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ORIGINAL ARTICLE

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Transcatheter aortic valve implantation using the ACURATE TA™ system: 1-year outcomes and comparison of 500 patients from the SAVI registries

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Abstract

OBJECTIVES: The ACURATE TA™ system is a self-expanding transcatheter heart valve system designed for transapical access which has been proven to be safe and effective in the controlled setting of clinical trials. The SAVI-1 and SAVI-2 registries aimed to assess whether these promising outcomes can be translated into all-comers clinical routine.

METHODS: From November 2011 to 2012 (SAVI-1), and November 2013 to 2014 (SAVI-2), a total of 500 patients were enrolled in the prospective, all-comers, multicentre, multinational SAVI registries. Patients were treated according to the standard of care at their respective hospitals. We report and compare 30-day and 1-year clinical outcomes between SAVI-1 and -2.

RESULTS: Patients were 80.8 ± 6.1 years old, the mean logistic EuroSCORE-I was 23.4 ± 14.3%. Valves were deployed under rapid pacing in 71.3% of the procedures in SAVI-1, and in 3.6% in SAVI-2. There was no relevant difference in clinical and echocardiographic outcomes between SAVI-1 and SAVI-2. Overall mortality at 30 days and 1 year was 6.8% and 19.9%, the stroke rate was 2.2% and 3.7%, respectively; 10.2% of patients had received a permanent pacemaker, and no transcatheter valve-related complications after discharge were observed. Paravalvular leakage ≥2+ was reported in 1.9% of the patients at the early follow-up, and in 2.6% at the 1-year follow-up.

CONCLUSIONS: The SAVI-registries have confirmed that transapical implantation using the ACURATE TA™ device is safe and effective in an all-comers setting with low complication rates and stable performance outcomes at short-term and 1 year; outcomes were similar between SAVI-1 and -2.

ClinicalTrials.gov: NCT02663375

Keywords: Transcatheter aortic valve • Transcatheter heart valve • ACURATE • Transapical • Self-expanding • Registry

INTRODUCTION

Almost a decade ago, the first transcatheter heart valves gained CE approval. Since then, transcatheter aortic valve implantation (TAVI) has become a widely adopted technique. In Germany, a 20-fold increase in TAVI procedures was observed from 2008 to 2014, and TAVI numbers started to exceed those of surgical aortic valve replacement in 2013 [1, 2].

Meanwhile, second-generation devices have been developed to address limitations observed in first-generation devices, amongst them the ACURATE TA™ transapical transcatheter heart valve system (Symetis SA, Ecublens, Switzerland), which gained CE approval in 2011. The most characteristic aspect of this system is its ease of use, mainly driven by intuitive positioning with tactile feedback as well as the anatomical (commissure to commissure) positioning and placement of the device [3, 4].

Safety and performance of the ACURATE TA™ system have been tested in 40 patients enrolled in the First-in-Men study and in 50 patients enrolled in the Pilot study, also called 'TA90 cohort' [3, 5]. To determine whether the outcomes obtained in controlled study settings can be translated to clinical routine, the first 250 commercially treated patients were enrolled in the 'Symetis ACURATE TA™ Valve Implantation' registry (SAVI-1) [5, 6]. One year later, SAVI-2 was started to continue to collect and monitor ongoing safety and efficacy data on the commercial use of the product. This report combines the 1-year outcomes of both registries.

MATERIALS AND METHODS

Study design and population

SAVI-1 and SAVI-2 are prospective, all-comers, multicentre registries conducted in 17 (SAVI-1) and 26 (SAVI-2) centres in Europe and Argentina, but predominantly in Germany. The study design and population of SAVI-1 has been described previously [6]. SAVI-2 has a similar design. Treatment and follow-up were according to the standard of care at the respective hospital. Clinical follow-up, including echocardiographic assessment, was scheduled at discharge or after 7 days, whichever was earlier; at 30 days, a telephone follow-up was conducted (for SAVI-1, clinical and echocardiographic follow-up was scheduled at 30 days). The last registry follow-up was at 12 months, including clinical and (voluntary) echocardiographic assessments. Each registry was scheduled to enrol 250 patients.

The inclusion criteria were broad to allow for an all-comers population and included all patients with severe aortic stenosis, native annulus diameter from ≥21 up to ≤27 mm, informed consent signature, and willingness to return for follow-up visits. Excluded were patients not eligible for TAVI with ACURATE TA™ as per the instructions for use. The registry was approved by the respective ethic committees.

Study device

The ACURATE TA™ valve has been previously described [4, 5]. In brief, it is a self-expanding nitinol prosthesis with porcine leaflets. Stabilizer arches serve to orientate the prosthesis within the ascending aorta during the deployment phase and avoid its tilting. The diabolo-shape facilitates self-alignment and self-centering of the prosthesis, and a PET skirt contributes to preventing paravalvular leaks (PVL). The prosthesis is available in three different sizes, S, M and L. The delivery system has a crossing profile of 33 F. Commissures of the prosthesis can be placed adjacent to the patients commissure and thus the valve is placed in a truely anatomical manner.

Endpoints and definitions

The primary endpoint of SAVI-1 was the rate of major cardiac and cerebrovascular events (MACCE) at 30 days and 1 year, defined as composite of death, myocardial infarction, reintervention, and stroke. The primary endpoint of SAVI-2 was the incidence of all-cause mortality at 30 days. Secondary end-points according to the Valvular Academic Research Consortium-2 (VARC-2) guidelines [7] were: mortality, stroke, myocardial infarction, bleeding complications, acute kidney injury, vascular complications, conduction disturbances and arrhythmias, and other TAVI-related complications (i.e. valve-in-valve, conversion to open heart, coronary obstruction, unplanned use of cardiopulmonary bypass, ventricular septal perforation, mitral valve apparatus damage/dysfunction, cardiac tamponade, endocarditis, valve thrombosis, valve migration/embolization) at 30 days and 1 year. Functional improvement from baseline was assessed via the New York Heart Association (NYHA) functional classification at the 30-day and 1-year follow-ups. We intend to compare safety and performance outcomes between SAVI-1 and -2.

Statistical analysis

No formal sample size calculation was conducted. Data were analysed according to the Intention-to-Treat population, which included all patients in whom an implant was attempted. Patients who received a prosthesis other than the study valve (e.g. conversion to open heart, valve-in-valve) were excluded from echocardiographic follow-up, but included in safety assessments. Data are presented using descriptive statistical methods. For quantitative variables, means and standard deviations (SD) were calculated, and for categorical data absolute and relative frequencies. When appropriate, 95% CIs were calculated. Event estimates were calculated using the Kaplan–Meier method; the log-rank test was used to compare overall mortality. Cox proportional hazards regression analysis was used to explore the association between SAVI-1 and SAVI-2. Data analysis was performed using SAS V9.3 (SAS Institute Cary, NC, USA).

RESULTS

Five hundred patients have been enrolled in the SAVI-1 and SAVI-2 registries. The patient flow is displayed in Figure 1. In SAVI-1, approximately 70% of centres were first-time users, and 15 (58%) new centres were included in SAVI-2. No centre enrolled more than 15% of patients. The centre list is provided in the Supplementary Material, Table S1.

Baseline and procedural characteristics are displayed in Table 1. Risk scores were slightly lower in the SAVI-1 compared to the SAVI-2 cohort (Logistic EuroSCORE-I of 22.3 ± 12.7% vs 24.7 ± 15.7%).

Of all 500 procedures, in SAVI-1 and SAVI-2, implantation of the ACURATE TA valve was successful in 489 (97.8%) patients. In

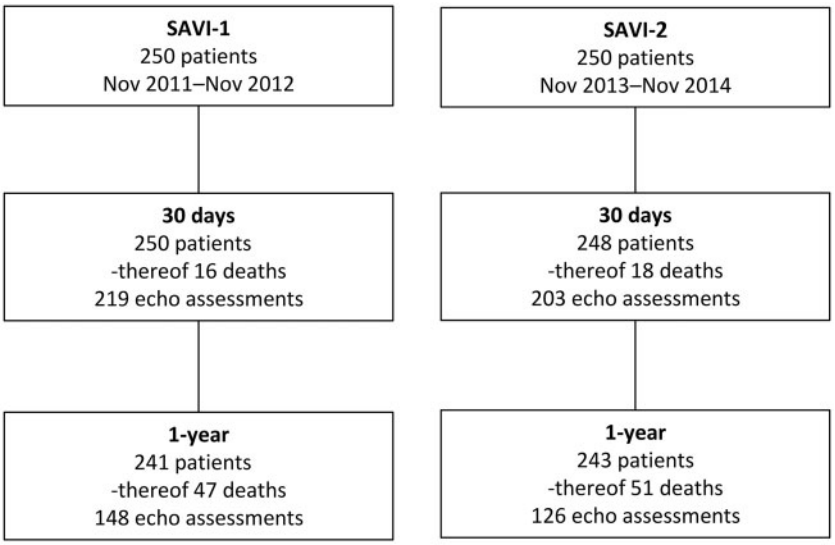

Figure 1: Patient flow diagram.

SAVI-1, 3 conversions to open-heart surgery occurred (1 intra-procedural event when the device was pulled into the left ventricle during delivery system withdrawal, 1 on post-procedure day 1 for severe aortic regurgitation, and another on day 7 for severe aortic regurgitation after tilted valve deployment). Two valve-in-valve procedures using another commercially available transcatheter heart valve were performed for severe aortic regurgitation. In SAVI-2, no conversion to open heart occurred, but 6 valve-in-valve procedures (of these, 1 was associated with coronary obstruction, 2 with valve migration 1 with coronary obstruction and valve migration), 1 unplanned use of cardiopulmonary bypass and 1 mitral valve apparatus damage/dysfunction. Both patients with coronary obstruction and valve-in-valve procedure were diagnosed with porcelain aorta at baseline.

Table 1: Baseline and procedural characteristics

	SAVI-1 $n = 250$	SAVI-2 $n = 250$	Total $n = 500$
Baseline			
Age [years]	80.9 ± 6.3	80.7 ± 5.9	80.8 ± 6.1
Male	126 (50.8)[a]	104 (41.6)	230 (46.2)
Logistic EuroSCORE-I [%]	22.3 ± 12.7	24.7 ± 15.7	23.4 ± 14.3
STS Score [%]	8.0 ± 5.9	11.9 ± 10.0	9.8 ± 8.3
Procedure			
Prior balloon valvuloplasty	240 (97.2)[b]	218 (87.2)	458 (92.2)
Device sizes used			
S	84 (33.6)	68 (27.2)	152 (30.4)
M	93 (37.2)	109 (43.6)	202 (40.4)
L	73 (29.2)	73 (29.2)	146 (29.2)
Deployment under rapid pacing	176 (71.3)[b]	9 (3.6)	185 (37.0)
Post-dilatation	97 (38.8)	110 (44.0)	207 (41.4)
Procedure			
Successful implant	245 (98.0)	241 (96.4)	489 (97.8)
Valve-in-valve procedure	2 (0.8)	6 (2.4)	8 (1.6)
Conversion to surgery	3 (1.2)	0	3 (0.6)

Data are presented as mean ± SD or *n* (%). NA: not assessed. [a]unknown in two patients, [b]unknown in three patients.

Echocardiographic parameters were similar between the registries, with slightly less paravalvular leakage ≥2+ at 1 year in SAVI-2 (0.8% vs 4.1%) (Table 2, Fig. 2). The NYHA classification improved from 93.5% of patients in NYHA class III/IV at baseline to 13.0% at 1 year (Fig. 3, Supplementary Material, Table S2).

Table 2: Echocardiographic assessments

	SAVI-1 $n = 250$	SAVI-2 $n = 250$	Total $n = 500$
Baseline			
Effective orifice area [mm^2]	0.71 ± 0.21	0.75 ± 0.31	0.73 ± 0.26
Mean gradient [mmHg]	43.1 ± 17.4	42.2 ± 14.9	42.7 ± 16.2
	$n = 219$ 30 days	$n = 203$ Discharge/7-days[a]	$n = 422$
Effective orifice area	1.44 ± 0.45	1.48 ± 0.43	1.45 ± 0.44
Mean gradient [mmHg]	12.4 ± 5.8	12.5 ± 6.0	12.5 ± 5.9
Paravalvular leak			
0: non/trace	159 (72.6)	141 (69.5)	300 (71.1)
1+: mild	55 (25.1)	59 (29.1)	114 (27.0)
2+: moderate	5 (2.3)	3 (1.5)	8 (1.9)
3+: moderate/severe	0	0	0
4+: severe	0	0	0
1 year	$n = 148$	$n = 126$	$n = 274$
Effective orifice area	1.51 ± 0.38	1.57 ± 0.40	1.54 ± 0.39
Mean gradient	12.9 ± 5.3	11.1 ± 4.4	12.1 ± 5.0
Paravalvular leak			
0: non/trace	111 (75.0)	80 (63.5)	191 (69.7)
1+: mild	31 (20.9)	45 (35.7)	76 (27.7)
2+: moderate	5 (3.4)	1 (0.8)	6 (2.2)
3+: moderate/severe	1 (0.7)	0	1 (0.4)
4+: severe	0	0	0

Data are presented as mean ± SD or *n* (%). Not all measurements were available for all patients displayed,.
[a]whichever was earlier.

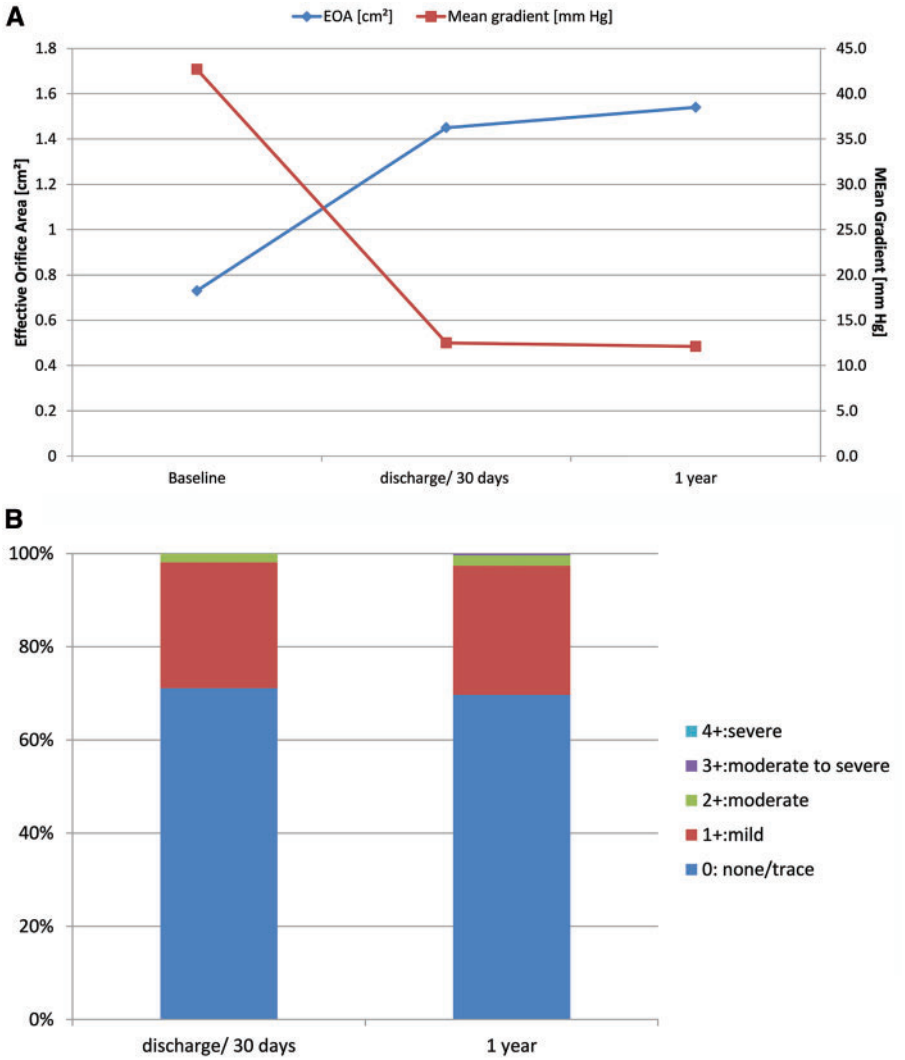

Figure 2: Echocardiographic parameters over time (SAVI-1 and SAVI-2). (**A**) Aortic valve haemodynamics, measured as mean gradient and effective orifice area (EOA), and (**B**) percentage of patients with paravalvular leakage. Values remained stable between early follow-up at discharge/30 days and 1 year.

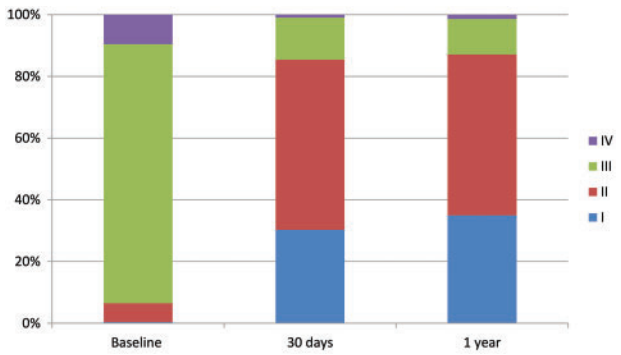

Figure 3: New York Heart Association (NYHA) classification at baseline and follow-up (SAVI-1 and SAVI-2).

Relevant safety outcomes are displayed in Table 3, and additional outcomes in Supplementary Material, Table S3. Notably, only SAVI-2 outcomes were categorized by VARC-2 criteria. In general, outcomes were similar between SAVI-1 and SAVI-2. Mortality at 30 days was 6.4% [95% CI: 3.3–9.4] for SAVI-1 and 7.2% [95% CI:3.9–10.4] for SAVI-2, and at 1 year 18.9% [95% CI:13.9–23.7] and 20.8% [95% CI:15.6–25.8] respectively, $P = 0.64$ (Fig. 4).

DISCUSSION

The real-world SAVI registries with 500 enrolled patients show very good safety and performance outcomes in patients treated with the ACURATE TA^{TM} system. Outcomes across the SAVI-1 and SAVI-2 registries and the 'TA90' First-in-man and pilot studies are consistent, e.g. moderate or severe PVL <3.5%, ∼10% permanent pacemaker implantation, and ∼20% 1-year mortality [3, 5]. This is remarkable as the 'TA 90' cohort were first-time users, as well as approximately 70% of centres in SAVI-1 [6], and speaks for the ease of use of the device. There was a difference in the rate of conversion to open heart between SAVI-1 and -2, though. This could have been a coincidental finding, but could also reflect the fact that, in general, complication management had improved. Similarly, during the same time period, the GARY registry observed an improvement in technical procedural complications [8]. Notably, the number of valve-in-valve procedures was higher in SAVI-2 (2.4% vs 0.8%)—eventually, patients who would have been converted in the early experience

Table 3: Kaplan–Meier estimates of relevant clinical outcomes at 30 days and 1 year

	SAVI-1[a]	SAVI-2	Total	HR
30 days				
Mortality	16 (6.4) [3.3–9.4]	18 (7.2) [3.9–10.4]	34 (6.8) [4.6–9.0]	1.12 (0.57:2.2)
Cardiovascular	5 (2.0) [0.3–3.8]	9 (3.6) [1.3–5.9]	14 (2.8) [1.4–4.3]	1.80 (0.60:5.37)
Non-cardiovascular	11 (4.5) [1.9–7.0]	9 (3.7) [1.3–6.0]	20 (4.1) [2.3–5.8]	0.82 (0.34:2.00)
Stroke[b]	7 (2.9) [0.8–4.9]	4 (1.6) [0.0–3.2]	11 (2.2) [0.9–3.5]	0.57 (0.17:1.95)
Myocardial infarction	1 (0.4) [0.0–2.0]	1 (0.4) [0.0–1.2]	2 (0.4) [0.0–1.0]	1.00 (0.06:15.99)
AKI stage 3	NA	7 (2.8) [0.7–4.9]	–	NA
Other TAVI-related complications post-discharge	0	0	0	NA
New onset of atrial fibrillation/atrial flutter	NA	20 (8.2) [4.7–11.5]	–	NA
Permanent pacemaker	25 (10.2) [6.3–14.0]	25 (10.2) [6.3–13.9]	50 (10.2) [7.5–12.9]	1.01 (0.58:1.76)
1 year	*n* = 241	*n* = 243	*n* = 484	
Mortality	47 (18.9) [13.9–23.7]	51 (20.8) [15.6–25.8]	98 (19.9) [16.3–23.3]	1.10 (0.74:1.64)
Cardiovascular	15 (6.4) [3.2–9.4]	19 (8.2) [4.5–11.6]	34 (7.3) [4.9–9.6]	1.31 (0.66:2.57)
Non-cardiovascular	32 (13.2) [8.9–17.4]	32 (13.8) [9.2–18.1]	64 (13.5) [10.4–16.5]	1.02 (0.62:1.66)
Stroke	10 (4.2) [1.6–6.7]	7 (3.2) [0.8–5.5]	17 (3.7) [1.9–5.4]	0.72 (0.27:1.89)
Other TAVI-related complications post-discharge	0	0	0	NA

Data are presented as *n* (%) [95% CI], and HR. AKI-acute kidney injury, HR-hazard ratio, calculated using the Cox proportional hazards regression analysis, NA-not assessed, TAVI-transcatheter aortic valve implantation, [a]no VARC classification, [b]not further specified if disabling or not disabling.

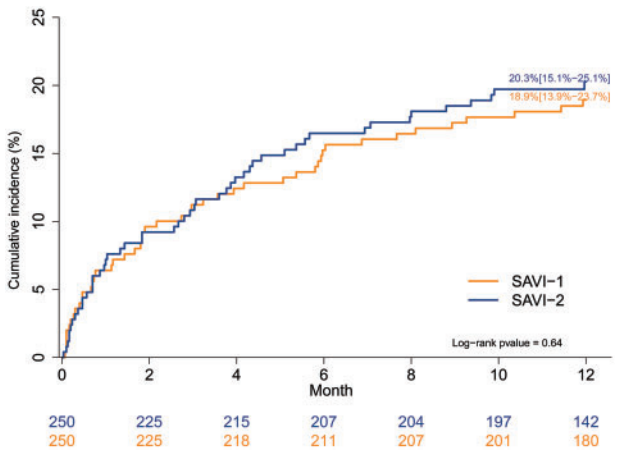

Figure 4: All-cause mortality per Kaplan–Meier estimate.

had received a valve-in-valve procedure in SAVI-2. Furthermore, the difference between SAVI-1 and -2 observed for rapid pacing probably reflects the increasing confidence in this technique.

Reasons for low complication rates and ease of use of the device have previously been reported: (i) re-sheathability, (ii) top-down implantation technique compressing the native leaflets and capturing them in the waist of the device, hence reducing the risk of paravalvular leakage and potentially also reducing the risk of coronary occlusion, (iii) stabilization arches allowing a coaxial self-alignment of the valve and stent commissure alignment during fluoroscopy, hence avoiding a stent-post in front of the coronary ostia and potentially easing later interventional access to the coronaries, (iv) the upper crown allows supra-annular anchoring, tactile feedback and stable positioning, (v) the waist conforms to the native annulus, (vi) the lower crown allows for minimal stent protrusion into the left ventricle and hence (in combination with the low radial force needed due to the anatomic shape of the valve) reduces the risk of conduction system interference with subsequent pacemaker implantation, and (vii) the PET skirt acts as a seal to prevent PVL [4–6, 9].

Regarding valve design, there could be a concern that the two-step deployment and the higher need for post-dilatation compared to balloon-expanding valves [10] might lead to a higher stroke rate. With the limitation of site-reported data and the lack of differentiation between minor and major stroke, we did not observe a high stroke rate in the SAVI-registries. This observation is confirmed by a transcranial doppler ultrasound study, comparing the frequency and pattern of high-intensity transient signals (HITs) in 22 patients receiving either the transapical ACURATE TA^{TM} or the balloon-expandable SAPIEN XT valve (Edwards Lifesciences LLC, Irvine, CA, USA), which found similar outcomes for both devices [11].

Kempfert *et al.* [6] compared early SAVI-1 results with those of the FRANCE-2 and SENTINEL registries using the CoreValve (Medtronic Inc., Minneapolis, MN, USA) and SAPIEN/SAPIEN XT prosthesis. Even though they included 75% transfemoral cases, early mortality was comparable, the leakage rate extremely promising, and the pacemaker rate within the range of the SAPIEN system and superior to the CoreValve system. Furthermore, SAVI-1 and -2 outcomes compare well to those of a recent review of transapical second-generation transcatheter heart valves [12], a recently published report of the JUPITER registry using the JenaValve (JenaValve Technology GmbH, Munich, Germany) [13], and the transapical cohort of the GARY registry [14]. Thirty-day mortality in our series was 6.8% compared to 8.9%, 11.1% and 7.7% (in-hospital mortality), and pacemaker were implanted in 10.2% compared to 12.1%, 14.4% and 11.3%, respectively. Bailout situation (valve-in-valve implantations and conversion to open heart) occurred in 2.2% of our series, compared to 5.0% in the JUPITER study and 2.0% (valve-in-valve procedures only) in the GARY registry.

Moderate to severe PVL at 30 days occurred in only 1.9% (2.6% at 1 year) of our cases. Accordingly, in a single-centre series, the ACURATE TA^{TM} valve had the lowest PVL-rate of next-generation transapical valves [15], and significantly less PVL than the transfemoral CoreValve prosthesis [16]. Overall, echocardiographic parameters (effective orifice area and mean gradient) and NYHA class remained stable between 30 days and 1 year.

Notably, even though the registries enrolled between 2011 and 2014, and many centres were first-time users, the pacemaker, stroke and PVL rates comply to the 'future targets for optimal quality centres' as published in a recent state-of-the-art review which postulated the following limits: new pacemaker <10%, major stroke <2% and moderate to severe PVL <5% [17].

These results confirm that the ACURATE TA^{TM} valve adds another valuable option to the TAVI armamentarium. Currently, it is the only commercially available self-expandable valve for transapical access. Due to its unique features, this valve might be particularly useful in (i) patients with low coronary ostia as the tissue will be pulled away from the ostia during implantation [6], (ii) patients with massive calcification, as well as an absence of calcification [5], or even in pure aortic regurgitation [18], (iii) due to its low pacemaker and PVL rates and implantability without rapid pacing—in patients with poor left ventricular ejection fraction, (iv) centres with little experience as the valve is easy to implant and resheathing and repositioning are possible until final release [4–6], and (v) low-volume centres as they ideally restrict themselves to two valve types to allow adequate device experience and therefore should select a valve type that can serve the transfemoral and transapical approach.

Undoubtedly, with the adaption of smaller introducer systems, transfemoral nowadays is the most common access route. Exemplary in Germany, the numbers of transapical cases have remained constant over the years while there has been a massive increase in transfemoral ones [2]. This has probably led to an even more severely diseased patient population for transapical cases, especially related to peripheral artery disease. Correspondingly, SAVI-2 patients had numerically higher risk scores than SAVI-1 patients. Nevertheless, 30-day mortality is nearly identical between both registries and there is no statistically significant difference in 1-year mortality, even though the Kaplan–Meier curves start to diverge after 3 months, which might be indicative of a more severely diseased patient population.

Though the majority of cases are transfemoral nowadays [2], the transapical approach is still relevant. When transfemoral access is not possible, it is the access of choice, as reported in a recently conducted survey [19]. It has not only the advantage of a short distance to the annulus, resulting in precise control of the device, but also avoids crossing of the aortic arch, which is especially helpful in severely calcified anatomy, and can ultimately be applied in almost all patients [10]. Furthermore, there is a development towards devices with smaller transapical delivery systems. Recently, the combination of ACURATE neo^{TM} with a 22F outer diameter transapical delivery system has been successfully tested [4] and a CE approval trial is currently enrolling.

Limitations of the SAVI registries are the ones inherent to registries, such as self-reporting of events. However, risk of underreporting was minimized due to the application of yes/no questions for safety endpoints. Furthermore, data were not monitored, nor adjudicated, no core laboratory was used, and SAVI-1 did not include VARC recommendations [7]. As—due to the nature of a registry—echocardiographic assessment was optional, only slightly more than 50% returned for echocardiographic assessment at 1 year. Furthermore, only rudimentary baseline information was available (e.g. preimplant pacemaker rate was not assessed). Baseline parameters would have been important to gain a better understanding of how the population changed between SAVI-1 and SAVI-2. Lastly, future research should include long-term follow-up.

CONCLUSION

The SAVI-registries have shown that transapical implantation using the ACURATE TA^{TM} device is safe and effective in an all-comers setting with low mortality, pacemaker and PVL rates, and stable haemodynamics throughout follow-up. There was no relevant difference in outcomes between SAVI-1 and -2.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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Conflict of interest: Jochen Börgermann is a consultant and proctor for Medtronic and receives speaker honoraria and travel compensation from Medtronic, Symetis and Edwards Lifesciences. David M. Holzhey is an advisor for Edwards Lifesciences and Medtronic, and a proctor for Symetis. Steffen Hoffmann is a proctor for Symetis. Hendrik Treede is proctor and advisor for Symetis. Jörg Kempfert is a proctor for Symetis and receives travel compensation and speaker honoraria. The other authors declared no conflict of interest.

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