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Long-term follow-up after stent graft placement for access-site and access-related vascular injury during TAVI – The Bonn-Copenhagen experience

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ABSTRACT

Aims: Stent graft placement is a safe and effective treatment option for vascular complications in the context of transcatheter aortic valve implantation (TAVI). This study aimed to provide long-term angiological follow-up of stent grafts used for this indication.

Methods and results: Seventy-one patients (64.8% female, log EuroScore 14.7 ± 6.8%) who had undergone TAVI between March 2010 and October 2015 with implantation of a Viabahn or Fluency stent graft to treat access-site or access-related vascular injury (ASARVI) were analyzed. Implantations were mostly due to access-site bleeding complications (83.1%) in the common femoral artery (97.1%). Follow-up was performed with duplex sonography in all patients after a median of 3.9 years after TAVI (interquartile range [IQR]: 895–1749 days). Ultrasound revealed tri- or biphasic flow patterns in 16.9% and 77.6%, respectively. Stent graft patency was 100% without signs of stent graft stenosis (mean peak velocity ratio 1.0 ± 0.2). Pseudo-aneurysms or endoleaks were diagnosed in 5.6% of patients. Additional fluoroscopic and/or computed tomography (CT)-imaging was available in 36.6% of patients and did not reveal any stent fracture.

Conclusion: Self-expanding stent grafts provide excellent long-term function with few complications when implanted in the context of TAVI-related ASARVI.

1. Background

Procedure-related vascular complications have accompanied the advent of transcatheter aortic valve implantation (TAVI) from the start and have been shown to be associated with increased morbidity and mortality. Although major vascular complications occur less frequently in current clinical practice, rates of 5% to 8% are still reported in modern TAVI cohorts [1,2]. The management of access-site and access-related vascular injury (ASARVI) is not standardized and depends largely on the extent of vascular injury as well as on the operator's preference and experience. Treatment options range from conservative approaches (e.g. manual compression) over balloon occlusion and stent graft placement to surgical vascular repair [3,4]. Stent graft placement has been shown to be a reliable option for acute management of vascular complications [5–7]. Long-term data on this bail-out approach are however lacking, especially regarding stent graft patency or failure.

The aim of this study was to assess long-term outcomes after management of TAVI-related ASARVI with stent graft implantation.

2. Methods

2.1. Study cohort and clinical endpoints

For the purpose of this cross-sectional cohort study conducted by two European TAVI centers, we examined patients who had undergone stent graft placement for the management of ASARVI during transfemoral TAVI.

In both centers, the transfemoral approach is considered the primary access route (>90%), with alternative access routes only used in case of prohibitive iliofemoral

Abbreviations: ASARVI, access-site and access-related vascular injury; CFA, common femoral artery; CT, computed tomography; PFA, profunda femoral artery; PVR, peak velocity ratio; RBC, red blood cell; SFAR, sheath-to-femoral-artery ratio; TAVI, transcatheter aortic valve implantation; VARC-2, Valve Academic Research Consortium.

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anatomy. Patients that had undergone TAVI with stent graft implantation at the access site before 2015, that were alive at the time of the investigation and living <100 km away from the hospital were invited to participate in the study. Patients accepting the invitation and with available ultrasound control of their vascular stent graft were included in the study.

Prior to the TAVI procedure, all patients underwent a comprehensive pre-operative evaluation including transthoracic and/or transesophageal echocardiography as well as a diagnostic left heart catheterization. Multi-detector computed tomography (MDCT) was performed in most patients and was systemically available in both centers since 2015. Patients were discussed in the local interdisciplinary Heart Team and agreed to undergo TAVI and have their data registered in the respective local TAVI registry. Clinical endpoints were defined according to the VARC-2 criteria [8].

Peripheral artery disease (PAD) was defined as any history of peripheral angioplasty or surgery, presence of claudication, an ankle-brachial-index <0.9, or the presence of a >50% stenosis in the iliofemoral artery [9]. Femoral artery tortuosity and calcification were determined using CT-angiography and/or access-site angiography and categorized from 0 to 3 [10]. For a detailed evaluation of the cause leading to stent graft placement, ASARVI was stratified into four categories as recently published by our group (ASARVI I–IV) [6]. For management of ASARVI, the Viabahn stent graft (Gore Inc., Flagstaff, AZ, USA) and the Fluency stent graft (C.R. BARD Inc., Murray Hill, NJ, USA) were used.

2.2. Angiological follow-up

Angiological follow-up included clinical examination and sonographic assessment. Triplex sonography (color and spectral Doppler with B-mode) was performed in all segments of the iliofemoral axis. When stent fractures were suspected, further evaluation was ordered by biplanar fluoroscopy and/or CT-angiography, based on the physician's preference and concomitant pathology. Stenosis of stent graft was determined by spectral ultrasound using an established cutoff of a 2.4-fold elevation of the peak velocity ratio (PVR), which was calculated as the ratio between peak systolic velocity within and proximal to the stent [11]. Flow pattern type was evaluated and mono-phasic flow was regarded as an indirect sign of stenosis in the iliofemoral segment. All sonographic examinations were performed by experienced angiologists (CS, NS, KLH). Stent graft fractures were classified as described by Jaff et al. [12], based on fluoroscopy and/or CT images.

2.3. Statistical analysis

Normally distributed variables are presented as mean ± standard deviation (SD). Continuous variables were tested for normal distribution with the use of the Kolmogorov–Smirnov test. Categorical variables are given as frequencies and percentages. For continuous variables, Student's *t*-test was performed for comparison between groups. For categorical variables, the χ^2 or Fisher's exact test was used. When comparing more than two groups, ANOVA or the Kruskal–Wallis test was used. All analyses were conducted with SPSS version 23.0 (IBM Corporation, Somer, NY). *P*-values <0.05 were considered statistically significant.

3. Results

3.1. Patient population

Overall, 1519 patients underwent transfemoral TAVI in the prespecified study period. Hereof, 277 patients (18.2%) were treated with a stent graft for the management of ASARVI (Fig. 1) and 178 patients

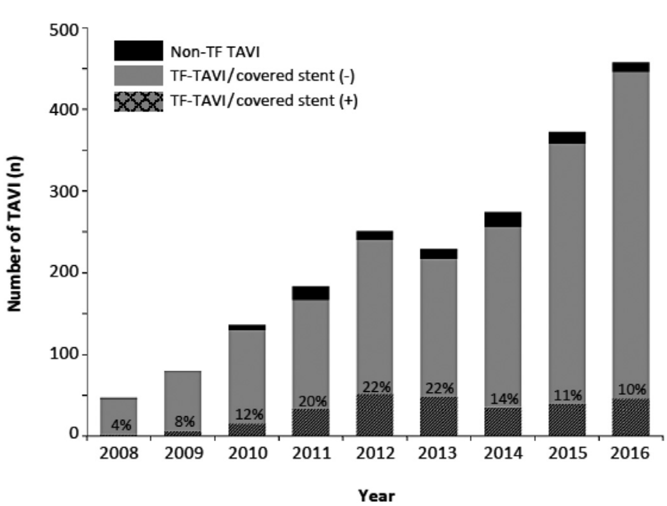

Fig. 1. Distribution of TF and non-TF TAVI in Bonn & Copenhagen as well as the proportion of patients receiving stent grafts between 2008 and 2016.

(11.7%) were alive two years after TAVI. Hereof, 71 patients were available for angiological follow-up exceeding more than two years after the procedure (Fig. 2). At the time of the procedure, patients were 82 ± 5 years of age and predominantly female (64.8%). All baseline characteristics are shown in Table 1.

3.2. Procedural details

The TAVI procedures were performed in general anesthesia in 43.7% of all patients, whereas 66.3% underwent a procedure in deep sedation or local anesthesia. Mean procedural length was 84 ± 30 min with a mean fluoroscopy time of 24 ± 10 min. Detailed procedural characteristics are shown in Table 2.

VARC-2-defined procedural success was achieved in all 71 patients (100%). None of the patients experienced peri-procedural myocardial infarction or stroke. Paravalvular aortic regurgitation ≥ moderate was documented in one patient (1.4%); mild paravalvular aortic regurgitation was seen in 47.5%. TAVI-related acute kidney injury ≥ grade II was reported in 6 out of 71 patients (8.5%) [13].

3.3. Stent graft placement

Stent grafts were implanted by a contra-lateral crossover technique, as previously described [5,6]. Bleeding complications (ASARVI I–III) accounted for the majority of stent graft implantations (83.1%) and stent grafts were implanted in 16.9% of cases because of a vascular occlusion, dissection, or stenosis (Supplemental Fig. 3).

Depending on center preference, the Fluency stent graft was used in 40/71 patients (56.3%), whereas 30/71 patients (43.7%) were treated with the Viabahn stent graft. Stent grafts were implanted in the common femoral artery (CFA) in the majority of cases (97.1%); stent grafts were implanted in the external iliac artery in two patients. More than one stent graft was needed in five patients (7.0%) due to persistent bleeding (n = 4) or insufficient coverage of a vessel dissection (n = 1). In two cases, additional interventions were necessary including snaring of the stent graft (n = 1) and surgical intervention due to complete obstruction of the profunda femoral artery (PFA; n = 1). Post-dilatation of the stent graft was performed in 39 out of 71 patients (54.9%).

3.4. VARC-2 defined outcomes

Of the 71 patients with a serious ASARVI, 51 patients (71.8%) were discharged with a minor vascular complication, whereas a major vascular complication was noted in only 20 patients (28.2%). VARC-2-defined major or life-threatening bleedings were noted in 26/71 patients (36.6%). Red blood cell (RBC) transfusion was given to 32 patients (45.1%) with a mean of 1.1 ± 1.5 RBC units per patient. The incidence of VARC-2 defined endpoints is shown in Supplemental Fig. 4A and units of RBC given in Supplemental Fig. 4B.

3.5. Angiological and imaging results

Duplex sonography was available in all patients at a median follow-up of 3.9 years (1412 days; interquartile range [IQR]: 895–1749 days). Follow-up was performed after a minimum of 730 days and a maximum of 2694 days after the TAVI procedure. Flow patterns were triphasic in 12/71 patients (16.9%) and biphasic in 55/71 patients (77.6%), whereas monophasic flow patterns were detected in 4 patients (5.6%). Doppler ultrasound revealed a mean peak velocity ratio (PVR) of 1.0 ± 0.2. Sonography showed partial or total compromise of blood flow to the PFA caused by the stent graft in 4 patients (5.6%), three of which reported symptoms of claudication, attributable to TAVI-procedure/the placement of the stent graft. Furthermore, residual pseudo-aneurysm/endoleak was detected in another 4 patients. Twenty-three patients (32.4%) were referred to biplane fluoroscopy after a median of 890 days (IQR 365–1409 days) in order to exclude stent fracture.

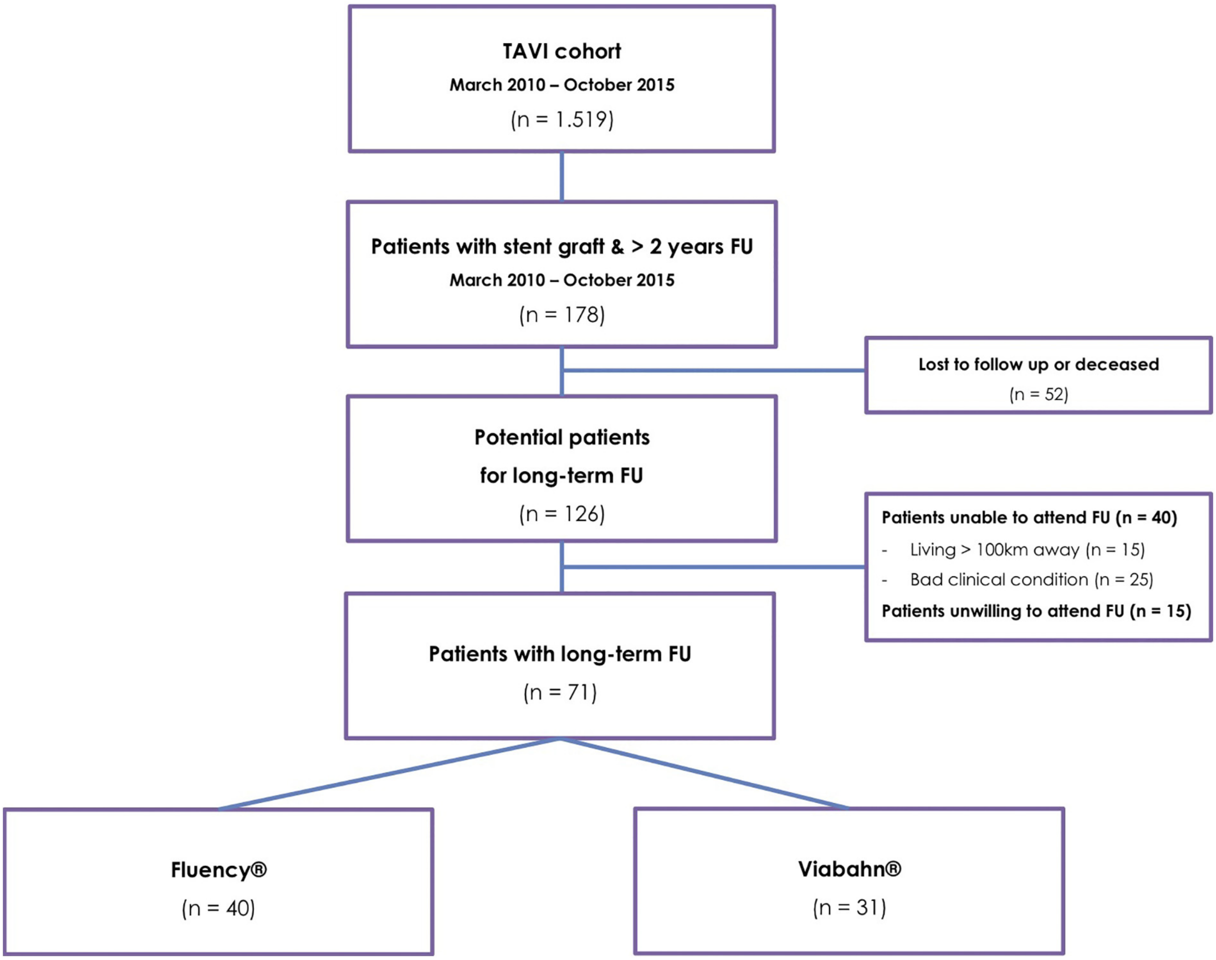

Fig. 2. Study flow chart.

CT-angiography was performed in 5 patients after a median of 1834 days (IQR 1547–1874) confirming three cases with a small distal stent edge pseudo-aneurysm in patients treated with the Viabahn stent graft. Among these patients undergoing additional imaging (fluoroscopy and/or CT), no cases of stent graft fracture were observed. (Supplemental Fig. 5).

4. Discussion

Stent graft implantation has been proven to be a safe and effective treatment strategy for the acute management of procedure-related vascular complications of the access-site in transfemoral TAVI [5,6,14]. However, long-term outcome data following stent graft placement – especially with regard to stent graft patency and fracture – is not available.

This study is the first to assess long-term outcomes after management of TAVI-related ASARVI with stent-graft implantation. In our two-center prospective analysis of 71 patients who had undergone implantation of either the Viabahn or the Fluency stent graft in the context of TAVI, we were able to demonstrate excellent stent graft patency after a median follow-up of 3.8 years without signs of in-stent restenosis. Doppler-assessed flow-patterns were mostly tri- or biphasic and a mean peak-velocity ratio of 1.0 ± 0.2 was detected. In 5.6% of patients, residual pseudo-aneurysms and/or endoleaks were diagnosed, this in patients treated with an (undersized) Viabahn stent graft. Major vascular complications, as defined by the VARC-2 criteria, were noted in 28% (20/71) whereas major or life-threatening bleeding was observed in 37% of cases. However, most of the latter were defined by transfusion of ≥2 RBCs while life-threatening bleedings were only apparent in 5 patients (7%) (Supplemental Fig. 4B). Consequently, it can be stated that aggressive management of ASARVI prevents life-threatening situations in case of TAVI-related vascular access complications.

Although stent graft implantation provides fast and secure management of access-site injury, implanting a covered stent graft in a so-called "bending area" is still somewhat controversial. Stent graft fracture and subsequent in-stent restenosis, stent graft thrombosis and/or stent graft failure are dreaded complications in regions of increased flexion [15]. Also, placement of a stent graft in the CFA, especially in younger, healthier TAVI patients may interfere with future percutaneous coronary and/or valve interventions via a femoral access. In our study cohort with long-term follow-up, no relevant stent graft restenosis was observed. This finding is reassuring and stands in contrast to results of primarily atherosclerotic lesions of the CFA treated by stent graft implantation, which have been reported to be associated with restenosis rates of 20% to 30% [15,16]. Given the fact that access-site bleeding complications were the main indication for stent graft placement, the lack of relevant stent graft stenosis is not surprising and underlines the safety and efficacy of the use of stent grafts in ASARVI.

Additional stent graft fluoroscopy was performed in approximately 1/3 of patients based on Doppler findings and did not reveal stent graft fracture. Although fluoroscopy was not routinely performed in all patients and thus may have led to an under-diagnosis of stent graft fracture, our findings appear to be in line with previously published results on this topic. In fact, stent fractures within the iliofemoral access appear to be rare (<5%) and seem to occur even less often in stent grafts implanted within the CFA [15–17].

Table 1
Baseline characteristics.

	N = 71
Patient characteristics	
Female	46 (64.8%)
Age, years	82 ± 5
Arterial hypertension	64 (90.1%)
Diabetes mellitus	21 (29.6%)
Body mass index (kg/m^2)	28 ± 6
Coronary artery disease	37 (52.1%)
Previous myocardial infarction	8 (11.3%)
Previous PCI	26 (36.6%)
Previous CABG	8 (11.3%)
Peripheral vascular disease	19 (26.8%)
Atrial fibrillation, history	24 (33.8%)
Cerebrovascular accident, history	9 (12.7%)
Chronic renal failure (eGFR <30 mL/min)	
COPD, moderate or severe	13 (18.3%)
Log. EuroScore (%)	14.7 ± 6.8
STS score (%)	5.1 ± 3.5
Echocardiographic assessment	
LVEF (%)	55 ± 9
Mean aortic valve gradient, mm Hg	48 ± 21
Aortic valve area, cm^2	0.7 ± 0.2
Pulmonary hypertension	15 (21.2%)
Vascular characteristics	
Common femoral artery – CFA	
Mean diameter (mm)	7.0 ± 1.6
Diameter <6 mm	17 (24.0%)
External iliac artery – EIA	
Mean diameter (mm)	7.6 ± 1.5
Diameter <6 mm	4 (5.6%)
Common iliac artery – CIA	
Mean diameter (mm)	9.4 ± 2.4
Diameter <6 mm	1 (1.4%)
Femoral calcification	0.9 ± 0.8
Femoral tortuosity	0.8 ± 0.8

CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; SFAR, sheath-to-femoral artery ratio, STS, Society of Thoracic Surgeons.

Table 2
Procedural characteristics.

	N = 71
Anesthesia	
General	31 (43.7%)
Conscious sedation/local	40 (56.3%)
THV type	
CoreValve/EvolutR	57 (83.1%)
Sapien XT/Sapien-3	8 (11.2%)
Portico	2 (2.8%)
Acurate	2 (2.8%)
Lotus	1 (1.4%)
Direct Flow Medical	1 (1.4%)
Vascular closure device	
ProStar™ XL	69 (97.2%)
ProGlide™	2 (2.8%)
Sheath/CFA diameter ratio	
Mean ratio	1.1 ± 0.3
Ratio <1.0	29 (40.8%)
Covered stent	
Viabahn covered stent	31 (43.7%)
Fluency covered stent	40 (56.3%)
Stent length (mm)	44.4 ± 5.0
Stent diameter (mm)	9.2 ± 1.4
Number of stents/patient	1.1 ± 0.3
Stent/CFA diameter ratio	1.4 ± 0.3
Postdilatation of covered stent	39 (54.9%)
Location of stent grafts	
Right CFA (%)	91.5
Left CFA (%)	7.0
Bilateral CFA (%)	1.5
Procedural data	
Procedural time (min)	84 ± 30
Fluoroscopy time (min)	24 ± 10
Contrast (mL)	154 ± 50
Outcome parameters	
Red blood concentrate (n)	1.1 ± 1.5
Red blood concentrate	32 (45.1%)
Acute kidney injury	6 (8.5%)
Aortic regurgitation ≥°II	1 (1.4%)
Periprocedural MI	0(0%)
Periprocedural stroke	0 (0%)
ICU stay (days)	2 ± 2
In hospital stay (days)	11 ± 8

CFA, common femoral artery; ICU, intensive care unit; MI, myocardial infarction THV, transcatheter heart valve.

As a potential complication of stent graft placement within the CFA, compromise of blood flow to the PFA may occur [18]. Partial or complete obstruction of the PFA was detected in 5.6% (4/71) of patients in our cohort. In fact, 3 of these patients reported clinical symptoms of claudication, indicating a certain clinical relevance of PFA obstruction. Although none of these patients needed to undergo specific treatment, compromise of the PFA should be avoided when stent grafts are implanted by optimization of puncture site and adequate selection of stent graft size and/or appropriate collateral blood flow.

Overall, our study indicates acceptable long-term efficacy of stent graft placement for ASARVI in patients undergoing transfemoral TAVI. Although no significant in-stent restenosis was observed in our two-center experience, a number of patients displayed pathological findings including compromised flow to the PFA as well as pseudoaneurysms/endoleaks. The latter mostly occurred with the use of the Viabahn stent graft, potentially due to a more pronounced degree of undersizing highlighting the need for precise sizing when using this specific stent graft (Stent/CFA-ratio: Fluency 1.4 ± 0.3 vs. Viabahn 1.2 ± 0.3, $P < 0.01$).

Despite these encouraging results, stent graft implantation should not be considered as the primary management strategy for access-site complications but should remain a "bail-out" option. Because of the lack of randomized data and only limited information on long-term follow-up results, alternative treatment options should be sought in a step-down approach including manual compression and cross-over balloon inflation [19] before stent grafts are implanted. Considering the negative impact of vascular complications on mortality even in modern intermediate risk TAVI cohorts [2,20], clinicians should be encouraged to prevent vascular access site complications by any means. Optimized pre-procedural imaging, appropriate choice of access-route and adequate preparation of the access-site – either by use of pre-closure devices or a surgical cut-down [21,22] – need to be implemented for optimal results. However, when stent graft placement is necessary, it appears to be a durable option with adequate long-term follow-up results.

5. Limitations

The overall use of stent grafts in our centers was rather liberal, especially in our early TAVI experience. This was triggered mainly by the primary transfemoral, true percutaneous strategies at both centers, which has led to the use of transfemoral access even in borderline anatomies. Regarding the presented results, a certain selection bias cannot be excluded, provided that only patients who were able to physically attend follow-up visits were analyzed. Patients living in nursing homes or severely ill patients were not included. Also the incidence of pathological findings in deceased patients remains unknown. Furthermore, additional imaging (biplanar fluoroscopy/CT) was not routinely performed in all patients. Thus under-diagnosis of stent graft pathologies is conceivable; the actual rates of stent graft stenosis and/or occlusion may be higher than observed in our study. However, given the relatively large number of patients in this long-term follow-up study, we believe these results are representative for daily clinical practice.

6. Conclusions

Covered stent grafts reveal excellent long-term outcomes when implanted to treat TAVI-related ASARVI. Although covered stent grafts should only remain a bail-out approach, results reported in this study indicate good long-term safety and excellent patency of the covered stent grafts.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2018.12.053.

Conflicts of interest

AS has received travel grants from Medtronic and C.R. BARD. JMS and NW have received speaker honoraria as well as research support from Medtronic Inc. NS received travel grants from Medtronic Inc. and W.L. Gore & Associates, Inc. GN has received speaker honoraria from Edwards Lifesciences as well as Medtronic Inc. LS received a research grant from W.L. Gore & Associates, Inc. ODB is a consultant for Abbott. All other authors have no conflicts of interest regarding this topic.

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