Structural Heart
The Journal of the Heart Team

ISSN: 2474-8706 (Print) 2474-8714 (Online) Journal homepage: https://www.tandfonline.com/loi/ushj20

Standardized Minimalistic Transfemoral Transcatheter Aortic Valve Replacement (TAVR) Using the SAPIEN 3 Device: Stepwise Description, Feasibility, and Safety from a Large Consecutive Single-Center Single-Operator Cohort

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To cite this article: Antonio H. Frangieh, Ilka Ott, Jonathan Michel, Anupama Shivaraju, Michael Joner, N. Patrick Mayr, Christian Hengstenberg, Oliver Husser, Costanza Pellegrini, Heribert Schunkert, Adnan Kastrati & Albert Markus Kasel (2017) Standardized Minimalistic Transfemoral Transcatheter Aortic Valve Replacement (TAVR) Using the SAPIEN 3 Device: Stepwise Description, Feasibility, and Safety from a Large Consecutive Single-Center Single-Operator Cohort, Structural Heart, 1:3-4, 169-178, DOI: 10.1080/24748706.2017.1358832

To link to this article: https://doi.org/10.1080/24748706.2017.1358832

STRUCTURAL HEART
2017, VOL. 1, NOS. 3–4, 169–178
https://doi.org/10.1080/24748706.2017.1358832

ORIGINAL RESEARCH

Standardized Minimalistic Transfemoral Transcatheter Aortic Valve Replacement (TAVR) Using the SAPIEN 3 Device: Stepwise Description, Feasibility, and Safety from a Large Consecutive Single-Center Single-Operator Cohort

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ABSTRACT

Background: To describe our updated minimalist approach (MA) for transfemoral transcatheter aortic valve replacement (TF-TAVR) using the SAPIEN 3 device and its evolution, as well as associated safety and efficacy parameters from a large cohort of patients.

Methods: A stepwise description of the MA technique for TAVR for 300 consecutive patients was detailed. Safety and efficacy parameters were assessed using the VARC-2 criteria at the in-hospital and 30-days follow-up.

Results: A total of 300 consecutive patients (80 ± 7 years; median Logistic EuroSCORE of 11.4% [7.5–17.8]) between January 2014 and May 2016 were evaluated. TF-TAVR was performed under conscious sedation in 247 (82%) patients. Device success was achieved in 286 (95.6%) patients, and intended prosthesis performance in 289 (96.3%) patients. Significant paravalvular leak (PVL) graded more than mild was noted in 7 (2%) patients. No patient had severe PVL. All-cause mortality was noted in one (0.3%) patient in-hospital and in 2 (0.7%) patients at the 30-days follow-up. Major stroke occurred in 4 (1.3%) patients. 9 (3%) patients had major vascular complications at 30-days follow up. MACCE (VARC-2 criteria) were observed in 21 (7%) in-hospital and 25 (8.3%) at 30 days. A new permanent pacemaker implantation was required in 29 (10.7%) patients, and was reduced from 18% to 5.6% (p = 0.001) in a subgroup analysis considering higher implantation position of the valve after the first year of experience.

Conclusion: MA of TF-TAVR, when simplified and standardized, is reproducible, safe and efficient, and should be encouraged to be accepted as the standard method of care.

ARTICLE HISTORY Received 4 May 2017; Revised 14 July 2017; Accepted 18 July 2017

KEYWORDS Minimalistic approach; Sapien 3; TAVR; transfemoral

Introduction

Transcatheter aortic valve replacement (TAVR) is a rapidly evolving technique. It has become a routine, standardized, and reproducible intervention. Currently, TAVR is considered the standard of care for severe symptomatic aortic stenosis (AS) in a large proportion of patients and a valid alternative to surgery for others.-[1–5] This is due to technical improvement of the valve prosthesis and the delivery system, increasing operator experience, and better planning and performance of the procedure; particularly with regards to transfemoral (TF) TAVR, which was shown to be superior to surgery in patients at intermediate surgical risk.[4,5]

Often, TF-TAVR can be performed in a standard cardiac catheterization laboratory under fluoroscopic guidance without general anesthesia or transesophageal echocardiography (TEE). Prior studies have demonstrated a minimalist approach (MA) for TF-TAVR to be safe and effective when compared to the standard approach (SA), with the additional benefits of shorter length of stay, lower resource utilization, and significantly lower hospital costs.[6]

The SAPIEN 3 (Edwards Lifesciences, Irvine, CA, USA) is the latest balloon-expandable transcatheter heart valve (THV) system on the market: it received the European CE Mark on January 27, 2014. Recent studies have shown promising results with this advanced valve system, in terms of device success and safety, over both the short and longer term.[5,7,8]

Although data from retrospective studies and registries reflect the real world in medical practice they are limited by including a diversity of techniques and approaches from many operators with different levels of experience. This may have an impact on diluting the rate of some serious complications or magnifying some others.

The purpose of our study was to describe our updated standardized MA for TF-TAVR using the SAPIEN 3 device, its evolution with the learning curve, in addition to associated safety

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Supplemental data for this article can be access on the publisher's website.

and efficacy parameters, from a large single-center single-operator cohort of patients.

Materials and methods

Standardized MA for TF-TAVR using the SAPIEN 3 THV system

Our TAVR procedural team consisted of interventional cardiologists, cardiovascular surgeons, and a dedicated anesthesiologist for all cases.

Diagnostic work-up for all patients before TAVR included electrocardiogram-gated 384-slice multidetector computed tomography (MDCT) of the heart and thoracoabdominal aorta, transthoracic echocardiography (TTE), and coronary angiography. Transesophageal echocardiography, aortic root angiography, and selective iliofemoral angiography were not routinely performed except for special indications.

MDCT protocol and image reconstruction

All patients underwent CT angiography using 384-slice Dual-Source CT Scanner (Somatom Force; Siemens, Forchheim /Germany). Studies were performed in flash technique with contrast medium enhancement using 50–90 mL of iodinated contrast agent (Imeron 350; Bracco Imaging, Constance, Germany) infused at a rate of 4 mL/s. Thoracic studies were acquired systolic-gated (30% RR): abdominal and pelvic studies were acquired non-gated. 0.75 mm slice thickness with 0.5 mm increment were used for reconstruction. No beta blockade was used.

All CT datasets were transferred to a dedicated workstation (Syngo via InSpace; Siemens). The aortic root and annulus plane were automatically generated by the software; annulus measurement was performed after verifying the annular plane. In case of poor image quality, the annulus alignment and measurement were performed manually, as described elsewhere.[9] Anatomy of the access vessels was evaluated from the ascending to the descending aorta and pelvic vessels from the iliac to the femoral bifurcations. Minimum vessel lumen diameter thresholds of 5.5 mm and 6.0 mm are considered for the 14-F and 16-F eSheaths respectively, taking into consideration the burden of arterial wall calcification. A puncture site above the femoral bifurcation and below the inguinal ligament with no anterior wall calcification was chosen. The puncture was performed under fluoroscopic guidance using the femoral head as an anatomical marker.

Valve size selection

Selection of the appropriate valve size (23 mm, 26 mm, and 29 mm) was based on the mean annular diameter measured on CT (minimal diameter + maximal diameter /2). A 23 mm prosthesis was implanted for mean annulus size ≥20 mm and <23.5 mm, a 26 mm prosthesis for mean annulus size ≥23 and <26.5 mm, and a 29 mm prosthesis for mean annulus size ≥26.0 and ≤29.5 mm. For annulus size >29.5 mm the 29 mm S3 valve was over expanded.[10] All patients, except valve-in-valve implantations, received balloon valvuloplasty with a 20 mm Edwards balloon (23 mm prosthesis), a 23 mm Edwards balloon (26 mm prosthesis), or a 25 mm Edwards balloon (29 mm prosthesis), respectively. For patients with annulus size falling in the "gray zone" in between two valve sizes: ≥23 and <23.5 mm or ≥26 and <26.5 mm, a 23 mm or 25 mm Edwards balloon were utilized for balloon sizing, as described previously.[11] For these patients the larger sheath size, if necessary, was chosen (the 14-F eSheath for prosthesis sizes between 23 and 26 mm, and the 16-F eSheath for prosthesis sizes between 26 and 29 mm). Undersizing, oversizing, or overexpansion in case of "borderline" annular dimensions, were decided based on balloon sizing and individualized anatomical considerations including the calcific burden of the native valve and annulus, as well as the risk of migration, significant paravalvular leak (PVL), or annular injury.

Anesthesia and hemodynamic monitoring

All patients were planned to undergo the procedure using conscious sedation. In addition to ASA recommended monitoring, a central venous catheter (internal jugular vein) and a radial artery catheter were placed. The method of sedation has been previously described.[12] In case of difficult central venous access, a transfemoral long dual-lumen central venous line was used instead. A Swan-Ganz catheter was not considered to be necessary. Oxygen was administered via face-mask at a rate of 8L/min. A combination of propofol/opioid or dexmedetomidine was used for sedation. Local analgesia was obtained with 2% lidocaine (20 mL on each femoral side).

Procedure description (see supplemental movie, available online)

(1) *Contralateral access*. Long sheaths (21 cm, 5 Fr and 6 Fr) are placed in the femoral artery and vein, respectively. Placement of a temporary balloon-tip pacemaker lead in the apex of the right ventricle (PACEL™ Bipolar Pacing Catheter, Right Heart Curve, St. Jude Medical, Inc.) is performed through the femoral vein access. An angled pigtail catheter (10 mm loop inner diameter) is placed in the right coronary cusp and used as a marker during the whole procedure. Starting at the CT predicted angle the optimal deployment projection was obtained using the "Right Cusp Rules"[13,14] (Figure 1.1). The injection volume for all root shots was 10 mL, with a flow of 10 mL/s.

(2) *The vessel puncture site*. The access vessel puncture site was chosen based on the pre-procedural MDCT. The vessel was pre-closed utilizing the Perclose ProGlide (Abbott Vascular) parallel suture vessel closure technique.[15]

(3) *Predilation and placement of the Edwards eSheath*. Predilation and placement over the Amplatz Extra-Stiff 0.035-inch guidewire (Cook, Inc., Bloomington, Indiana, USA): in cases of severely kinked pelvic vessels, the sheath is placed over a Back-up Meier guidewire (Boston Scientific).

(4) *The retrograde native valve crossing is performed*. This is performed following the "Right Cusp Rule, Part III"[16] (Figure 1.2) using an Amplatz left 1 (AL 1) 5-F catheter and a straight standard wire. After crossing the native

valve, the AL 1 catheter is exchanged for a straight 5-F pigtail catheter which is placed in the LV-apex in an RAO 30° view. The manually curved Amplatz Extra-Stiff 0.035-inch guidewire (Cook, Inc.) is then advanced through the pigtail catheter into the LV apex (Supplemental Figure 1, available online).

(5) *Balloon valvuloplasty is performed under rapid pacing.* A rate of 180–200 beats/min is used to bring systolic pressure below 50 mmHg (pulse pressure <10 mmHg). If balloon sizing of the annulus is required, contrast (10–15 mL with a flow of 10 mL/s) is then injected through the pigtail placed in the aortic sinus during full balloon inflation[11] (Figure 1.3).

(6) *The delivery catheter is introduced.* The valve is aligned on the deployment balloon in the descending aorta. The aortic arch and native valve is crossed with the "half" flexed system. The flex catheter is pulled-back and the SAPIEN 3 valve is placed coaxial to the annulus. Coaxial alignment of the prosthesis can be reached by changing tension on the wire, flexing or deflecting the catheter system, or rotation of the delivery system (maximum 180°).[17,18]

- *Implantation height of the SAPIEN 3 valve*: during the early phase of experience, the valve placement followed the company recommended positioning. The SAPIEN 3 deployment balloon center marker (3 mm length) was placed 50/50 at the height of the aortic annulus ("low implantation")[18] (Figure 1.4.A). Following a local consensus meeting, 1 year after the first SAPIEN 3 implantation, the placement strategy was changed because of an observed high pacemaker rate. The deployment balloon center marker was subsequently placed 3 mm higher than the "low implantation" position ("high implantation")[18] (Figure 1.4.C).

(7) *Slow deployment.* A reference picture is stored with the optimal root shot (Figure 1.1). The pigtail catheter is positioned slightly above the valve. Under rapid pacing (180–200 beats/min), when the systolic pressure is less than 50 mmHg (pulse pressure <10 mmHg), 10 mL of contrast agent are injected at 10 mL/s. After fine adjustment, if needed, the prosthesis is slowly deployed. To ensure a complete valve deployment the balloon should stay fully inflated for 3 seconds.

(8) *Assessment of the valve position and deployment.* After implantation, an angiogram in the coaxial plane is performed (with 10 mL of contrast agent at a flow rate of 10 mL/s) to check the implantation height in relation to the aortic annulus, the patency of the

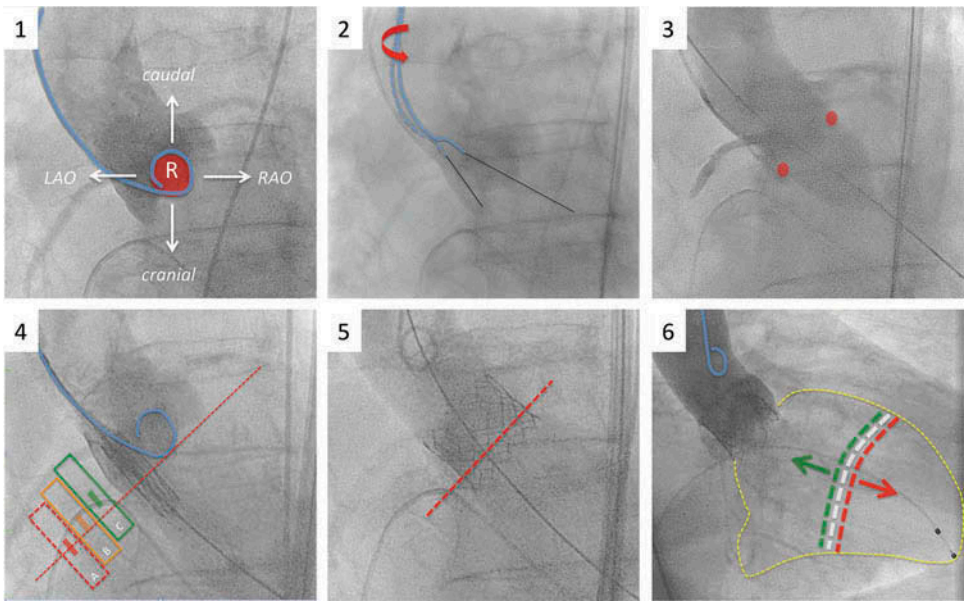

Figure 1. TAVR procedure description.

1. Optimal deployment projection: an angled Pigtail is placed in the right cusp. Navigation of the right cusp under fluoroscopy in the middle in between non-coronary and left-coronary cusp. Right Cusp Rule 1 + 2.

2. Retrograde crossing in coplanar view: Starting with AL1 and straight standard wire from the non-coronary side and turning clockwise to move to the middle (posterior to anterior). Alternatively, starting in the left-coronary cusp and turning counter-clock wise. Right Cusp Rule 3.

3. Balloon-sizing: CT-Annulus-Measurement mean diameter of 23.5 mm, additional Balloon-sizing with 23 mm balloon. The Balloon touches the hinge points, no backflow of contrast, no balloon movement. Decision for overexpanded SAPIEN 3 23 mm +2 ml extra volume in deployment balloon. Right Cusp Rule 4.

4. Placement of the SAPIEN 3 Valve: (A) First recommended valve positioning by Edwards at the height of the Annulus ("Cohort 1"). (B) Bottom to bottom positioning: current recommendation by Edwards. In our experience position for SAPIEN 3 when overexpansion is expected (more expected foreshortening), shown case. (C) Optimal "high" position of SAPIEN 3 based in our experience to avoid pacemaker and PVL ("Cohort 2").

5. Angiographic control in coplanar view: Optimal implantation height: 80% aortic, 20% ventricular. Patent coronary arteries.

6. Angiographic control of functional result in RAO 30°: the Pigtail is placed 10 mm above upper valve frame, 30 ml contrast volume with a flow of 15ml/sec. PVL is considered significant (more than mild) in one of two cases: if backflow contrast crosses the middle line of the LV or if backflow contrast has the same density in LV compared to the aorta.

coronary arteries, and the deployment of the valve frame[18] (Figure 1.5). In case of under-deployment due to heavy calcification of the native valve, post-dilation with additional volume in the deployment balloon can be considered. In case of misplacement of the valve, implantation of a second valve can be discussed. If valve position and deployment are adequate, the guidewire is then pulled-back.

(9) *Assessment of the valve function*. A final angiogram (with 30 mL of contrast agent at a flow rate of 15 mL/s) in an RAO 30° view is obtained to assess the functional result and to visualize and grade aortic regurgitation using the modified angiographic classification of aortic regurgitation described elsewhere[17,18] (Figure 1.6).

(10) *Closure of the access vessel*. The eSheath is removed and the puncture site closed using the previously placed ProGlide sutures. An exchange guidewire is kept in the vessel until successful closure. If a suture fails, a third ProGlide suture is then placed in the middle between the first ProGlides. Access site hemostasis and intact perfusion are confirmed by complete distal abdominal aortogram using the contralateral access side (with 10 mL of contrast agent at a flow rate of 10 mL/s). Finally, the contralateral arterial sheath is removed and closed with an Angio-Seal device (St. Jude Medical, Inc.). In case of conduction disturbances after implantation, the pacemaker lead stays in place with the inflated balloon tip to avoid right ventricular perforation, otherwise the venous sheath is also removed.

Procedural medications

During the procedure, anticoagulation was achieved with intravenous heparin with target ACT over 250 s. Before vessel closure, heparin was completely reversed with protamine, except in patients with strict indications for anticoagulation where heparin was only partially reversed with protamine.

After the procedure, patients were discharged on life-long aspirin with an oral dose of 100 mg per day and clopidogrel 75 mg per day for 3 months except for patients with additional percutaneous intervention before TAVR. Anticoagulation treatment (when indicated) was restarted 6 hours after the procedure and patients were discharged on oral anticoagulants without additional anti-platelet therapy.

Patient population

From January 31, 2014 to May 18, 2016, we prospectively evaluated 300 consecutive patients with severe symptomatic AS treated with TF-TAVR using the SAPIEN 3 in the same standardized MA described above, from a single center single operator registry. All TAVR indications were decided and approved by a Heart-Team consensus.

Procedural endpoints and definitions

Clinical, procedural data, and in-hospital outcome were prospectively collected and 30-days follow-up data were assessed during routine ambulatory visits at the outpatient clinic, by referring to the treating physician or contacting the patient directly. All patients underwent post-procedural, pre-discharge TTE evaluation performed by an independent specialist in cardiac imaging. Clinical endpoints, procedural success, and MACCE at 30 days were categorized using the Valve Academic Research Consortium (VARC-2) criteria (composite of all-cause mortality, stroke [disabling and non-disabling], major vascular complication, life-threatening bleeding, stage 2 or 3 acute kidney injury, coronary artery obstruction requiring intervention, or valve-related dysfunction requiring repeat procedure).[19] Device success was defined as absence of procedural mortality, and correct positioning of a single prosthetic heart valve into the proper anatomical location, and intended performance of the prosthetic heart valve with no prosthesis-patient mismatch, mean aortic valve gradient <20 mmHg or peak velocity <3 m/s, no moderate or severe prosthetic valve regurgitation. All-cause mortality, cardiac mortality, stroke, re-hospitalization for worsening heart failure, vascular complications, bleeding, acute kidney injury, myocardial infarction, valve-related dysfunction, and endocarditis or valve thrombosis up to 30 days were assessed. The incidence of permanent pacemaker implantation was recorded.

Statistical analysis

Categorical data are presented as frequencies and percentages. Continuous data are presented as mean ± standard deviation or median and interquartile range. After checking for normality of distribution, comparisons of continuous data were performed using the unpaired Student *t*-test or the Mann–Whitney U test. Categorical data were analyzed using the Fisher's exact test or the χ^2 test as appropriate. A value of $p < 0.05$ was considered statistically significant. All analyses were performed using SPSS version 20.0 for Windows (SPSS, Inc., Chicago, IL).

In a subgroup analysis, patients were dichotomized into two groups (cohort 1 including the first year of experience with the SAPIEN 3 THV, and cohort 2 including the subsequent consecutive patients treated in the time following the first year of experience). Intubated and non-intubated subgroups were also compared.

Results

Patient characteristics

A total of 300 consecutive patients (80 ± 7 years, 47% females) were evaluated in this study. Baseline characteristics are shown in Table 1. Logistic EuroSCORE had a median [IQR] of 11.4% [7.5–17.8] and EuroSCORE II of 3.8% [2.4–6.9] with 62 (21%) over 20% and 45 (15%) over 10% on these two scores, respectively. Overall, 7 (2%) valve-in-valve procedures were performed on previously operated patients with surgical aortic bioprosthesis.

Table 1. Baseline characteristics.

	Total cohort	Cohort 1	Cohort 2	
	N = 300	*n* = 120	*n* = 180	p value
Age (years)	80 ± 7	81 ± 6	80 ± 7	0.4
Female	140 (47)	52 (43)	88 (49)	0.4
BMI (kg/m^2)	26.8 ± 5	27.5 ± 6	26.5 ± 5	0.1
Diabetes mellitus	87 (29)	35 (29)	52 (29)	1.0
Hyperlipidemia	205 (68)	76 (63)	129 (72)	0.2
Hypertension	267 (89)	106 (88)	161 (89)	0.9
Previous pacemaker	28 (9)	9 (8)	19 (11)	0.4
Previous myocardial infarction	29 (10)	12 (10)	17 (9)	1.0
Coronary artery disease	212 (71)	83 (69)	129 (72)	0.7
Previous PCI	125 (42)	47 (39)	78 (43)	0.6
CCS score				
CCS 0	204 (68)	77 (64)	127 (71)	0.4
CCS 1	28 (9)	13 (11)	15 (8)	
CCS 2	49 (16)	19 (16)	30 (17)	
CCS 3	19 (6)	10 (8)	8 (4)	
CCS 4	1 (0.3)	1 (1)	0 (0)	
PAD	32 (11)	11 (9)	21 (12)	0.6
Extracardiac arteriopathy	71 (24)	31 (26)	40 (22)	0.5
Mitral regurgitation II +	9 (3)	3 (3)	6 (3)	0.7
Previous CABG	29 (10)	12 (10)	17 (9)	1.0
Previous AVR (valve-in-valve)	7 (2)	3 (3)	4 (2)	1.0
Cancer	63 (21)	28 (23)	35 (19)	0.5
Previous stroke	28 (9)	10 (8)	18 (10)	0.7
COPD	46 (15)	15 (13)	31 (17)	0.3
NYHA functional class III/IV	190 (63)	88 (73)	102 (57)	0.005
Logistic EuroSCORE I (%)	11.4 [7.5–17.8]	12.3 [7.4–17.8]	11.3 [7.9–18.4]	0.8
High EuroSCORE I (>20%)	62 (21)	22 (18)	40 (22)	0.47
EuroSCORE II (%)	3.8 [2.4–6.9]	4.0 [2.7–7.1]	3.7 [2.2–6.8]	0.5
High EuroSCORE II (>10%)	45 (15)	19 (16)	26 (14)	0.87
LVEF (%)	60 [49–60]	60 [46–60]	60 [50–60]	0.09
Maximum aortic gradient (mm Hg)	70 ± 24	70 ± 24	70 ± 25	0.8
Mean aortic gradient (mm Hg)	44 ± 16	43 ± 17	45 ± 16	0.4
Aortic valve area (cm^2)	0.7 ± 0.2	0.7 ± 0.2	0.7 ± 0.2	0.4
GFR (ml/min)	56 ± 22	55 ± 22	56 ± 21	0.8
Admission ECG				
Atrial fibrillation	72 (24)	28 (23)	44 (24)	0.8
Left bundle branch block	16 (5)	5 (4)	11 (6)	0.7
Right bundle branch block	21 (7)	11 (6)	13 (7)	

Note. BMI, body mass index; CABG, coronary artery bypass graft; CCS, Canadian cardiovascular society; ECG, electrocardiogram; GFR, glomerular filtration rate; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; TIA, transient ischemic attack; Depicted are counts; *N* incidence (%).

When comparing cohort 1 and cohort 2 subgroups, no differences were noted concerning patients' baseline characteristics, except for clinical presentation with New York Heart Association (NYHA) class III/IV, which were more prevalent in the first group (88 (73%) vs. 102 (57%), p = 0.005) (Table 1).

Procedural characteristics

Procedural characteristics are shown in Table 2. TAVR was performed under conscious sedation in 247 (82%) patients. The reasons for intubation are detailed in Supplemental Table 1, available online. A median of 100 mL of contrast media was injected per procedure. Puncture to closure time was 49 min with a minimum of 20 min and maximum of 149 min. Altogether, 98% of patients received balloon valvuloplasty. SAPIEN 3 23 mm, 26 mm, and 29 mm were implanted in 46%, 35% and 18%, respectively. VARC-2 device success was achieved in 286 (95.6%) patients, and intended prosthesis performance in 289 (96.3%) patients. Significant PVL graded more than mild was noted in 9 (3%) patients when angiographically assessed, while it was confirmed in only 7 (2%) patients when assessed on TTE before discharge. No patient had severe PVL. No device embolization, no multiple valves, no annulus rupture, no conversion to surgery and no coronary obstruction were noted. Successful vascular access, delivery, deployment of the device and successful retrieval of the delivery system

Table 2. Procedural characteristics.

	Total cohort	Cohort 1	Cohort 2	
	N = 300	n = 120	n = 180	p value
Intubation	53 (18)	38 (32)	15 (8)	<0.001
Contrast volume (mL)	100 [80–120]	103 [85–134]	95 [80–110]	0.006
Dose area product (cGy cm^2)	124.8 [60.8–244.8]	221.9 [120.8–402.4]	84.9 [45.6–155.4]	<0.001
Fluoroscopy time (min)	10.3 [8.2–13.4]	12.2 [9.2–15.8]	9.5 [7.5–11.4]	<0.001
Puncture to Balloon time (min) {min-max}	28 [23–34] {8–63}	32 [27–40]	25 [21–30]	<0.001
Puncture to valve time (min) {min-max}	37 [30–44] {12–71}	42 [36–50]	33 [26–40]	<0.001
Puncture to closure time (min) {min-max}	49 [41–57] {20–146}	55 [47–62]	45 [38–53]	<0.001
Predilation	295 (98)	117 (98)	178 (99)	0.7
Postdilation	78 (26)	25 (21)	53 (29)	0.1
Vascular closure using Proglide	293 (98)	116 (98)	177 (99)	1
Valve size				
23 mm	139 (46)	50 (42)	89 (49)	0.3
26 mm	106 (35)	49 (41)	57 (32)	
29 mm	55 (18)	21 (18)	34 (19)	
Device success	287 (96)	114 (95)	173 (96)	0.8
Procedural mortality	1 (0.3)	0 (0)	1 (0.6)	1
Intended performance	289 (96)	114 (95)	175 (97)	0.4
Multiple valves	0 (0)	0 (0)	0 (0)	.
Correct position of the device in the proper anatomical location	300 (100)	120 (100)	180 (100)	.
Successful vascular access, delivery, deployment of the device and successful retrieval of the delivery system	298 (99)	120 (100)	178 (99)	0.5
Annulus rupture	0 (0)	0 (0)	0 (0)	.
Tamponade	3 (1)	2 (1.7)	1 (0.6)	0.6
Ventricular wire/pacemaker perforation	3 (1)	2 (1.7)	1 (0.6)	0.6
Rethoracoromy	1 (0.3)	1 (0.8)	0 (0)	0.4
Device embolization	0 (0)	0 (0)	0 (0)	.
Snare/repositioning	0 (0)	0 (0)	0 (0)	.
Coronary obstruction requiring intervention	0 (0)	0 (0)	0 (0)	.
Conversion to surgery	0 (0)	0 (0)	0 (0)	.
Paravalvular Leakage				
Angio:				
Moderate or more	9 (3)	4 (3)	5 (3)	1
AKI 2/3, including renal replacement therapy	2 (1)	0 (0)	2 (1)	0.5

Note. AKI, acute kidney injury; Depicted are counts; *N* incidence (%).

were achieved in 298 (99%) patients. Three cases of tamponade were recorded, due in one case to right ventricle temporary pacemaker catheter perforation treated conservatively with pericardial drainage, and in the two other cases to left ventricular wire perforation—one patient required thoracotomy and the second died due to severe hemodynamic disturbance despite pericardial drainage and extracorporeal membrane oxygenation (ECMO).

When considering the evolution from cohort 1 to cohort 2 after the first year of experience with the SAPIEN 3 THV, intubation rate was reduced from 32% to 8% ($p < 0.001$) and contrast volume injected from 103 ml [85–134] to 95 ml [80–110] ($p = 0.006$). Fluoroscopy time and puncture to closure time were also reduced: 12.2 min [9.2–15.8] versus 9.5 min [7.5–11.4] ($p < 0.001$) and 55 min [47–62] versus 45 min [38–53] ($p < 0.001$), respectively (Figure 2). Procedural safety and efficacy criteria did not differ significantly (Table 2), except

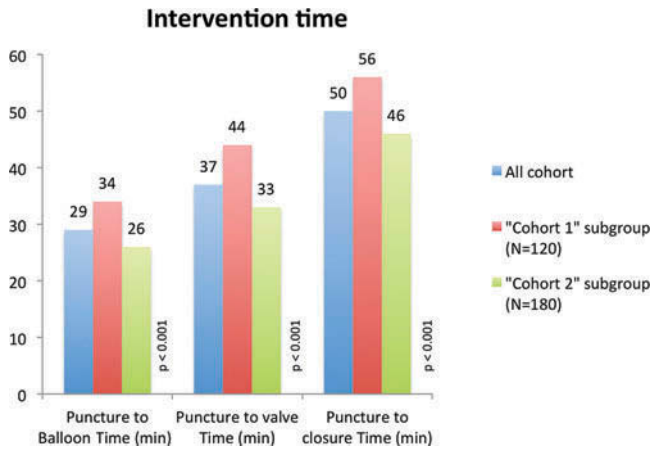

Figure 2. TAVR intervention time; comparison between "cohort 1" and "cohort 2" subgroups.

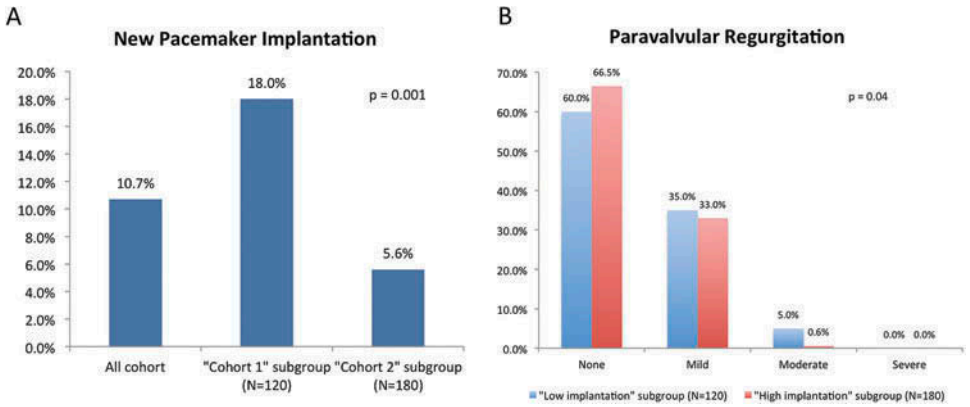

Figure 3. New pacemaker implantation, and paravalvular regurgitation rates as assessed by pre-discharge transthoracic echocardiography. Comparison between "cohort 1" and "cohort 2" subgroups.

that TTE assessed significant PVL was noted in only one (0.6%) patient in the cohort 2 subgroup compared to 6 (5%) patients in the cohort 1 subgroup (p = 0.04) (Table 2, Figure 3).

Outcome: In-hospital and 30-days follow up

Outcome data are shown in Table 3. All-cause mortality was noted in one (0.3%) patient in-hospital (patient mentioned above) and in 2 (0.7%) patients at the 30-days follow up. All strokes were noted in 6 (2%) patients (major stroke in 4 (1.3%) patients). Overall, 8 (2.7%) and 9 (3%) patients had major vascular complications during the in-hospital and 30-day follow-up periods, respectively. NYHA functional class III or IV was noted in 18 (6%) patients at 30-days follow-up (Supplemental Figure 2, available online). A new permanent pacemaker implantation was required in 29 (10.7%) patients.

MACCE were observed in 21 (7%) in-hospital and 25 (8.3%) at 30 days.

No difference in outcome was noted when comparing cohort 1 and cohort 2 subgroups, except for new permanent pacemaker implantation, which was reduced from 18% to 5.6% (p = 0.001) (Figure 1.4.A vs. 1.4.C).

Intubated and non-intubated patients were compared and showed no significant difference in baseline characteristics, procedural safety and efficacy parameters, and in-hospital as well as 30-day follow-up results (Supplemental Tables 2, 3 and 4, available online.

Discussion

This paper describes a step-by-step standardized minimalist approach for TF-TAVR using the SAPIEN 3 device from a single operator—single high volume center. This didactic and simplified method was developed over time with growing experience, and tools and techniques have been published previously.[9–11,13–17] In this paper, we included a complete overview of MDCT study for measurements, device sizing, and vascular access decision. The intervention itself was also described in details: femoral puncture, optimal angiographic deployment projection, retrograde crossing of the stenotic aortic valve, valve positioning prior to deployment then final evaluation of safety and efficacy results, ending by percutaneous closure and final puncture site angiographic control.

The landmark of our MA for TF-TAVR is that the intervention is standardized and simplified in 10 steps, all done under fluoroscopic guidance. This method provides a suitable framework for inexperienced operators starting to perform MA TAVR.

The evolution and establishment of the TF-TAVR technique described in this manuscript has clearly shown an evolution in the results over the first 300 consecutive patients treated with the SAPIEN 3 THV. First, the rate of intubation was reduced from 32% to 8% after the first year of experience, without any difference in patients' baseline characteristics, which shows that this trend reflects our heart-team concept evolution and the dedication of the anesthesiology team in achieving a minimalist approach for TAVR. In addition, the time of intervention was reduced significantly, as well as radiation time and injected contrast volume. Second, the optimized "higher implantation" position of the SAPIEN 3 valve (the center marker placed 3 mm higher than the "low implantation" position) (Procedure Description Step 6 and Figure 1.4.C), used in cohort 2 subgroup, was associated with significantly lower rate of periprocedural and 30-day new permanent pacemaker implantation (18%–5.6%), along with reduction in moderate PVL from 5% to 0.6% as evaluated by TTE before discharge, without any significant difference in other efficacy and safety parameters between the two groups. The association between implantation height and new permanent pacemaker rate has been well described in previous studies.[20–22] Our results were similar to those published by Schwerg and colleagues[22] that showed a reduction of periprocedural pacemaker rate from 32% to 4.7% with the optimized "high implantation" technique using the SAPIEN 3 device. Permanent pacemaker implantation remains one of the primary limitations of TAVR, particularly when considering extension of treatment to lower risk and younger patients.

Additionally, the overexpansion strategy (undersize and over-deploy the SAPIEN 3 by intentional overfilling of the deployment balloon with additional volume)[10] compared with the strategy of underdeploying a larger valve size, may allow for a safe valve implantation with a lower risk of annular rupture,

Table 3. Outcome.

	Complete cohort		Cohort 1	Cohort 2		Cohort 1	Cohort 2	
	In-hospital N = 300	30-days follow-up N = 300	In-hospital n = 120	In-hospital n = 180	p value	30-days follow-up n = 120	30-days follow-up n = 180	p value
All-cause mortality	1 (0.3)	2 (0.7)	0 (0)	1 (0.6)	1	0 (0)	2 (1.1)	0.5
Cardiac mortality	1 (0.3)	2 (0.7)	0 (0)	1 (0.6)	1	0 (0)	2 (1.1)	0.5
All strokes	6 (2)	6 (2)	1 (0.8)	5 (2.8)	0.4	1 (0.8)	5 (2.8)	0.4
Disabling stroke	4 (1.3)	4 (1.3)	1 (0.8)	3 (1.7)	0.7	1 (0.8)	3 (1.7)	0.7
Non-disabling stroke	2 (0.7)	2 (0.7)	0 (0)	2 (1.1)	0.5	0 (0)	2 (1.1)	0.5
Hospitalization: valve-related symptoms or worsened CHF	.	5 (1.7)	.	.	.	2 (1.7)	3 (1.7)	1
Major vascular complication	8 (2.7)	9 (3)	2 (1.7)	6 (3.3)	0.5	2 (1.7)	7 (3.9)	0.3
Life-threatening bleeding	6 (2)	9 (3)	4 (3.3)	2 (1.1)	0.2	4 (3.3)	5 (2.8)	1
Coronary artery obstruction requiring intervention	0 (0)	0 (0)	0 (0)	0 (0)	.	0 (0)	0 (0)	.
Myocardial infarction	0 (0)	0 (0)	0 (0)	0 (0)	.	0 (0)	0 (0)	.
Valve-related dysfunction requiring repeat procedure (BAV, TAVR, or SAVR)	0 (0)	0 (0)	0 (0)	0 (0)	.	0 (0)	0 (0)	.
Endocarditis	0 (0)	1 (0.3)	0 (0)	0 (0)	.	0 (0)	1 (0.6)	1
Valve thrombosis								
Repeat procedure	0 (0)	0 (0)	0 (0)	0 (0)	.	0 (0)	0 (0)	.
NYHA functional class III/IV	.	18 (6) *n* = 279				5 (4.2)	13 (7.2)	0.2
New pacemaker implantation[a]	29 (10.7) *n* = 272	29 (10.7) *n* = 272	20 (18) *n* = 111	9 (5.6) *n* = 161	0.001	20 (18) *n* = 111	9 (5.6) *n* = 161	0.001
TTE on follow-up								
Paravalvular leakage on TTE								
None	191 (64)	130 (52) *n* = 252	72 (60)	119 (66.5)	0.04	56 (54)	74 (50) *n* = 148	0.7
Trivial/Mild	101 (34)	121 (48) *n* = 252	42 (35)	59 (33)		48 (46)	73 (49) *n* = 148	
Moderate	7 (2)	1 (0.4) *n* = 252	6 (5)	1 (0.6)		0 (0)	1 (0.7) n = 148	
Severe	0 (0)	0 (0)	0 (0)	0 (0)		0 (0)	0 (0) *n* = 148	
Max aortic gradient (mm Hg)[b]	23 ± 8	22 ± 9	23 ± 8	23 ± 9	0.7	22 ± 9	22 ± 10	0.9
Mean aortic gradient (mm Hg)[b]	12 ± 5	12 ± 5	12 ± 5	13 ± 5	0.1	12 ± 4	12 ± 5	0.7
Aortic valve area (cm^2)[b]	1.7 ± 0.4	1.6 ± 0.5	1.8 ± 0.5	1.6 ± 0.4	0.08	1.7 ± 0.5	1.5 ± 0.4	0.2
MACCE[c]	21 (7)	25 (8.3)	6 (5)	15 (8.3)	0.4	6 (5)	19 (10.6)	0.1
Days in ICU (after TAVR)[d]	1 [1–2]	.	1 [1–2]	1 [1–1]	0.001	.	.	.
Days in hospital (after TAVR)[d]	5 [4–6]	.	5 [4–7]	5 [4–6]	0.1	.	.	.

Note. [a]After excluding patients with previous pacemaker prior to TAVI; [b]Mean ± SD; [c]Valve Academic Research Consortium (VARC)-2 early safety endpoint at 30 days (composite of mortality, stroke, major vascular complication, life-threatening bleeding, stage 2 or 3 acute kidney injury, coronary artery obstruction, or repeat procedure for valve-related dysfunction); [d]Median [IQR].

BAV, balloon aortic valvuloplasty; ICU, intensive care unit; MACCE, major adverse cardiac and cerebrovascular events; NYHA, New York Heart Association; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement; TTE, transthoracic echocardiography; Depicted are counts; *N* incidence (%).

with no significant central regurgitation. Furthermore, over-expanded THVs are more circular when fully deployed,[10] which may positively affect the long-term durability of the valve. This needs to be selectively evaluated in future studies.

A high rate of success in terms of VARC-2 efficacy and safety parameters were demonstrated in this study cohort. These patients were classified mainly in the intermediate to high-risk range, which reflects the current trend toward treatment of lower risk patients in our center, in Germany, and in Europe.[23–25] VARC-2 device success was achieved in 95.6% of patients, and intended prosthesis performance in 96.3% of patients. Significant PVL—graded more than mild—was noted in 9 (3%) patients when angiographically assessed, while it was confirmed in only 7 (2%) patients when assessed on TTE before discharge in the complete cohort and in only one patient (0.7%) in cohort 2. No patient had severe PVL. This study also demonstrates that the modified angiographic classification of aortic regurgitation (Procedure Description Step 9 and Figure 1.6) was highly sensitive and specific to identify (or at least rule out) significant (moderate to severe) PVL, which is associated with worse prognosis in terms of survival.[26] In addition to sizing algorithms and deployment strategies, the SAPIEN 3 THV design, compared with former balloon-expandable SAPIEN and SAPIEN XT devices, presents with peri-prosthetic sealing cuffs and external skirt that may contribute to the reduction in PVL.

Simplification and standardization of the TAVR procedure in a minimalist setting is growing and spreading mostly in European centers, targeting pre-procedural screening tools, the intervention itself, and post-procedural pathways.[27–30] In our practice, TAVR became a routine, simplified, and reproducible procedure, and was at least as safe and effective as the standard approach, when compared to data from randomized trials and registries.[4,5,7,23]

Furthermore, lower-profile femoral access systems, especially the 14-F eSheath for SAPIEN 3, has allowed an expansion in the use of TF-TAVR compared to other TAVR access sites, and facilitated the performance of fully percutaneous procedures avoiding general anesthesia (GA). It is known that avoiding GA may potentially be associated with a lower cardiac and pulmonary risk, earlier patient mobilization, and improvement in neuromuscular function and independence scores.[31,32] Data from a large meta-analysis showed that there is no significant difference in outcomes using either

monitored/local anesthesia care or GA for TAVR procedures.-[33] While GA can have advantages, including improved periprocedural imaging, local anesthesia may be associated with more stable periprocedural hemodynamics, direct patient neurologic monitoring (speaking with the patient), reduced procedural time, and shorter hospital stay. In our experience, intra-procedural TEE is not needed for implantation or functional evaluation of valve function post deployment. Angiographic assessment of regurgitation is highly sensitive for greater than mild leakage. Nevertheless, a TTE should be available in the room and could be used as bailout in some cases, for instance when pericardial effusion and cardiac tamponade are suspected. The issue of second day discharge, even if it is technically feasible and safe, is not currently possible in Germany for administrative and reimbursement reasons. This explains why the median in-hospital stay after TAVR in our cohort of patients was 5 days. Reducing the hospital stay, at least for selected patients, may have an important impact on hospital turnover and logistics, in addition to general health care costs and effectiveness.

TF-TAVR—in contrast to surgical aortic valve replacement—has the distinct advantage that when simplified and standardized in a standard cardiac catheterization laboratory under fluoroscopic guidance, as described above, every experienced interventional cardiologist can perform this procedure in a safe and efficient way, without requiring a very long learning curve. Following the current trend, this may be very essential in the future, when TAVR becomes the standard of care for the treatment of AS, including low-risk patients.

Study limitations

SAPIEN 3 20mm THV is lacking in this cohort of patients, since this device size was not available in Germany until November 2016 and those selected patients were treated with SAPIEN XT 20 mm THV.

Despite the large sample size, the study limitations of the data presented here are consistent with limitations of any retrospective study from a single-center single-operator cohort. Our study design was conceived in that way to show the results of an exclusive single "doctrine," in addition to the safety and efficacy of the minimalist TF-TAVR approach. Widespread adoption of this standardized technique would enable the possibility of a multicenter study to confirm these results and present a strong proof of concept in this regard.

Conclusion

The minimalist approach of TF-TAVR—when simplified and standardized—is reproducible, safe, and efficient, and should be encouraged to be accepted as the standard way of care.

Disclosure statement

Dr. Kasel and Dr. Hengstenberg have served as consultants for Edwards Lifesciences. Dr. Kasel receives research support from Edwards Lifesciences. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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