1.704				
New myocardial infarction	0.029	2.308	1.089	4.891	0.010	2.938	1.287	6.704
New clinically relevant stroke or TIA	0.016	1.833	1.119	3.005	0.019	1.887	1.111	3.205

CI = confidence interval, COPD = chronic obstructive pulmonary disease, LVEF = left ventricular ejection fraction, NYHA = New York Heart Association, TIA = transient ischemic attack.

SAPIEN or CoreValve implantations, among low, intermediate and high risk patients as based on EuroSCORE stratification. Finally, as in other reports, the need for new pacemaker implantation in our patient series was significantly higher with CoreValve [12].

Medium Term Outcome

Clinical outcomes up to 1 year after TAVI have been frequently reported. However, data on further outcome after TAVI are still relatively scarcely reported, and only one group has reported 5 year outcomes in a single center [13]. Survival after TAVI at 1 year was 83%, at 2 years 74%, at 3 years 53%, at 4 years 42%, and at 5 years 35%. In this single center study ($n = 88$), completeness of follow up was 96%.

Three registries compared the Edwards SAPIEN THV with the CoreValve THV [6,10,14]. According to the UK TAVI Registry ($n = 870$), survival at 1 year and 2 years was 78.6% and 73.7%, respectively. Although the exact numbers were not reported, Moat et al stated that there was no difference in survival at 1 year between patients in the Edwards SAPIEN cohort compared with the CoreValve cohort ($n = 862$). According to the PRAGMATIC Plus Initiative ($n = 793$), survival at 1 year was 82.6% for the CoreValve-treated patients, and 86.4% for the Edwards SAPIEN-treated patients ($P > 0.05$). Survival at 1 year in the Spanish national TAVI registry ($n = 1{,}416$) was 84% for the CoreValve-treated patients, and 81% for the Edwards SAPIEN-treated patients ($P > 0.05$).

Completion of medium and long-term follow-up in registries remains a challenging issue, especially when follow-up is based on voluntary cooperation of the different centers, as was the case in this registry. However, this is also a limitation in other published

registries. In the PRAGMATIC Plus Initiative, the completeness of follow-up (up to 1 year after TAVI), based on their survival rate and numbers at risk was lower than in this study (~70%) [10]. Based on the same parameters, the completeness of follow up 1 year after TAVI was ~50% in the Spanish national registry and in the UK TAVI Registry ~96%. Although mortality tracking was achieved in 100% (at December 12, 2010), the completeness of follow up was reduced at 2 years after TAVI (approximately 50%), and the number at risk at 3 years after TAVI was only 30. This marks the additional value of the Belgian TAVI Registry, with a more complete follow-up at 2 and 3 years after TAVI.

Edwards Sapien vs. Medtronic CoreValve TAVI: Comparative Analysis Based on Additional EuroSCORE Stratification

The choice of a THV is generally guided by operator's preference and specific anatomical and technical considerations. Direct comparisons between available systems have not yet been reported, except for procedural characteristics and early outcomes in patients treated in a randomized comparison between SAPIEN and CoreValve in the CHOICE trial [15]. Based on the analysis of the baseline patient characteristics of the Edwards SAPIEN THV and CoreValve-treated patients, it seems that the Edwards SAPIEN-treated patients had significantly more associated co-morbidities and more severe aortic valve disease. Most probably, some of the larger Belgian CoreValve sites were somewhat more restrictive in performing TAVI in patients with very high logistic EuroSCORE (related to limited reimbursement for TAVI in Belgium and limited hospital resources), by this contributing to somewhat lower EuroSCORE values of the total CoreValve cohort. Therefore, stratification of patients according to access route and EuroSCORE remains of interest to compare clinical outcomes with different devices. Despite its limitations, the EuroSCORE remains a valuable tool to distinguish patient cohorts at low, intermediate or high overall risk. Moreover, taking into account that all patients in this Belgian Registry were treated at centers exclusively using the SAPIEN valve or alternatively the CoreValve bioprosthesis, this specific comparative analysis, at least in our interpretation, is contributive and relatively unique.

Predictors of Mortality

As confirmed by other registries, myocardial infarction and clinically relevant stroke or TIA were found to be predictors of 30-day mortality [16]. EuroSCORE, previous stroke or TIA and procedural myocardial infarction [17] were significant predictors of increased midterm mortality. These predictors are in line with the recently published predictors in the ADVANCE study [5].

Limitations of the Study

Data were self-reported by participating centers, without formal monitoring or adjudication of risk scores and events via source documentation. Analysis is based on a non-randomized comparison between valves. Paravalvular aortic regurgitation after the TAVI was not uniformly quantified by central corelab, and therefore not included in the report.

CONCLUSION

Cumulative midterm 3-year survival after transfemoral TAVI in "real world" patients who were not candidates for SAVR, with similar baseline EuroSCORE risk profile is not different between the Edwards SAPIEN or Medtronic CoreValve THVs.

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APPENDIX A: PARTICIPATING BELGIAN TAVI CENTERS

Edwards SAPIEN centers [11]

Centre Hospitalier Universitaire de Charleroi (18 patients from June, 2010 till July, 2011)

Cliniques Catholique Universitaires UCL Mont-Godinne (32 patients from May, 2009 till December, 2011)

Cliniques Saint-Luc, University of Louvain, Brussels (128 patients from January, 2008 till December 2011)

OLV Ziekenhuis Aalst (76 patients from October, 2007 till December 2011)

Katholieke Universiteit Leuven Gasthuisberg (73 patients from March, 2008 till January, 2012)

Clinique Saint-Luc Bouge (30 patients from July, 2009 till September, 2011)

Hôpital Erasme (24 patients from September, 2009 till February, 2012)

Ziekenhuis Oost-Limburg Genk (20 patients from March, 2009 till Novermber, 2011)

Centre Hospitalier Régional de la Citadelle (25 patients from April, 2010 till Febuary 2012)

Hôpital Saint-Joseph (Gilly) and Hôpital de Jolimont (La Louvière) (34 patients from March, 2010 till February 2012)

Medtronic CoreValve centers [12]

Universitair Ziekenhuis Antwerpen (112 patients from December, 2007 till March, 2012)

Centre Hospitalier Universitaire de Liège Sart-Tilman (81 patients from July, 2008 till March 2012)

Middelheim Ziekenhuis Antwerpen (28 patients from April, 2008 till April 2010)

Sint-Jan Ziekenhuis Brugge (19 patients from April, 2009 till December 2011)

Virga Jesse Ziekenhuis Hasselt (19 patients from November, 2009 till December 2011)

Universitair Verplegingscentrum Brugmann (13 patients from October, 2010 till March 2012)

Centre Hospitalier Régional de Namur (15 patients from July, 2010 till March 2011)

Stedelijk Ziekenhuis Roeselare (25 patients from August, 2010 till January 2012)

Maria Middelares Gent (15 patients from May 2010 till March 2012)

Academisch Ziekenhuis Jette (VUB), Imelda Ziekenhuis Bonheiden and Stedelijk Ziekenhuis Aalst (81 patients from February, 2009 till January 2012)

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