Early commercial experience with a newly designed balloon-expandable transcatheter heart valve: 30-day outcomes and implications of preprocedural computed tomography

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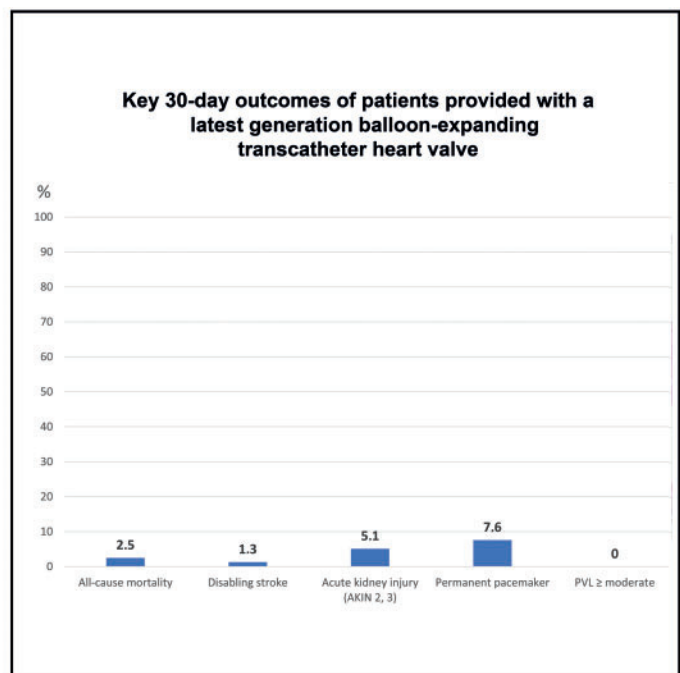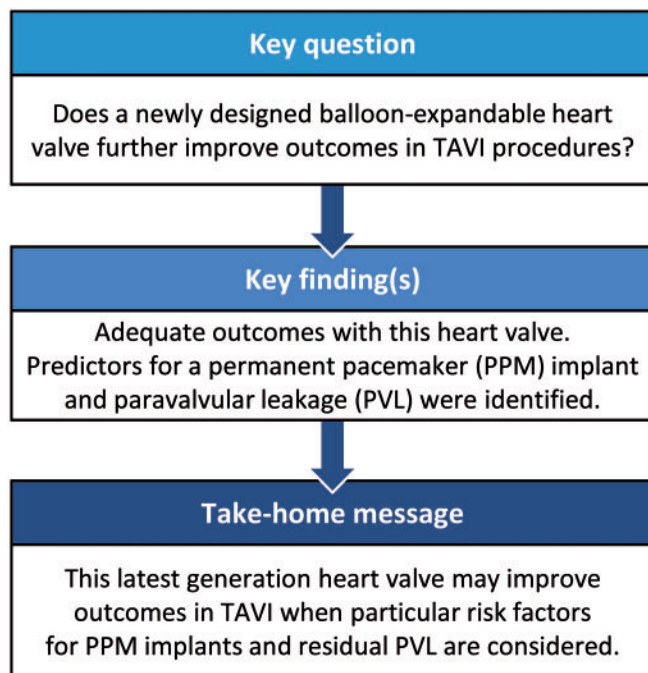
Abstract

OBJECTIVES: We herein report a single-centre experience with the SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve implantation (TAVI) system.

METHODS: Between March 2019 and January 2020, a total of 79 consecutive patients received transfemoral TAVI using the SAPIEN 3 Ultra device. Data were retrospectively analysed according to updated Valve Academic Research Consortium-2 definitions. Detailed analysis of multislice computed tomography data was conducted to identify potential predictors for permanent pacemaker (PPM) implantation and residual paravalvular leakage (PVL) post TAVI.

RESULTS: Device success and early safety were 97.5% (77/79) and 94.9% (75/79) with resulting transvalvular peak/mean pressure gradients of 21.1 ± 8.2/10.9 ± 4.4 and PVL >mild in 0/79 patients (0%). Mild PVL was seen in 18.9% (15/79) of cases. Thirty-day mortality was 2.5% (2/79). The Valve Academic Research Consortium-2 adjudicated clinical end points disabling stroke, acute kidney injury and myocardial infarction occurred in 1.3% (1/79), 5.1% (4/79) and 0% (0/79) of patients. Postprocedural PPM implantation was necessary in 7.6% (6/79) of patients. Multislice computed tomography analysis revealed significantly higher calcium amounts of the right coronary cusp in patients in need for postprocedural PPM implantation and a higher eccentricity index in patients with postinterventional mild PVL.

CONCLUSIONS: First experience with this newly designed balloon-expandable-transcatheter heart valve demonstrates adequate 30-day outcomes and haemodynamic results with low mortality, low rates of PPM implantation and no residual PVL >mild. The herein-presented multislice computed tomography values with an elevated risk for PPM implantation and residual mild PVL may help to further improve outcomes with this particular transcatheter heart valve in TAVI procedures.

Keywords: Transcatheter valve therapy • Valve disease • Transcatheter aortic valve implantation Transcatheter aortic valve replacement • Balloon-expandable

ADULT CARDIAC

ABBREVIATIONS

BE   Balloon-expandable
LVOT   Left ventricular outflow tract
NYHA   New York Heart Association
PPM   Permanent pacemaker
PVL   Paravalvular leakage
S3U   SAPIEN 3 Ultra
TAVI   Transcatheter aortic valve implantation
THV   Transcatheter heart valve
TTE   Transthoracic echocardiography

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is an established therapy for severe aortic valve stenosis in patients with an intermediate- or high-risk profile for surgical aortic valve replacement, when a suitable anatomy for the interventional approach is present [1–3]. Accordingly, TAVI has been incorporated in international guidelines [4, 5]. Recent results of a randomized controlled trial comparing TAVI and surgical aortic valve replacement in low-risk patients suggest superiority of a latest-generation balloon-expandable (BE) transcatheter heart valve (THV) (SAPIEN 3; Edwards Lifesciences Inc., Irvine, CA, USA) compared to surgical aortic valve replacement [6]. While expansion of TAVI indication to low-risk patients remains controversial, mainly due to a higher risk of postprocedural permanent pacemaker (PPM) implantation, residual paravalvular leakage (PVL) and lack of long-term durability data as shown in registry analysis [7–9], evolution of THV and corresponding delivery systems is continuing.

The most recent BE device is the SAPIEN 3 Ultra (S3U) THV System (Edwards Lifesciences Inc.). The S3U THV is the successor of the SAPIEN 3 and consists of a bovine pericardial tissue valve mounted in a low-profile cobalt-chromium frame as known from the SAPIEN 3. Structural modification was added to the outer positron emission tomography skirt, which is now 40% higher compared to the precursor without increase of the inner skirt height. At present, this novel BE THV is available in 3 sizes (20, 23, 26 mm) covering an annulus range of 18.6–26.4 mm according to multislice computed tomography (MSCT) measurements. Further changes were implemented regarding the delivery system which was initially launched with an on-balloon valve crimping technique omitting the need for intraprocedural valve alignment

and flex catheter retraction, and the introducer sheath (Axela sheath), which is a seamless expandable 14 Fr sheath for all available valve sizes [10, 11] (see Fig. 1). We herein aimed to evaluate all patients at our centre, who received a S3U THV, since the system received CE mark at the end of 2018.

MATERIALS AND METHODS

Patients

Between March 2019 and January 2020, a consecutive series of 79 patients received transfemoral-TAVI using the S3U system for treatment of severe symptomatic calcified aortic valve stenosis as determined by transthoracic echocardiography (TTE) and transoesophageal echocardiography. In the same period, an overall number of 407 TAVI procedures were conducted at our centre.

Written informed consent was obtained from all patients. Decision to implant this particular THV was left to operators' discretion and there were no specific anatomical criteria for using the S3U system. However, after 'eye-balling' of the preprocedural MSCT, patients with an extensive calcium load of the left ventricular outflow tract (LVOT) were excluded from S3U implantation after consensus of the local heart team due to an increased risk of LVOT rupture caused by the high radial forces of BE THV. Allocation of patients to TAVI followed current international recommendations [4] after consensus of the local dedicated heart team.

Diagnostic work-up and study procedure

As already described in Refs [12, 13], the preprocedural diagnostic work-up followed institutional standards: By routine, all patients received preoperative TTE and transesophageal echocardiography for evaluation of cardiac functional status. Furthermore, diagnostic work-up included contrast-enhanced, electrocardiogram-gated MSCT. Data sets were analysed using the 3mensio Medical Imaging Software (3mensio, Medical Imaging, Bilthoven, Netherlands) for calculation of native aortic annulus dimensions and determination of adequate THV size as well as assessment of aortic root anatomy and morphology (e.g. distribution and severity of valvular calcification, aortic root dimensions or height of coronary ostia take-off), prediction of optimal c-arm angulation and assessment of aorto-iliac and peripheral vascular status.
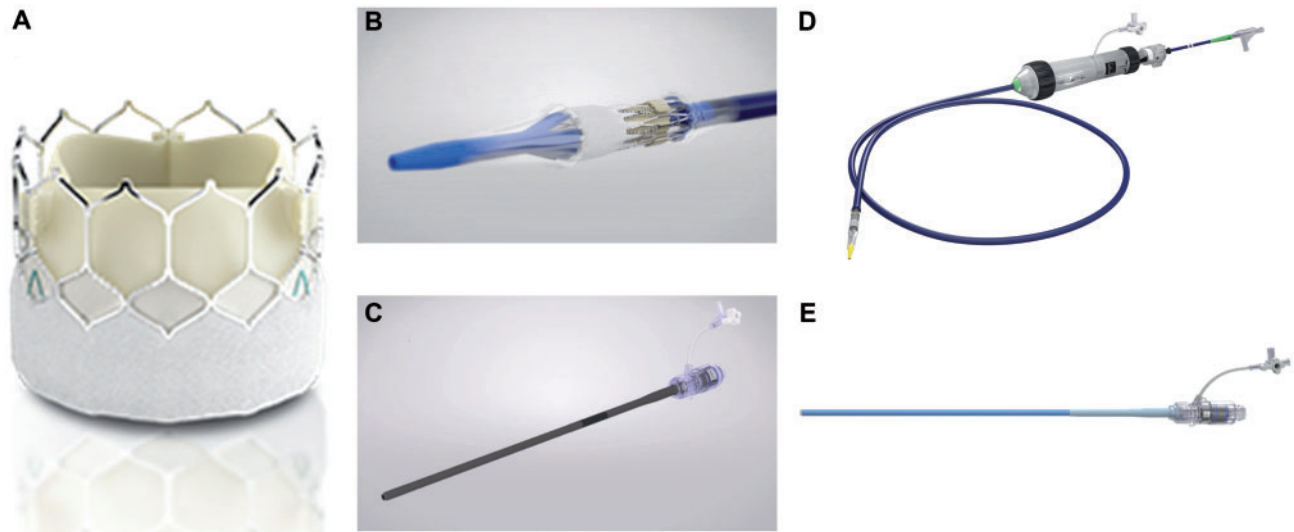
Figure 1: A newly designed balloon-expandable transcatheter heart valve with high outer positron emission tomography skirt (**A**) and corresponding on balloon valve crimping delivery system (**B**), seamless expandable 14 Fr introducer sheath (**C**), precursor delivery system 'Commander' (**D**) and introducer sheath 'e-sheath' (**E**).

First-line approach for all procedures was local anaesthesia and/or analgosedation. All procedures were performed in a specially equipped hybrid operating suite by a dedicated team of cardiologists, cardiac surgeons and anaesthesiologists. THV function was assessed by invasive measurements of haemodynamics, aortic root angiography and TTE.

Multislice computed tomography data analysis

Analysis of MSCT was described before [14]. In brief, the aortic annulus was defined as the virtual basal plane containing the basal attachment of the 3 aortic cusps. The cover index was assessed to adjust for oversizing of the THV and calculated as $100 \times$ (THV area - annulus area)/THV area. Eccentricity of the aortic annulus was evaluated with an index calculated as 1 - (minimum diameter/maximum diameter). Asymmetry of calcium distribution was calculated as maximum absolute difference in calcium volume between leaflet sectors for both aortic valve complex and LVOT.

Calcium quantification was performed utilizing an automated volume-scoring tool with an empiric threshold of 500 Hounsfield units. Two regions were evaluated for calcium load: the aortic valve complex including the basal plane to coronary ostia (zone 1) and the LVOT including the subannular region from 10 mm inferior to basal plane (zone 2). Calcium distribution within the aortic valve and the LVOT was sectioned according to left-, right- and non-coronary cusps.

To mitigate interobserver variability, all MSCT were analysed by 1 investigator.

Statistical analysis

Baseline, intraprocedural and acute follow-up data up to 30 days were retrospectively collected and entered into a standardized database and analysed. Clinical end points were adjudicated in accordance with the updated standardized Valve Academic Research Consortium-2 definitions [15]. Data are presented as absolute numbers and percentages for categorical variables and mean values and standard deviation for continuous variables unless stated otherwise. All variables were tested for approximately normal distribution. Continuous variables were compared by unpaired t tests. *P*-values were reported without correction for multiple testing. A level of significance was set to 2-tailed *P*-value <0.05. All statistical analyses were performed using Prism© (GraphPad Software, San Diego, CA, USA).

RESULTS

Baseline demographics

Seventy-nine consecutive patients received transfemoral-TAVI using the S3U THV (40.5% female, 79.8 ± 7.1 years, logistic European System for Cardiac Operative Risk Evaluation I 12.1 ± 8.8%). Patients presented with a moderate comorbidity burden, comprising 43/79 (54.4%) patients with concomitant coronary artery disease, 13/79 (16.5%) patients with diabetes mellitus and 6/79 (7.6%) with previous sternotomy. One-third of the herein-investigated patients were highly symptomatic with a New York Heart Association (NYHA) functional class ≥III and baseline left ventricular ejection fraction was 52 ± 14%. Detailed patient demographics are summarized in Table 1.

Periprocedural data

Baseline effective orifice area and peak/mean pressure gradients of the aortic valve were 0.75 ± 0.19 cm^2 and 63 ± 23.4/ 37.5 ± 14.9 mmHg, respectively, as determined by preprocedural transesophageal echocardiography. Procedure time, fluoroscopy time and contrast agent used were 67.4 ± 21.5 min, 18.1 ± 9.1 min and 176.9 ± 53.3 ml, respectively. No S3U valves size 20 mm were used. A cerebral protection system (SENTINEL™ Cerebral Protection System, Boston Scientific Co., Marlborough, MS, USA) was utilized in 9/79 (11.4%) cases. Invasive measurements of pre- and postimplant pressure gradients revealed a decrease in peak gradient from 41.4 ± 20.9 to 4.7 ± 5.8 mmHg (*P*<0.001) and decrease in mean gradient from 40.4 ± 17.2 to 8.3 ± 5.6 mmHg (*P* < 0.001) (see Fig. 2).

Majority of patients were treated under local anaesthesia and/or analgosedation (76/79, 96.2%). One-third of patients received balloon aortic valvuloplasty after THV insertion due to significant residual PVL. Detailed periprocedural data are summarized in Table 2.

Echocardiographic outcome data

In the study group, peak and mean transvalvular gradients as determined by TTE decreased from 63 ± 23.4 to 21.1 ± 8.2 mmHg and 37.5 ± 14.9 to 10.9 ± 4.4 mmHg (both $P < 0.001$). Effective orifice area increased from 0.8 ± 0.2 to 1.8 ± 0.3 cm^2 ($P < 0.001$) (see

Fig. 2). Postinterventionally, PVL >mild was found in 0% (0/79) of patients. Mild PVL was seen in 18.9% (15/79) of patients. Echocardiographic outcome parameters are documented in Table 3.

Clinical outcome data

All-cause 30-day mortality was 2.5% (2/79) (overall mortality of all TAVI patients during the same time period: 2.9%) due to 1 pulseless electric activity immediate prior to PPM implantation on postoperative day 4 and 1 unclear fulminant cerebral embolism on postoperative day 3. Device success and early safety were 97.5% (77/79) and 94.9% (75/79), respectively. Rates of the Valve Academic Research Consortium-2-adjudicated clinical end points disabling stroke, myocardial infarction and acute kidney injury were 1.3% (1/79), 0% (0/0) and 5.1% (4/79). Postprocedural PPM implantation due to atrioventricular block was indicated in 7.6% of patients (6/79). All patients who received postprocedural PPM implantation presented with atrial fibrillation, left/right bundle branch block or both prior to TAVI.

Intensive care unit and hospital stay were 1.6 ± 1.2 and 11.6 ± 5.3, respectively. Postinterventional NYHA functional class assessment presented 1 patient in NYHA functional class III (1.3%) and 78/79 patients with NYHA functional class I or II.

Detailed clinical outcome data are summarized in Table 3. Key outcomes are depicted in Fig. 3.

Multislice computed tomography and electrocardiogram data

The study group exhibited the following calcium loads of both predefined zones of the aortic annulus: zone 1 (aortic annulus to coronary ostia) showed a mean total calcium load of 942.2 ± 631.8 mm^3 and zone 2 (subannular from AA 10 mm in LVOT) a mean total calcium load of 36.1 ± 87 mm^3. Patients provided with postprocedural PPM implantation presented with

Table 1:	Baseline demographics
	Study group (n = 79)
Age (years), mean ± SD	79.8 ± 7.1
Female gender, n (%)	40.5 (32)
BMI (kg/m^2), mean ± SD	27.2 ± 5.5
logEuroSCORE I (%), mean ± SD	12.1 ± 8.8
Diabetes mellitus, n (%)	16.5 (13)
Arterial hypertension, n (%)	74.7 (59)
Stroke, n (%)	6.3 (5)
Coronary artery disease, n (%)	54.4 (43)
Previous sternotomy, n (%)	7.6 (6)
Extracardiac atheropathy$^\infty$, n (%)	11.4 (9)
Arrhythmia, n (%)	37.9 (30)
COPD$^\infty$ >Gold II, n (%)	5.1 (4)
Creatinine (mg/dl), mean ± SD	1.1 ± 0.4
NYHA ≥III, n (%)	36.7 (29)
LVEF (%), mean ± SD	52 ± 14

BMI: body mass index; COPD: chronic obstructive pulmonary disease; logEuroSCORE: logistic European System for Cardiac Operative Risk Evaluation; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; SD: standard deviation; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; ∞extracardiac atheropathy, ∞COPD according to EuroSCORE definitions.
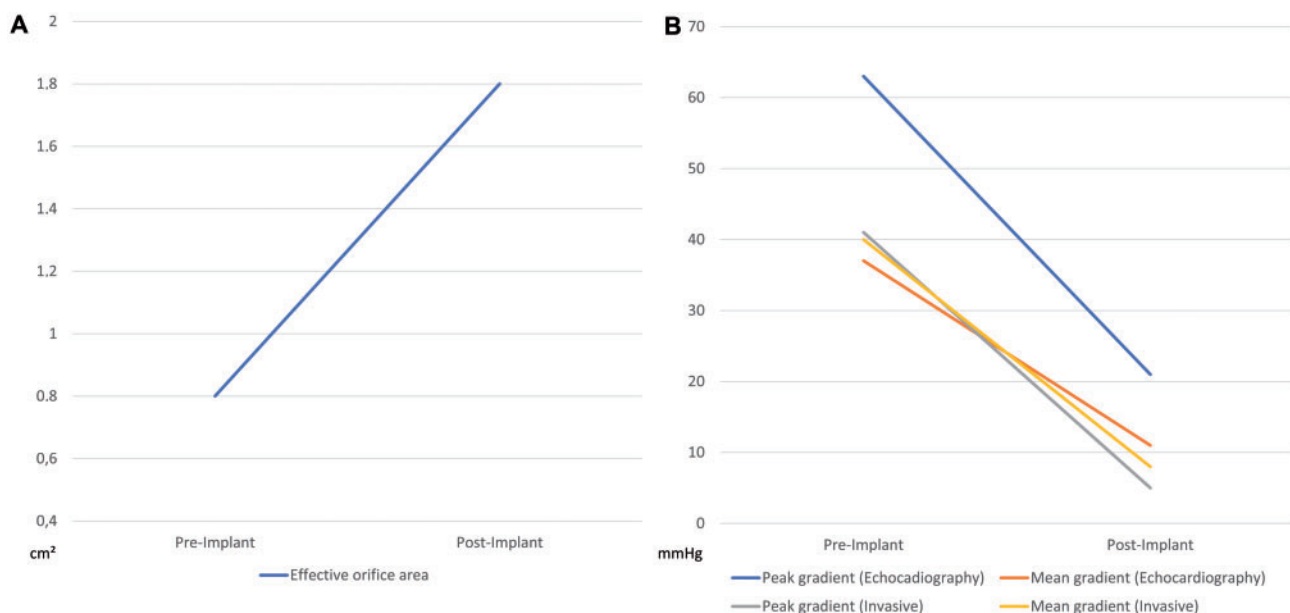
Figure 2: Comparison of pre- and postimplantation effective orifice area (**A**) and peak and mean pressure gradients of the aortic valve in echocardiography and invasive measurements (**B**).

Table 2: Periprocedural data

	Study group (n = 79)
Baseline EOA (cm^2), mean ± SD	0.8 ± 0.2
Baseline peak gradient (mmHg), mean ± SD	63 ± 23.4
Baseline mean gradient (mmHg), mean ± SD	37.5 ± 14.9
Invasive pre-implant peak gradient (mmHg), mean ± SD	41.4 ± 20.9
Invasive pre-implant mean gradient (mmHg), mean ± SD	40.4 ± 17.2
Procedure time (min), mean ± SD	67.4 ± 21.5
Fluoroscopy time (min), mean ± SD	18.1 ± 9.11
Contrast agent (ml), mean ± SD	176.9 ± 53.31
Valve size (mm), n (%)	
20	0 (0)
23	31.6 (25)
26	68.4 (54)
Predilatation, n (%)	44.3 (35)
Postdilatation, n (%)	32.9 (26)
Cerebral protection, n (%)	11.4 (9)
Anaesthesia, n (%)	
General anaesthesia	3.8 (3)
Local anaesthesia conscious sedation	96.2 (76)
Invasive postimplant peak gradient (mmHg), mean ± SD	4.7 ± 5.8
Invasive postimplant mean gradient (mmHg), mean ± SD	8.3 ± 5.6

EOA: effective orifice area; LVEF: left ventricular ejection fraction; SD: standard deviation.

**Table 3:** Clinical outcome and echocardiographic results at 30 days

	Study group (n = 79)
All-cause mortality (30 days), n (%)	2.5 (2)
Cardiovascular or unknown	2.5 (2)
Stroke (disabling), n (%)	1.3 (1)
Stroke (minor), n (%)	1.3 (1)
Myocardial infarction, n (%)	0 (0)
Bleeding (major/life threatening), n (%)	6.3 (5)
Access site complications (major), n (%)	6.3 (5)
Acute kidney injury (AKIN[a] 2, 3), n (%)	5.1 (4)
PPM implantation, n (%)	7.6 (6)
Device success[b], n (%)	97.5 (77)
Early safety[c], n (%)	94.9 (75)
Intensive care unit stay (days), mean ± SD	1.6 ± 1.2
In-hospital stay (days), mean ± SD	11.6 ± 5.3
EOA (cm^2), mean ± SD	1.8 ± 0.3
Peak gradient (mmHg), mean ± SD	21.1 ± 8.2
Mean gradient (mmHg), mean ± SD	10.9 ± 4.4
Mild PVL, n (%)	18.9 (15)
PVL >mild, n (%)	0 (0)

[a]AKIN Acute Kidney Injury Network; VARC-2 definitions.
[b]Device success: absence of procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical position, intended performance of the prosthetic heart valve (no prosthesis–patient mismatch and mean aortic valve gradient <20 mmHg or peak velocity <3 m/s and no moderate or severe prosthetic valve regurgitation).
[c]Early safety at 30 days: all-cause mortality (at 30 days), all stroke (disabling and non-disabling), life-threatening bleeding, acute kidney injury stage 2 or 3 (including renal replacement therapy), coronary artery obstruction requiring intervention, major vascular complication, valve-related dysfunction requiring repeat procedure (Balloon aortic valvuloplasty, TAVI or SAVR).
EOA: effective orifice area; PPM: permanent pacemaker; PVL: paravalvular leakage; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation; VARC-2: Valve Academic Research Consortium-2.
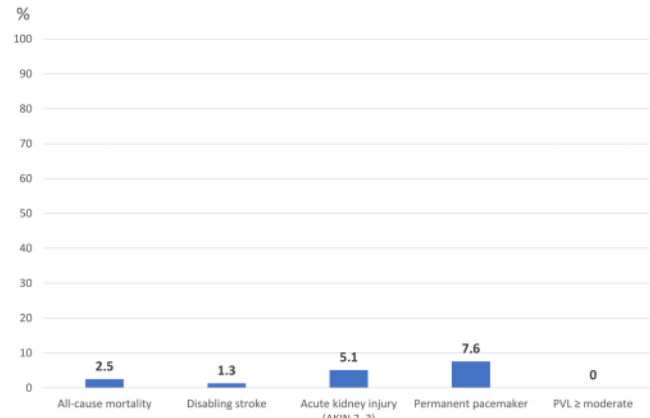
Figure 3: Key 30-day outcomes of patients provided with a latest-generation balloon-expanding transcatheter heart valve. AKIN: Acute Kidney Injury Network; PVL: paravalvular leakage

significant higher calcium loads of the right coronary cusp in zone 1 (269.4 ± 197.8 vs 467.6 ± 131.6 mm^3, $P = 0.02$).

Cover index, eccentricity index and annulus diameter were 3.7 ± 3.7, 0.23 ± 0.06 and 24.1 ± 1.6 mm with a significant higher eccentricity index for patients with residual mild PVL (0.21 ± 0.06 vs 0.25 ± 0.07, $P = 0.02$).

Detailed MSCT data are summarized in Table 4.

DISCUSSION

Main findings

Main findings of the herein-conducted study are: (i) use of the investigated BE-THV resulted in adequate 30-day outcomes regarding mortality and Valve Academic Research Consortium-2-adjudicated clinical end points, (ii) echocardiography demonstrated adequate postprocedural effective orifice area and transvalvular pressure gradients with no cases of PVL >mild, (iii) patients presenting with mild PVL after 30 days showed a significantly higher eccentricity index in preprocedural MSCT, (iv) rate of postinterventional PPM implantation was low with 7.6% and (v) patients who received PPM implantation after TAVI presented with preoperative conduction disorders and significantly higher calcium loads of the right coronary cusp at the height of the aortic annulus.

Real-world data for S3U system were recently reported by Saia and colleagues. In this multicentre registry, comparable clinical outcomes are reported with a mortality of 0%, a rate of PVL ≥moderate of 1.4% and a rate of PPM implantation of 4.4% in 139 patients [16]. Registry data of the precursor THV also demonstrated similar or at least comparable outcomes with a mortality of 2.2%, PPM rate of 12% and a rate of residual postoperative PVL ≥moderate of 3.1% in the SOURCE (SAPIEN Aortic Bioprosthesis European Outcome)-3 registry [7]. Also, stroke rates were low with an incidence between 0% and 1.4% in the mentioned studies.

In this, so far, largest single-centre experience utilizing the S3U, first detailed MSCT measurements were conducted for identification of possible calcification patterns leading to residual mild PVL and PPM implantation. Here, a higher calcium load of the right

Table 4: Preprocedural MSCT imaging[a]

	Study group (n = 79)	PPM (n = 6)	P-value[b]	Mild PVL (n = 15)	P-value[b]
Calcium load zone 1[c] (mm^3), mean ± SD					
Right-coronary cusp	273.7 ± 197.3	467.6 ± 131.6	0.02	244.8 ± 196.3	0.52
Left-coronary cusp	246 ± 189.5	235.3 ± 169.7	0.89	187.6 ± 125.7	0.18
Non-coronary cusp	422.5 ± 340.3	389.7 ± 295.6	0.80	392.5 ± 246.1	0.71
Total calcium load zone 1	942.2 ± 631.8	1090.1 ± 514.4	0.57	824.9 ± 515.1	0.49
Calcium load zone 2[d] (mm^3), mean ± SD					
Right-coronary cusp^{LVOT}	7.9 ± 24.3	18.1 ± 42.7	0.29	7.4 ± 27	0.92
Left-coronary cusp^{LVOT}	12.3 ± 38.6	3.8 ± 5.9	0.58	6.2 ± 9.8	0.50
Non-coronary cusp^{LVOT}	15.9 ± 35.7	21.3 ± 41.3	0.70	11.1 ± 26.8	0.57
Total calcium load zone 2	36.1 ± 87.2	41.8 ± 85.4	0.89	24.1 ± 54.9	0.67
Asymmetry calcium load[e] (mm^3), mean ± SD					
Zone 1 asymmetry	268.2 ± 245.4	175 ± 103.9	0.34	238 ± 146.8	0.60
Zone 2 asymmetry	18.3 ± 34.8	21.3 ± 38.8	0.79	13.7 ± 25.4	0.57
Sinotubular junction length (mm), mean ± SD	24.4 ± 2.5	23.7 ± 2.8	0.52	23.9 ± 2.2	0.39
Distance to RCA (mm), mean ± SD	18.2 ± 2.9	18.6 ± 2.3	0.74	18.9 ± 3.3	0.34
Distance to LCA (mm), mean ± SD	15.1 ± 2.8	17.1 ± 2.5	0.09	15.5 ± 3.1	0.71
Area of AA (mm^2), mean ± SD	448.6 ± 58.9	473.1 ± 58.8	0.23	449.5 ± 56.3	0.95
Perimeter of AA (mm), mean ± SD	75.9 ± 5.5	78.2 ± 4.9	0.31	76.3 ± 4.8	0.42
Annulus diameter (mm), mean ± SD	24.1 ± 1.6	24.5 ± 1.3	0.89	24 ± 1.4	0.32
Eccentricity index[f]	0.23 ± 0.06	0.19 ± 0.07	0.02	0.25 ± 0.07	0.02
Cover index[g]	3.7 ± 3.7	3.7 ± 1.3	1	4.7 ± 3.2	0.33

[a]Threshold 500–600 HU.

[b]P-values for comparison of subgroup vs study group-subgroup (values of study group-subgroup are not quoted).

[c]From AA to coronary ostia.

[d]Subannular, from AA 10 mm in LVOT.

[e]Calculated by maximum absolute difference in calcium volume between leaflet sectors for AVC/LVOT.

[f]Calculated by 1 – (minimum diameter/maximum diameter), & ([nominal THV diameter-measured diameter]/nominal THV diameter)*100.

[g]([nominal THV diameter-measured diameter]/nominal THV diameter)*100.

AA: aortic annulus; AVC: aortic valve complex; ECG: electrocardiogram; LCA: left coronary artery; LVOT: left ventricular outflow tract; MSCT: multi-slice computed tomography; PPM: permanent pacemaker; RCA: right coronary artery; THV: transcatheter heart valve.

coronary cusp in zone 1 was seen in patients with postinterventional PPM implantation. Although it has to be emphasized that the herein-compared patient groups are rather small, this is a different finding compared to self-expandable THV in which higher calcium loads of the left coronary cusp were shown to be predictive for postinterventional PPM implantation [13]. Also, all patients receiving postinterventional PPM implantation suffered from preoperative atrial fibrillation or a left or right bundle branch block. These factors are also known for promoting post-TAVI conduction disorders [17]. In our patient cohort, no PVL >mild was observed. Whether this is an effect of the higher outer skirt of the S3U is speculative in a small patient cohort, but the higher skirt may be the main advantage of the S3U compared to the SAPIEN 3. However, in 18.9% of patients, mild PVL was found during 30-day follow-up. In those patients, MSCT presented a higher eccentricity of the aortic annulus, which is already known as a risk factor for postinterventional mild PVL for the SAPIEN 3 THV [18]. As PPM implantation and mild PVL are known to increase 1-year mortality in TAVI patients [19, 20], it should be of paramount interest for the heart team to further improve these particular outcomes, especially when expansion of TAVI indications to younger low-risk patients should be taken into consideration. The herein-documented first findings for this latest generation THV may be helpful regarding patient selection and periprocedural aspects (e.g. utilization of pre- and postdilatation, oversizing strategy).

With the new introducer sheath and delivery system of the S3U, omitting some major procedural steps of the SAPIEN 3 implantation, shorter procedure and fluoroscopy times as well as amount of used contrast agent were expected. However, these values were rather mildly increased in this patient cohort compared to earlier reports of the SAPIEN 3 [21], most likely due to a more cautious implantation procedure with novel or altered THV devices. It has to be mentioned that after half of the herein-performed cases, the delivery system and the Axela sheath were recalled from the market due to increased rates of adverse clinical events such as rupture of delivery balloons [22]. Since then, implantations were performed using the eSheath and the Commander delivery system known from the SAPIEN 3 with the same procedural steps and operability known from the SAPIEN 3 system (see Fig. 1).

Limitations

Limitations are inherent in the retrospective, single-centre study design with limited patient numbers: patients were not randomized to a specific treatment or valve; therefore, patient preselection with hidden confounders may apply. Also, MSCT measurements were not implemented in a multivariate statistical model comprising e.g. valve implantation depth or length of the membranous septum, and therefore also here hidden confounders may interfere. Furthermore, a patient preselection regarding high LVOT calcium loads was conducted, which may influence results of this study.

CONCLUSIONS

First experience with this latest-generation BE-THV resulted in adequate 30-day outcomes and haemodynamic results with low mortality, low rates of PPM implantation and no residual PVL>mild. The herein-presented MSCT values with an elevated risk for PPM implantation and residual mild PVL may help to further improve outcomes with this particular THV in TAVI procedures.

Author contributions

Andreas Schaefer: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Writing—original draft. **Fabienne Plassmeier:** Formal analysis; Methodology; Writing—review & editing. **Niklas Schofer:** Formal analysis; Methodology; Writing—review & editing. **Lukas Vogel:** Data curation; Formal analysis; Methodology; Writing—review & editing. **Sebastian Ludwig:** Formal analysis; Methodology; Writing—review & editing. **Yvonne Schneeberger:** Data curation; Formal analysis; Methodology; Writing—review & editing. **Matthias Linder:** Formal analysis; Methodology; Writing—review & editing. **Till Demal:** Data curation; Formal analysis; Writing—review & editing. **Moritz Seiffert:** Data curation; Formal analysis; Methodology; Writing—review & editing. **Stefan Blankenberg:** Methodology; Supervision; Writing—review & editing. **Hermann Reichenspurner:** Investigation; Supervision; Writing—review & editing. **Dirk Westermann:** Formal analysis; Investigation; Methodology; Supervision; Writing—review & editing. **Lenard Conradi:** Conceptualization; Formal analysis; Investigation; Supervision; Writing—review & editing.

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