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ORIGINAL PAPER

Transaxillary transcatheter aortic valve implantation utilizing a novel vascular closure device with resorbable collagen material: a feasibility study

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Abstract

Objectives We herein aimed to evaluate technical feasibility of transaxillary (Tax) transcatheter aortic valve implantation (TAVI) utilizing a novel vascular closure device with a resorbable collagen plug and absence of suture material.

Methods Between 05/2018 and 8/2018, eight patients (76.0 ± 5.9 years, 62.5% male, logEuroSCORE I 23.6 ± 4.7) received Tax-TAVI using the MANTA™ vascular closure device. Implanted transcatheter heart valves consisted of Edwards Sapien 3, NVT Allegra, Medtronic CoreValve EvolutR and SJM Portico.

Results Puncture location depth was variable (3.5–7.5 cm). The left subclavian artery was used in five cases, the right subclavian artery in three cases. Low-pressure balloon-angioplasty for vessel closure was performed in 5/8 patients. VARC-2 defined device success was met in all patients. Major access site complication occurred in one patient with aneurysma spurium of the subclavian artery and consecutive stent implantation on postoperative day 5.

Conclusion The MANTA™ device is applicable in Tax-TAVI, with potential particular advantages regarding easiness of use and marked access for subsequent interventions in case of vascular complications. Before conclusions regarding clinical efficacy and safety can be made, the device has to be evaluated in larger patient cohorts.

Keywords Transcatheter aortic valve implantation · Transaxillary · Vascular closure device

Abbreviations

TA	Transapical
TAVI	Transcatheter aortic valve implantation
Tax	Transaxillary
TF	Transfemoral
THV	Transcatheter heart valve

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Introduction

Transcatheter aortic valve implantation (TAVI) is the standard of care for treatment of severe symptomatic aortic stenosis in high-risk patients and is increasingly being used in intermediate-risk patients [1, 2]. Over the past years paramount improvements of transcatheter heart valves (THV) and corresponding delivery systems, with decreasing sheath sizes, led to distinct changes in access site proportions. While the transfemoral (TF) and transapical (TA) access were distributed equally till 2012, a subsequent shift towards TF-TAVI with a TA-TAVI share of 6.1% in the US in 2015 is documented [3, 4]. Compared to the TF approach, TA-TAVI is commonly considered to be associated with impaired outcomes, in terms of postoperative morbidity and mortality [5, 6]. Therefore, certain alternative access routes were described. To maintain transvascular access in patients not eligible for TF approach, mainly due to severe calcifications of iliac vessels, transaxillary (Tax), transcarotid and transcaval access sites can be taken into consideration for implantation of THV [7–9]. Particularly, Tax-TAVI is increasingly being performed and presents periinterventional results, comparable to outcomes of the TF standard [10]. Commonly, vascular closure devices utilized in TF-TAVI are likewise applied in Tax-TAVI procedures. Established devices for percutaneous vessel closure are the ProStar™ XL 10-F system and the ProGlide™ device (both: Abbott Vascular Inc., Abbott Park, IL, USA) [11, 12]. Recently, a novel vascular closure device with resorbable collagen material and absence of suture material was introduced for TF-TAVI. The MANTA™ device (Essential Medical Inc., Malvern, PA, USA) is capable of closing arterial access sites, priorly provided with devices or sheaths up to 25 Fr. Currently, safety and efficacy of the system in TF-TAVI are evaluated in the Safe-MANTA study [13]. To date, Tax-TAVI utilizing the MANTA™ system for closure of the subclavian artery is only reported anecdotally [14, 15].

Materials and methods

Patients

Between 05/2018 and 8/2018, eight patients received Tax-TAVI for treatment of severe symptomatic aortic stenosis using a novel collagen-based vascular closure device. Allocation of patients to TAVI followed current international recommendations [1] after consensus of the local dedicated heart team. All included patients presented with severe calcifications or s/p multiple stenting of the iliac vessels leading to ineligibility for TF access (see Fig. 1).

Diagnostic work-up

The preprocedural diagnostic work-up followed institutional standards and was described before [16]: all patients received preoperative TTE and TEE for evaluation of cardiac functional status. Furthermore, diagnostic work-up included contrast-enhanced, electrocardiogram-gated MSCT. Datasets were analyzed using the 3mensio Medical Imaging Software (3mensio, Medical Imaging, Bilthoven, The Netherlands) for calculation of native aortic annulus dimensions and determination of adequate THV size as well as assessment of aortic root anatomy and morphology, prediction of optimal c-arm angulation and assessment of aorto-iliac and peripheral vascular status. Since all patients revealed inappropriate iliac vessels for TF-TAVI, reconstruction of both, left and right subclavian arteries, was performed and side for Tax-TAVI was chosen according to calcification patterns and expected suitable implantation angle (least kinking) for the respective THV.

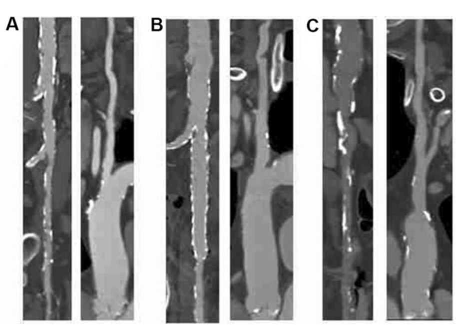

Fig. 1 Examples of 3mensio reconstruction of transfemoral and transaxillary access. Depiction of femoral and axillary vessels with severe calcifications (**a**), s/p multiple stenting (**b**) of the iliac vessels and reconstruction of the left subclavian artery; and severe calcifications of iliac vessels and reconstruction of the right subclavian artery (**c**)

Study procedure

TAVI procedures were performed under general anesthesia or conscious sedation in a specially equipped hybrid operating suite by a dedicated team of cardiologists, cardiac surgeons and anesthesiologists. The herein performed institutional Tax-TAVI approach was described before [11]. In brief, a long wire was placed via the ipsilateral brachial artery and then externalized through the femoral artery as guide wire in case balloon angioplasty or stent implantation at the height of subclavian access was necessary. The axillary artery was punctured under constant aspiration and fluoroscopic guidance. THV advancement and deployment procedures followed institutional standard protocols for the respective THV system. THV function was subsequently assessed by TEE and aortic root angiography.

For access vessel closure the MANTA™ device was utilized. For this purpose, the depth of the initial subclavian puncture was determined using a puncture locating dilator, which was inserted over the wire for detecting puncture depth by outlet backflow/stop of backflow, a principle known from smaller vessel closure devices like the Angio-Seal (Terumo Interventional Systems, Somerset, NJ, USA). Depth was defined at skin-level. For later vessel closure, device position deployment depth was defined as puncture depth at skin level plus 1 cm. After completion of TAVI, the THV introducer sheath was retracted and the MANTA™ sheath was fully inserted over the wire and the dilator removed. Subsequently, the MANTA™ device was inserted over an integrated insertion tool and then, the whole system was slowly removed in a steady 45° angle and under constant retraction force. By observing markings on the sheath, deployment depth was adjusted and a lever was rotated for toggle release. Now, the system was further retracted from the subclavian artery until tension appeared and the indicator field showed yellow/green. By advancing the lock advancement tool until a click was heard, the puncture was sealed via a collagen plug. The collagen plug is low-profile, non-thrombogenic and bio-resorbable. When hemostatis was obtained the guide-wire was removed and the lead-suture was cut. At the end of the procedure, a stainless steel lock remains visible in angiography for possible subsequent interventions (see Fig. 2) (an instructional video of this device can be found at: http://www.essmedclosure.com/technology.html).

For all herein performed procedures, angioplasty balloon stand-by (placed at the height of the proximal subclavian artery) over an externalized (left/right brachial artery to left/right femoral artery) Plywire (OptiMed Global Care, Ettlingen, Germany) was established for rapid occlusion of subclavian access in case of insufficient vessel closure. In cases of complex anatomy with complicated vessel access, low-pressure balloon-angioplasty (3–4 atmospheres) was administered at the height of the initial puncture while closing the MANTA™ device to facilitate adequate vessel closure (see Fig. 3). For intraoperative macroscopic result after vessel closure see Fig. 4.

Analysis

Baseline and intraprocedural data were retrospectively collected and entered into a standardized database and analyzed. Clinical endpoints regarding access site complications and bleeding were adjudicated in accordance with the updated standardized VARC-2 definitions [17]. Data are presented as absolute numbers and percentages for categorical variables and mean values and standard deviation for continuous variables.

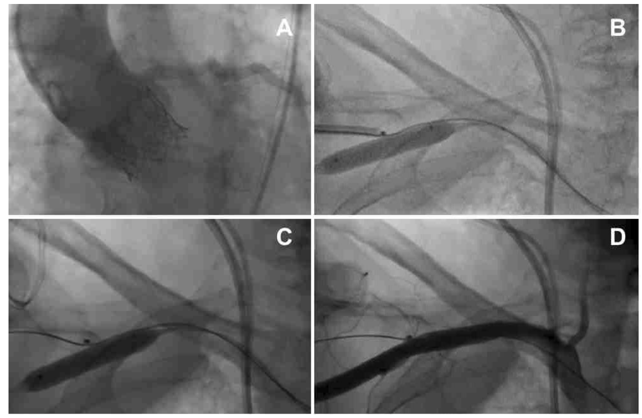

Fig. 3 Transaxillary transcatheter aortic valve implantation providing the right subclavian artery with a novel vascular closure device and low-pressure balloon support for vascular closure. After valve deployment (**a**) and insertion and retraction of the MANTA™ sheath and tool, the lock advancement tool is pushed down on the right subclavian artery with concomitant inflation (low pressure: 3–4 atmospheres) of an angioplasty balloon (**b**), which was priorly inserted over a Plywire (OptiMed Global Care, Ettlingen, Germany) (externalized from right brachial artery to right femoral artery); after retrieval of the lock advancement tool balloon inflation is held for few minutes; (**c**), final angiography with guide wire still in place (**d**)

Results

Baseline demographics

All included patients (76.0 ± 5.9 years, 62.5% male, logEuroSCORE II 6.4 ± 0.5) were highly symptomatic (NYHA ≥ III 8/8) and the entire cohort suffered from coronary artery

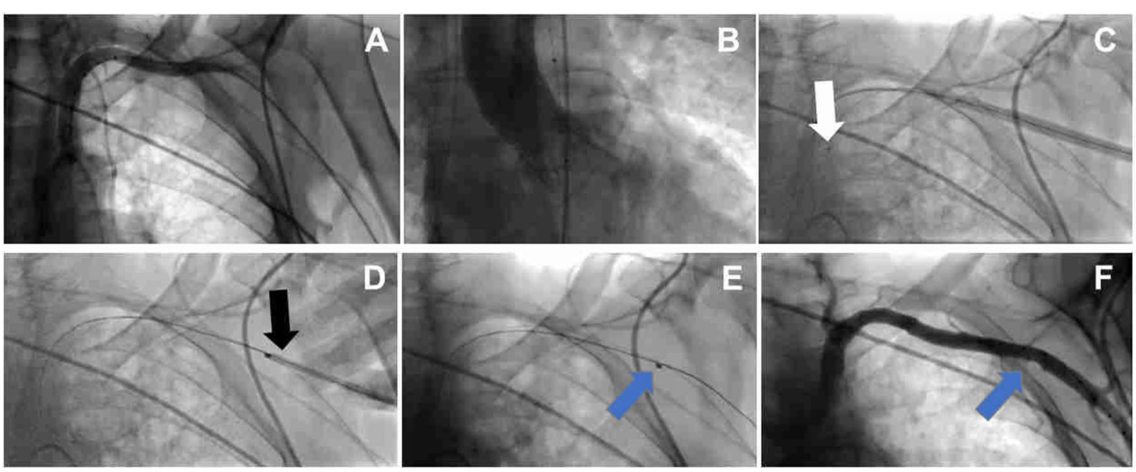

Fig. 2 Transaxillary transcatheter aortic valve implantation providing the left subclavian artery with a novel vascular closure device. Initial angiography of the left subclavian artery via distal brachial access (**a**) using a marked pigtail catheter; after valve deployment (**b**) the introducer sheath is retracted and the MANTA™ sheath and tool are fully inserted into the subclavian artery (**c**) accompanied by angioplasty balloon stand-by (white arrow); subsequent to retraction of the device and release of the toggle, the lock advancement tool (black arrow) is brought down to stabilize the vessel (**d**); remaining stainless steel lock (blue arrow) after vessel closure (**e**) and in final angiography (**f**)

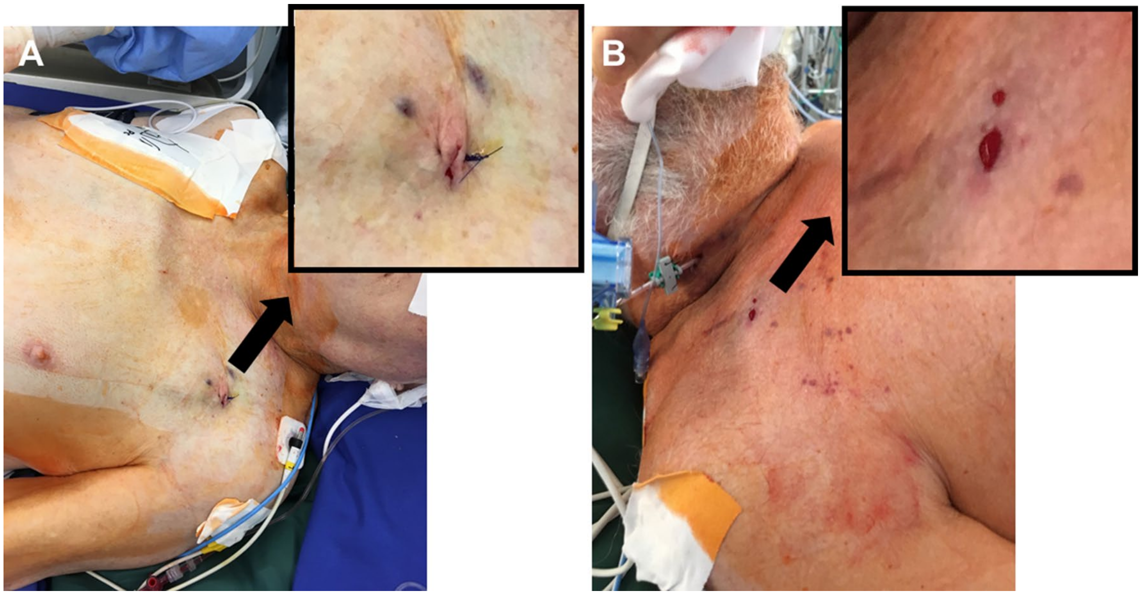

Fig. 4 Macroscopic results after transaxillary transcatheter aortic valve implantation utilizing a novel vascular closure device. Infraclavicular area after transaxillary transcatheter aortic valve implantation via left subclavian artery (**a**), right subclavian artery (**b**) and vascular closure using the MANTA™ device

Table 1 Baseline characteristics of patients provided with Tax-TAVI and a novel vascular closure device

	Patient no.								
	1	2	3	4	5	6	7	8	Σ
Age, years	77	80	88	75	73	72	69	74	76.0 ± 5.9
Gender, male/female	Female	Male	Male	Male	Male	Male	Female	Female	62.5% male
BMI, kg/m^2	23.5	19.5	20.9	18.2	23.3	28.7	22.9	32.2	23.6 ± 4.7
logEuroSCORE I, %	18.2	15.6	9.5	16.6	21.1	18.1	10.1	17.6	15.9 ± 4.1
logEuroSCORE II, %	6.57	6.36	7.18	6.74	6.36	6.13	5.40	6.65	6.4 ± 0.5
STS PROM, %	2.79	2.93	3.82	1.93	2.13	4.32	1.86	2.81	2.8 ± 0.9
Diabetes mellitus, ✓/✗	✓	✗	✗	✓	✗	✗	✗	✗	2/8 ✓
Arterial hypertension, ✓/✗	✓	✓	✓	✓	✓	✓	✓	✓	8/8 ✓
Prior stroke, ✓/✗	✗	✓	✗	✗	✗	✗	✗	✗	1/8 ✓
Coronary artery disease, ✓/✗	✓	✓	✓	✓	✓	✓	✓	✓	8/8 ✓
Previous sternotomy, ✓/✗	✗	✗	✗	✗	✗	✗	✓	✗	1/8 ✓
Extracardiac atheropathy,✓/✗	✓	✓	✓	✓	✓	✓	✓	✓	8/8 ✓
Arrhythmia, ✓/✗	✗	✓	✗	✓	✗	✗	✗	✗	2/8 ✓
COPD > gold II, ✓/✗	✓	✗	✗	✓	✓	✓	✗	✗	4/8 ✓
Creatinine, mg/dl	0.9	4.0	2.0	1.7	1.1	9.9	0.7	4.0	3.0 ± 3.0
Pulmonary hypertension > 60 mmHg, ✓/✗	✗	✗	✗	✗	✓	✗	✗	✗	1/8 ✓
NYHA ≥ III, ✓/✗	✓	✓	✓	✓	✓	✓	✓	✓	8/8 ✓

LVEF, Left ventricular ejection fraction; BMI, Body mass index; logEuroSCORE, logistic European System for Cardiac Operative Risk Evaluation, STS-PROM, Society of Thoracic Surgeons Predicted Risk of Mortality, COPD, chronic obstructive pulmonary disease, NYHA, New York Heart Association disease and extracardiac artheropathy. Two patients presented with terminal chronic renal failure and established hemodialysis. Detailed patient demographics are summarized in Table 1.

Periprocedural data

Five procedures were performed under conscious sedation. Of three Tax-TAVI under general anesthesia, two were started under conscious sedation and converted during the procedure due to agitated patient behavior. Puncture location depth was highly variable with depths from 3.5 to 7.5 cm. Tax-TAVI was performed utilizing the left subclavian artery in five cases and the right subclavian artery in three cases. Low-pressure balloon-angioplasty for vessel closure was performed in 5/8 patients. Implanted THV included Allegra (New Valve Technology AG, Muri, CH), EvolutR (Medtronic Inc., Minneapolis, MN, USA), Portico (Abbott Vascular Inc., Abbott Park, IL, USA) and Sapien 3 (Edwards Lifesciences Inc., Irvine, CA, USA). Detailed periprocedural data including procedure and fluoroscopy time are summarized in Table 2.

Access site and echocardiographic outcome data

In the study group, peak and mean transvalvular gradients as determined by TTE prior to discharge decreased from 59.4 ± 13.5 to 10.6 ± 5.6 mmHg and 34.5 ± 7.7 to 7.1 ± 3.5 mmHg, indicating adequate relief of aortic valve stenosis and regular THV function. In patient no. 7 concomitant Tax-TAVI and transcoronary ablation of septal hypertrophy was performed with postprocedural persisting significant pressure gradient of the left ventricular outflow tract. Furthermore, no relevant paravalvular leakage was detected during 30-day follow-up.

The composite endpoint device success was met in all patients. Two deaths occurred during the 30-day follow-up, both due to exacerbation of preexisting severe pulmonary disease. Regarding access site two minor complications (hematoma) without need for re-intervention occurred, and one aneurysma spurium of the subclavian artery was seen with consecutive stent implantation on postoperative day 5. In this patient also VARC-2 defined major gastrointestinal bleeding occured. Clinical and echocardiographic outcome parameter are documented in Table 3.

Discussion

Utilization of the herein described novel collagen-based vascular closure device is feasible in Tax-TAVI. Potential advantages are the easiness of application, absence of suture material in a more precarious access site compared to TF-TAVI and the remaining extravascular stainless steel lock indicating the exact position of vessel entry for possible re-interventions in case of later vessel complications. The herein seen slightly prolonged procedure time and increased amount of utilized contrast agent compared to TF-TAVI procedures are most likely not associated with the closure device but with the more complex and less standardized

Table 2 Periprocedural characteristics of patients provided with Tax-TAVI and a novel vascular closure device

	Patient no.								
	1	2	3	4	5	6	7	8	Σ
Baseline EOA, cm^2	0.7	0.5	0.6	1.0	0.9	0.8	0.8	0.7	0.8 ± 0.2
Baseline peak gradient, mmHg	62	45	66	44	67	49	84	58	59.4 ± 13.5
Baseline mean gradient, mmHg	31	28	41	23	37	33	48	35	34.5 ± 7.7
Anesthesia, general/CS	CS	General	CS	General	General	CS	CS	CS	5/8 CS
Procedure time, min	85	95	90	143	65	80	126	111	99.4 ± 25.7
Fluoroscopy time, min	34	29	32	40	20	24	50	27	32.0 ± 9.5
Contrast agent, ml	180	260	170	200	150	160	270	121	188.8 ± 52.3
Puncture locator depth, cm	5	5.5	7.5	4	3.5	4.5	4.5	4.5	4.8 ± 1.2
Valve type, size (mm)	Allegra, 27	EvolutR, 34	EvolutR, 34	Portico, 29	S3, 26	S3, 26	S3, 23	S3, 26	/
Side of subclavian artery, right/left	left	left	left	left	right	right	right	left	5/8 left
Low-pressure balloon-angioplasty for vascular closure, ✓/✗	✓	✗	✗	✓	✗	✓	✓	✓	5/8 ✓
Re-sheathing, ✓/✗	✓	✓	✗	✗	✗	✗	✗	✗	2/8 ✓
Predilatation, ✓/✗	✓	✗	✓	✓	✓	✓	✓	✗	6/8 ✓
Postdilatation, ✓/✗	✓	✗	✗	✗	✗	✗	✗	✗	1/8 ✓
Cerebral protection, ✓/✗	✗	✗	✗	✗	✗	✗	✗	✗	0/8 ✓

EOA, effective orifice area; CS, conscious sedation; S3, Sapien 3

Table 3 Clinical outcome including access site complications and echocardiographic results at discharge of patients provided with Tax-TAVI and a novel vascular closure device

	Patient no.								
	1	2	3	4	5	6	7	8	Σ
All-cause mortality (30 days), ✓/✗	✓	✗	✗	✗	✓	✗	✗	✗	2/8 ✓
Stroke (disabling), ✓/✗	✗	✓	✗	✗	✗	✗	✗	✗	1/8 ✓
Myocardial infarction, ✓/✗	✗	✗	✗	✗	✗	✗	✗	✗	0/8 ✓
Bleeding (major/life threatening), ✓/✗	✓	✗	✗	✗	✗	✗	✗	✗	1/8 ✓
Access site complications, ✓/✗	Aneurysma and stent implantation	✗	✗	Hematoma	✗	Hematoma	✗	✗	3/8 ✓
Acute kidney injury (AKIN 2, 3), ✓/✗	✗	✗	✗	✗	✓	✗	✗	✗	1/8 ✓
PPM implantation, ✓/✗	✓	✗	✗	✗	✗	✗	✗	✗	1/8 ✓
Device success[a], ✓/✗	✓	✓	✓	✓	✓	✓	✓	✓	8/8 ✓
Early safety[b], ✓/✗	✗	✗	✓	✓	✗	✓	✓	✓	5/8 ✓
Intensive care unit stay, days	7	7	1	2	20	1	2	1	5.1 ± 6.5
In hospital stay, days	7	13	7	30	20	11	14	7	13.6 ± 8.0
Mean gradient, mmHg	9	5	3	5	5	12	/[c]	11	7.1 ± 3.5
PVL ≥ moderate, ✓/✗	✗	✗	✗	✗	✗	✗	✗	✗	0/8 ✓

AKIN Acute kidney injury network, PPM, permanent pacemaker; PVL, Paravalvular leakage

[a]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)

[b]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 (BAV, TAVI, or SAVR)

[c]s/p TASH with persisting LVOT pressure gradient

Tax-TAVI procedure compared to the TF approach. The two deaths during follow-up were not associated with the procedure itself, but with postoperative exacerbated pulmonary disease. One patient had to be converted to general anesthesia during the procedure and one patient had to be invasively ventilated shortly after Tax-TAVI. Both were not weanable from ventilation, which is emphasizing again the importance of awake procedures in this severely comorbid study population, especially in patients with an impaired pulmonary function.

Despite reduction of introducer sheath diameter in latest generation THV systems, rates of vascular access site complications are still high, varying between 15 and 25% in TF-TAVI [18]. Different strategies were described to improve these outcomes, e.g. surgical cut-down or the parallel suture technique with the ProGlide system [19, 20]. However, none of these strategies were proven in larger patient cohorts or trials and vessel closure is still a major concern in TAVI procedures. This is especially and also true for Tax-TAVI. Rates of access site complications are in the same range as in TF-TAVI [7]. However, once a complication occurs, management is technically more demanding compared to the TF approach and usefulness of balloon stand-by via an externalized long wire was already described [11]. Besides this strategy, an easy, reproducible and reliable system for vessel closure is of paramount importance in Tax-TAVI. The herein described MANTA™ device has the potential to simplify and facilitate vessel closure in these procedures. In this first series of Tax-TAVI utilizing this collagen-based system, fast hemostasis with varying puncture depths and one major vascular complication was seen. Due to the small number of patients, general conclusions regarding clinical efficacy and safety cannot be made. However, first data of TF-TAVI using MANTA™ indicate similar results regarding access-site related outcomes [21]. Especially, in complicated Tax vessel access and tortuoised subclavian artery anatomy this novel system has the potential to improve outcomes regarding vascular complication rates, particularly when combined with low-pressure balloon-angioplasty for vessel closure. These results will have to be confirmed in larger patient numbers for further clinical evaluation.

Limitations

Limitations are inherent in a single-center study design with limited patient numbers: patients were not randomized to a specific treatment or vessel closure device; therefore, patient preselection with hidden confounders may apply.

Conclusions

The MANTA™ device is applicable in Tax-TAVI, with potential particular advantages regarding easiness of use and marked access for subsequent interventions in case of vascular complications. Before conclusions regarding clinical efficacy and safety can be made, the device has to be evaluated in larger patient cohorts especially for confirmation of reliable vessel closure and evaluation of the potential risk of hemodynamic relevant stenosis in small subclavian arteries after vessel closure with an anchor-based system.

Compliance with ethical standards

Conflict of interest A. Schaefer received travel compensation from Symetis SA and Abbott Vascular Inc. L. Conradi is a Proctor for Symetis SA and Edwards Lifesciences Inc. and received travel support and lecture fees from Abbott Vascular Inc., Edwards Lifescieences Inc., Boston Scientific Co. and Medtronic PLC. U. Schäfer is a Proctor for Symetis SA, Medtronic, Bostons Sci, Edwards Lifesciences Inc.; New Valve Technology, Abbott Vascular, and received travel support and lecture fees from Symetis SA, Medtronic, Bostons Sci, Edwards Lifesciences Inc.; New Valve Technology, Abbott Vascular.

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