Simplified trans-axillary aortic valve replacement under local anesthesia – A single center early experience

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ABSTRACT

Background: The axillary artery is an alternative route for patients with comorbidities and unfavorable femoral arteries who need transcatheter aortic valve replacement (TAVR). Simplified trans-axillary transcatheter aortic valve replacement (TAx-TAVR) implies a completely percutaneous approach under local anesthesia and arteriotomy closure with vascular closure techniques. Herein, we report on early experience with simplified TAx-TAVR under local anesthesia.
Methods: We enrolled all consecutive patients who underwent simplified TAx-TAVR in our center. Main study parameter was the incidence of axillary access related major vascular complications within 30 days. Secondary parameters included a composite early safety endpoint, axillary access-site related vascular/bleeding complications and short-term mortality. Post TAVR axillary stent patency was evaluated during follow-up by CT-analysis.
Results: Between July 2018 and April 2020, Tax-TAVR was attempted in 35 patients with a mean age of 79 years. Local anesthesia and conscious sedation were used in 91.4% ($n = 32$) and 8.6% (n = 3) respectively. A covered stent was needed for complete axillary hemostasis in 44.1% ($n = 15$). Device success was achieved in 91.2% ($n = 31/34$). The 30-day axillary artery major vascular and ≥major bleeding complication rates were 14% ($n = 5$) and 11% ($n = 4$). The early safety endpoint was reached in 22.9% ($n = 8$). Mortality rates at 30 days and six months were 2.9% and 11.6%. Computed tomography (CT) confirmed axillary stent patency during follow-up in 82% ($n = 9/11$).
Conclusions: In patients with high/prohibitive surgical risk and unsuitable femoral access, simplified TAx-TAVR under local anesthesia offers a valuable alternative for transfemoral TAVR but requires advanced access site management techniques including covered stents. Our data suggest an unmet clinical need for dedicated TAx closure devices.

1. Introduction

Transfemoral transcatheter aortic valve replacement (TAVR) is now a valid alternative to surgical aortic valve replacement for symptomatic severe aortic stenosis (AS) in elderly patients [1–4]. With unsuitable femoral arteries, thoracic (apex and direct aorta) and upper body arterial (carotid and axillary) routes are possible but may come at increased procedural risk and less favorable outcome [5–9]. TAVR registries in the United States and Europe reported non-transfemoral access strategies in approximately 15% of TAVR patients [7].

Alternative access typically requires surgical involvement and general anesthesia. General anesthesia prolongs procedure time and in-hospital stay [10]. Previous reports described the feasibility of a completely percutaneous trans-axillary approach [11,12]. We further simplified trans-axillary TAVR (TAx-TAVR) using (in principle) only local anesthesia, ultrasound guided axillary artery access and arteriotomy closure with vascular closure devices and covered stents in case of incomplete closure [13].

Herein, we report on our early experience with simplified TAx-TAVR in patients at high or prohibitive operative risk and no suitable femoral

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artery access including computed tomography (CT) follow up of patients in whom covered stents were required for closure device failure.

2. Methods

We enrolled all patients with an attempted TAx-TAVR in the Erasmus University Medical Center (EMC).

Eligibility for TAx-TAVR was by heart team consensus involving imaging specialists, interventional cardiologists, cardiac surgeons and geriatricians. All patients were deemed at high or prohibitive operative risk. CT evaluation ruled out safe femoral artery accessibility (for large-bore sheaths) and confirmed axillary artery suitability to accommodate large bore access for TAVR. This included an axillary diameter of >5 mm.

A dedicated database captured relevant patient demographics, co-morbidities, clinical status, ECG, echocardiography, CT and procedure data. Adverse events were classified according to the Valve Academic Research Consortium II consensus document (VARC-II) [14]. All patients were followed up in the outpatient clinic at 30 days post-TAVR. Patients in whom a covered stent was required to achieve complete hemostasis after closure device failure underwent follow up CT evaluation of the stented artery. All patients provided written informed consent for the TAVR procedure and subsequent data analysis for research purposes. The study complied to the principles of the Declaration of Helsinki and did not fall under the scope of the Medical Research Involving Human Subjects Act per EMC Institutional Review Board.

2.1. Simplified transaxillary aortic valve recplacement under local anesthesia

Our completely percutaneous trans-axillary aortic valve replacement technique under local anesthesia has been described elsewhere [13]. In brief, ultrasound guided lidocaine administration and large bore access to the axillary artery was obtained in the deltopectoral groove, to avoid entry into the thoracic space (Fig. 1A-B). Left side access was preferred unless the left internal thoracic artery had been used for coronary bypass surgery or in case of unattractive left axillary/subclavian artery appearance (tortuosity, atherosclerotic disease, calcium). A 7F Slender sheath (Terumo Corp., Somerset NJ) was inserted in the

ipsilateral radial or ulnar artery to accommodate bail out stent delivery when needed (Fig. 1C). Additional 6F access was obtained to a common femoral artery or (in the later experience) contralateral radial artery to advance a pigtail catheter for contrast injections (Fig. 2).

The TAVR procedure evolved with contemporary self-expanding supra-annularly functioning transcatheter heart valves (14F Evolut R or 16F Evolut Pro or 16F Evolut XL, Medtronic Inc. Minneapolis, MN). Percutaneous large bore arteriotomy closure was attempted with either a plug-based MANTA (Teleflex, Wanye, PA) or double suture-based ProGlide (Abbott Laboratories, Chicago, IL) technique (Fig. 1D-E). A 6F diagnostic catheter was advanced through the ipsilateral radial/ulnar artery and parked distal to the arteriotomy site for selective angiography after sheath removal and arteriotomy closure to confirm hemostasis and/or advance an 0.035″ wire for ballooning or (covered) stenting (Figs. 1F-H, 2).

2.2. Study parameters

The main study endpoint was the incidence of axillary access major vascular complications within 30 days. Secondary endpoints included a composite of mortality, stroke, acute kidney injury stage II-III, coronary obstruction and valve related dysfunction requiring a repeat procedure at 30 days (VARC-II early safety endpoint), all major and minor vascular complications and VARC-II specified bleeding complications related to the axillary access and need for new permanent pacemaker implantation at 30 days [14]. Additionally, incidence of an in-hospital delirium as evaluated by a geriatrician was recorded.

Contemporary vascular closure devices were originally designed for femoral use but were applied for axillary arteriotomy closure in this study. Because of its extra-thoracic location, the axillary artery could be manually compressed in case of closure device failure and additional bail out maneuvers could be applied to achieve hemostasis. Adjunctive covered stenting was considered part of the procedure and was therefore not deemed a vascular complication. We opted for balloon expandable Advanta V12 covered stents (Maquet, Rastatt, Germany) that are 7F compatible and could be delivered through the 7F slender sheath that was inserted in the radial/ulnar artery downstream from the large bore axillary access. Successful arteriotomy closure was defined by
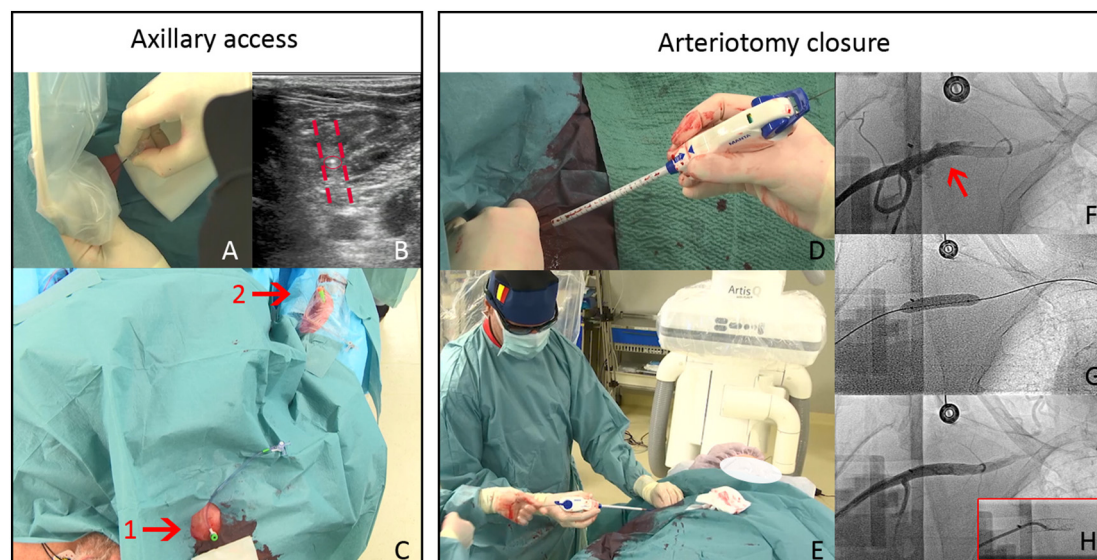

Fig. 1. Aspects of axillary access and arteriotomy closure. (A) Ultrasound guided access of the right axillary artery. (B) Echocardiographic view of the advancing needle (within red circle) towards the axillary artery. (C) Overview of right axillary (lower red arrow) and radial (upper red arrow) access. (D) Deployment of MANTA vascular closure device at the right axillary artery. (E) Position of the operator during deployment of closure device. (F) Angiographic check after closure with evident blush at the arteriotomy site (red arrow). The radio-opaque marker of the VCD does not make contact with the vessel wall. (G) Deployment of a 6 mm covered stent in the right axillary artery. (H) Angiographic control after stent placement shows complete hemostasis. Adequate stent expansion was confirmed (red box). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)
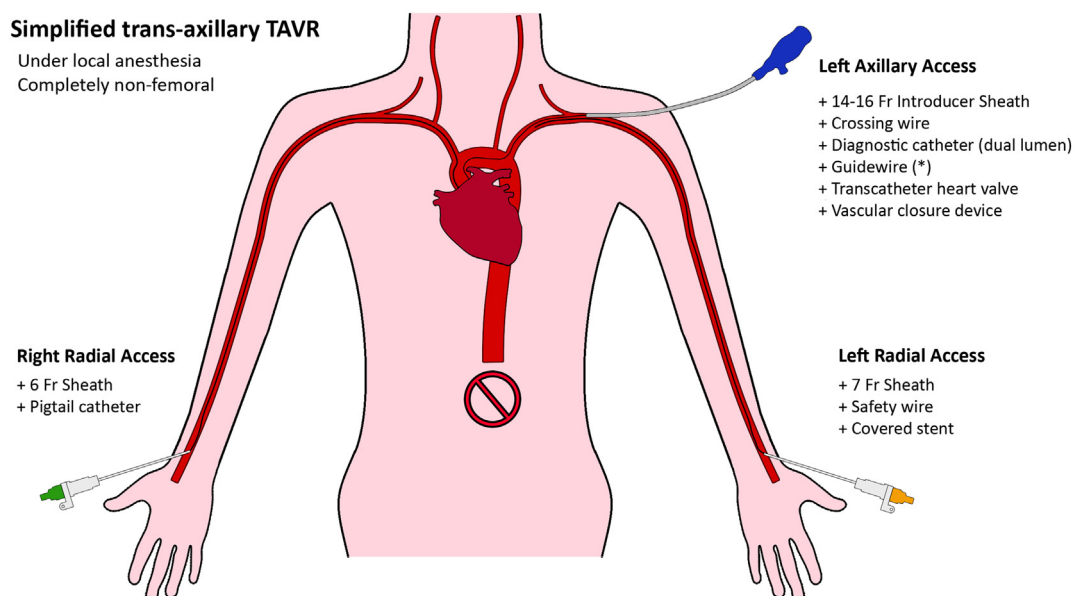
Fig. 2. Access sites in simplified trans-axillary TAVR - a schematic overview. The left axillary artery is the primary access site. Should the procedure be performed with the right axillary artery as the primary access site, the function of the right and left radial artery accesses are interchanged. (*) Rapid pacing during implantation is done over the left ventricular guidewire.

complete hemostasis through use of a closure device and a covered stent if needed.

2.3. Follow-up of covered stent patency

All patients who received a covered stent in the axillary artery for hemostasis underwent CT angiography during follow up to assess stent patency, deformation or fracture. Patency was defined as the absence of >50% narrowing of the stent lumen relative to the distal reference vessel diameter (i.e. no stenosis), deformation was defined as stent bending leading to a significant stenosis [15]. Stent fracture was scored according to standardized fracture grading [16]. Patients were clinically assessed for signs and symptoms of ipsilateral distal ischemia during in-hospital stay and at the 30-days follow up visit.

2.4. Statistics

Continuous variables were presented as mean with standard deviation (SD) if normally distributed. Median with interquartile range [IQR] was provided if not normally distributed. Pre and post TAVR invasive measurements were analyzed using paired *t*-tests or Wilcoxon signed-rank test depending on normality. Nominal data are presented as frequencies and compared using either Pearson's Chi-square or Fishers exact test for unpaired data if applicable. A Kaplan-Meier estimate was used to estimate 6-month survival probability. A two-sided P value of <0.05 was considered to indicate statistical significance. All statistical analyses were performed with SPSS 25.0 (IBM, Armonk, NY).

3. Results

A total of 35 patients underwent an attempted TAx-TAVR. The indication was a severe symptomatic native aortic stenosis in 34 (97.1%) patients and a failing surgical bioprosthesis with severe regurgitation in 1 patient. All patients were treated between July 2018 and April 2020 and our Tax-TAVR cohort represented 7.4% ($n = 35/473$) of the total TAVR cohort in that time window. Tax-TAVR was the only non-transfemoral approach after transapical access was no longer applied since early 2018.

3.1. Baseline and procedural characteristics

Baseline demographics are displayed in Table 1. Mean age was 78.7 years (SD ± 6.3) and all patients were suffering from peripheral arterial disease that precluded transfemoral TAVR. Mean Society of

Table 1
Baseline characteristics.

Baseline characteristics	n = 35
Age - years	78.7 ± 6.3
Male	20 (57.1)
Hypertension	26 (74.3)
Diabetes mellitus	15 (42.9)
Stroke/TIA	6 (17.1)
Peripheral vascular disease	35 (100.0)
COPD	14 (40.0)
Chronic kidney disease (GFR <35 ml/min)	7 (20.0)
Previous myocardial infarction	8 (22.9)
Previous percutaneous coronary intervention	14 (40.0)
Previous coronary-artery bypass grafting	8 (22.9)
Previous TAVR	1 (2.9)
Previous aortic valve surgery	1 (2.9)
Previous non-aortic valve surgery	2 (5.7)
Atrial fibrillation	14 (40.0)
Permanent pacemaker or ICD	5 (14.3)
NYHA functional class	
I	2 (5.7)
II	12 (34.3)
III	18 (51.4)
IV	3 (8.6)
STS-PROM score	4.3 ± 1.8
HAS-BLED score[α]	5.8 [4.1–5.8]
Baseline anticoagulation and anti-platelet therapy	
Vitamin K antagonist or NOAC	14 (40.0)
Aspirin	17 (48.6)
Clopidogrel or Ticagrelor	13 (37.1)
Baseline echocardiogram	
LVEF (%)	52.2 ± 10.6
LVEF ≤25%	2 (5.7)
Aortic stenosis - severe	34 (97.1)
Aortic regurgitation ≥moderate	5 (14.3)
Mitral regurgitation ≥moderate	5 (14.3)
Tricuspid regurgitation ≥moderate	4 (11.4)

Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score was 4.3% (SD ± 1.8). All patients were deemed at high or prohibitive operative risk by heart team consensus. Reasons were: advanced frailty ($n = 17$), hostile chest and previous thoracic surgery ($n = 8$), advanced lung disease ($n = 4$), active malignancy ($n = 3$), poor LVF with advanced age ($n = 2$) and patient refusal ($n = 1$).

Procedural characteristics are tabulated in Table 2. Thirty-two patients (91.4%) received local anesthesia only and 3 patients (8.6%) conscious sedation. Access was obtained via the left axillary artery in 25 (71.4%) and via the right axillary artery in 10 (28.6%) patients. Femoral arteries were left untouched in 12 (34.3%) patients (i.e. pigtail or safety wire via radial arteries). One patient suffered a stroke while advancing the delivery catheter and the procedure was aborted with no transcatheter valve implant. The 14F Evolut R was the preferred transcatheter heart valve (THV) because of its lowest profile and was used in 91.2% of patients. Two patients needed >1 THV implant. Device success was achieved in 31 (91.2%) patients. One procedural death resulted from aortic root rupture after TAVR and postdilatation.

Axillary arteriotomy closure was attempted with a VCD in 34 patients. A MANTA VCD was used in 31 (91.2%) patients and double ProGlides in 3 (8.8%). VCD failure occurred in 15 (44.1%) patients (MANTA $n = 14/31$, double ProGlide n = 1/3) and required covered stent implantation to achieve complete hemostasis. Percutaneous arteriotomy closure was accomplished in 33 (97.1%) patients. Median procedure time was 67 min (IQR 41–134) and median amount of contrast used was 80 ml (IQR 61–100). Invasive hemodynamic measurements over the aortic valve are reported in Supplementary Table 1. No significant residual gradients over the aortic valve were observed. Moderate paravalvular leak occurred in one patient (3.0%).

In-hospital and 30 day complications are reported in Table 3. Overall mortality was restricted to the patient who died per procedurally. Stroke occurred in 2 (5.7%) patients, including the patient in whom the TAVR was aborted, while one (2.9%) patient experienced a transient ischemic attack (TIA). Acute kidney injury (AKI) stage II occurred in 1

Table 2
Procedural characteristics.

Procedural characteristics	n = 35
Anesthesia	
- Local	32 (91.4)
- Conscious sedation	3 (8.6)
Valve in valve	2 (5.7)
Valve placement attempted	34 (97.1)
Valve type used$^\alpha$	
- Evolut R	31 (91.2)
- Evolut Pro	3 (8.8)
More than one valve placed$^\alpha$	1 (2.9)
Predilatation$^\alpha$	4 (11.8)
Postdilatation$^\alpha$	13 (38.2)
VARC-II device success*$^\alpha$	31 (91.2)
Immediate procedural mortality	1 (2.9)
Embolization	0
Tamponade	1 (2.9)
Emergency surgery	0
Heparin used (IU)	5000 [5000–6000]
Protamine used (no.)	9 (25.7)
Contrast used (ml)	80 [61–100]
Procedure time (min)	67 [41–134]
Access-site related characteristics	
Completely non-femoral	12 (34.3)
Axillary access side	
- Left	25 (71.4)
- Right	10 (28.6)
Closure device$^\beta$	
- MANTA	31 (91.2)
- Double ProGlide	3 (8.8)
VCD failure – VARC II$^\beta$	15 (44.1)
Covered stent used$^\beta$	15 (44.1)
Successful arteriotomy closure$^{\S\beta}$	33 (97.1)

Table 3
In-hospital and 30 day complications.

Complications	In-hospital (n = 35)	30 days$^\alpha$ (n = 35)
Mortality	1 (2.9)	1 (2.9)
- Cardiovascular cause	1 (2.9)	1 (2.9)
Acute myocardial infarction	0	0
Stroke	2 (5.7)	2 (5.7)
TIA	1 (2.9)	1 (2.9)
New permanent pacemaker	5 (14.3)	5 (14.3)
Acute kidney Injury		
- Stage I	2 (5.7)	–
- Stage II	1 (2.9)	
- Stage III	0	
Non-access site*		
- Life threatening bleeding	1 (2.9)	1 (2.9)
- Major vascular complication	1 (2.9)	1 (2.9)
Delirium	3 (8.6)	3 (8.6)
Admission time (days)	5 [3–8]	–
Access site related complications		
Access site related vascular complication$^\beta$		
- Major	4 (11.4)	5 (14.3)
- Minor	0	0
Reintervention at access site	1 (2.9)	2 (5.7)
Access site related bleeding		
- Life threatening	2 (5.7)	2 (5.7)
- Major	2 (5.7)	2 (5.7)
- Minor	3 (8.6)	3 (8.6)
Freedom from access site related major vascular complication or ≥major bleeding	31 (88.6)	30 (85.7)
Brachial plexus impairment access site arm	2 (5.7)	2 (5.7)
Early safety endpoint and functional class at 30 days		
Composite early safety endpoint – VARC II	–	8 (22.9)
Any NYHA class improvement	–	24 (80.0$^+$)

patient (2.9%). Five patients (14.3%) required a permanent pacemaker due to a total AV-block.

3.2. Vascular and bleeding complications

The main endpoint of axillary access major vascular complications occurred in 5 (14.3%) patients. In one patient a malapposed covered stent resulted in continued bleeding at the arteriotomy site, which was resolved by postdilatation. One patient experienced a major bleeding around the access site requiring multiple transfusions. One patient (in whom the TAVR was aborted as described above) suffered an axillary artery dissection that generated a stroke and life-threatening bleeding with an active blush on CT which was treated with manual compression and multiple transfusions. In another patient, significant procedural blood loss caused a large hematoma and required intermittent vasopressor support (qualified as a life-threatening bleeding). Lastly, one patient experienced a major vascular complication after hospital discharge with bilateral upper extremity paresthesia and pain. The right axillary covered stent appeared underexpanded and the left radial artery (that had received a 6F radial sheath) showed a total occlusion. The stent was postdilated and a PTA was performed in the left radial artery. The total number of access site reinterventions by day 30 was 2 (5.7%) (both featured a postdilatation). Major and life-threatening access-site related bleeding complications occurred in 2 (5.7%) and 2 (5.7%) patients respectively. Three patients (8.6%) experienced minor access-site related bleedings.

Median hospital stay was 5 days [IQR 3–8] and included admission time in referring hospitals. Delirium, diagnosed by a geriatrician, occurred in 3 (8.6%) patients. At 30 days, 30 (85.7%) patients were free of access-site related major vascular or ≥major bleeding complications.

The VARC-II defined early safety endpoint at 30 days was reached in 8 (22.9%) patients (Table 3 and Supplementary Table 2). The incidence of the primary endpoint, major bleeding and the early safety endpoint

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remained stable throughout the experience (no initial learning curve effect) (Supplementary Table 3). NYHA functional class at 30 days was improved by ≥1 grade in 80% of patients. Median follow-up duration was 56 days [IQR 39–198] with a 30 day and 6 month mortality of 1 (2.9%) and 3 (8.6%) respectively with a Kaplan-Meier estimated survival at 6 months of 88.4%.

Two patients developed post-procedural brachial plexus neuropathy of the access-site arm. One patient (who had received a covered stent) experienced subtle limitations of fine motor skills of the ipsilateral hand that persisted at 1-year clinical follow up while the other patient (who had an otherwise uneventful course) reported transient sensory impairment of the ipsilateral fingers.

Of the 15 patients who received a covered stent 11 (73%) had a follow-up CT of the axillary artery at a mean follow-up of 205 days (Table 4). Two patients (18%) showed stent deformation and significant stenosis of which details are described in Fig. 3. No vessel occlusions or strut fractures were observed. CT-confirmed stent patency was 82% ($n = 9/11$).

4. Discussion

This case series describes our initial experience with a completely percutaneous simplified TAx-TAVR technique. Main observations are: 1) simplified TAx-TAVR was feasible and relatively safe. 2) Axillary artery major vascular and ≥major bleeding complication rates were 14% and 11% respectively. 3) Contemporary vascular closure device technology (originally designed for femoral arterial access closure) had important flaws and therefore covered stents should be considered an essential part of simplified TAx-TAVR. 4) Bail-out covered stent placement to secure complete hemostasis requires meticulous implantation and may include low-threshold postdilatation to achieve complete expansion, apposition and secure stent patency.

Percutaneous axillary access was applied in 7.2% of the overall TAVR population, which is consistent with recent European and American registries and underscores the importance of alternative non-transfemoral routes [7,17,18]. Alterative access patients typically have extensive peripheral arterial disease and other comorbidities. Still, we demonstrated device implantation success in 91.2% with the simplified TAx approach under local anesthesia which mimics the results of other TAx-TAVR and alternative access routes that predominantly required general anesthesia and/or surgical techniques. Surgical cut-down as typically applied in a transapical, direct aortic, transcarotid or subclavian approach increases patient morbidity [19–21]. General anesthesia and mechanical ventilation may also imply need for post procedural ICU care and potential subsequent complications [22]. TAx-TAVR in awake patients may expedite procedure and recovery time, preclude ICU care, reduce the risk for infections and delirium and offers the ability for per procedural monitoring for neurological events. Indeed, 1 case in our series was aborted as the patient was losing consciousness while advancing the delivery catheter through the subclavian artery. The avoidance of general anesthesia may have also contributed to the relatively low post-operative delirium rate (8%) which compares to approximately 21% in other series of non-femoral TAVR [23], short procedure time (median of 67 min) and decreased in-hospital stay (median

5 days vs. mean 8 days in other TAx-TAVR series) [11]. The TAx approach further grants the ability to directly monitor the access site and may be less prone to covert bleedings as opposed to the completely percutaneous transcaval strategy that may be associated with occult retroperitoneal bleedings [20]. We believe access to the subclavian artery comes with a risk of pneumothorax and occult intrathoracic bleedings and is therefore less suitable for a completely percutaneous approach.

Our series demonstrated the limitations of current generation vascular closure devices with a need for bail out covered stents in almost half of the attempted cases. ProGlide and MANTA VCD were originally designed for the common femoral artery, which is notably different from the axillary artery (i.e. thinner wall, surrounded by more rigid tissue). Further modification of a plug-based closure technique by deploying the toggle under ultrasound guidance was recently suggested, however it remains questionable whether this will improve VCD success in general and with the axillary approach in particular [24]. Until dedicated axillary VCDs are available, covered stents remain an indispensable part of the toolbox for completely percutaneous TAx-TAVR. The 97.1% arteriotomy closure success rate should be weighed against the 14% major vascular complication rate but may be acceptable in patients who appeared at high/prohibitive operative risk with no transfemoral access. Additionally, as this is an initial experience with novel techniques, these rates are expected to decrease as numbers increase.

The VARC-II defined early safety endpoint was reached in 8 (22.9%) patients and is mainly driven by the number of major vascular complications. An explanation for these numbers can be found in the substantial baseline morbidity of our cohort. All patients suffered from peripheral vascular disease, hypertension was common and comorbidities associated with bleeding risk were extensive (i.e. elevated HASBLED-score at baseline). The reported numbers are in line with the previously reported high-risk cohorts and lead to similar rates of vascular complications [1,25].

Studies on completely percutaneous TAx-TAVR are scarce. The Hamburg experience on 100 consecutive patients reported a remarkably low complication rate [11]. The Hamburg technique included general anesthesia (in 72% of cases), the creation of an arterial femoral-radial rail, and suture-based closure with balloon occlusion. Procedure time was 85 min and mean amount of contrast used was 167 ml (vs. medians of 67 min and 80 ml in our cohort). Closure device success appeared higher with an 11% covered stent use vs. 44% in our series. We introduced the plug based MANTA VCD for its relatively rapid time to hemostasis, single device use and marking of the arteriotomy site on angiography. Arguably, this technology was not developed for axillary access, precludes the use of additional closure devices in case of failure and cannot be applied using the balloon occlusion technique because adequate blood pressure is required for optimal deployment of the intravascular device component. Mortality at 30 days follow-up was decreased compared to the incidence reported by the Hamburg group (2.9% vs. 6%).

Persistent brachial plexus injury with the axillary approach at the deltopectoral groove was rare in our series and seemed no major clinical issue as previously suggested [26]. Of note, the two reported cases in this series both followed a bleeding event with prolonged manual compression.

To our knowledge, this is the first study to report on CT-assessed axillary stent patency post TAx-TAVR. CT analysis of patients who received a covered stent confirmed two cases (18% of scanned patients) of significant stent deformation and stenosis with only 1 being symptomatic. These scans provide important information on the mechanism of stent deformation in post TAx-TAVR patients. In both patients, stent deformation and stenosis was evidently located next to an osseous structure (rib, humeral head) (Fig. 3B-C) and in both patients post-procedural and post-stent deployment manual compression was required. Conceivably, the relatively superficial location of the axillary artery close to bone structures (humeral head and 1st rib) allows complete hemostatic control through manual compression but may come at the price

Table 4
Post procedural CT assessment of axillary stent.

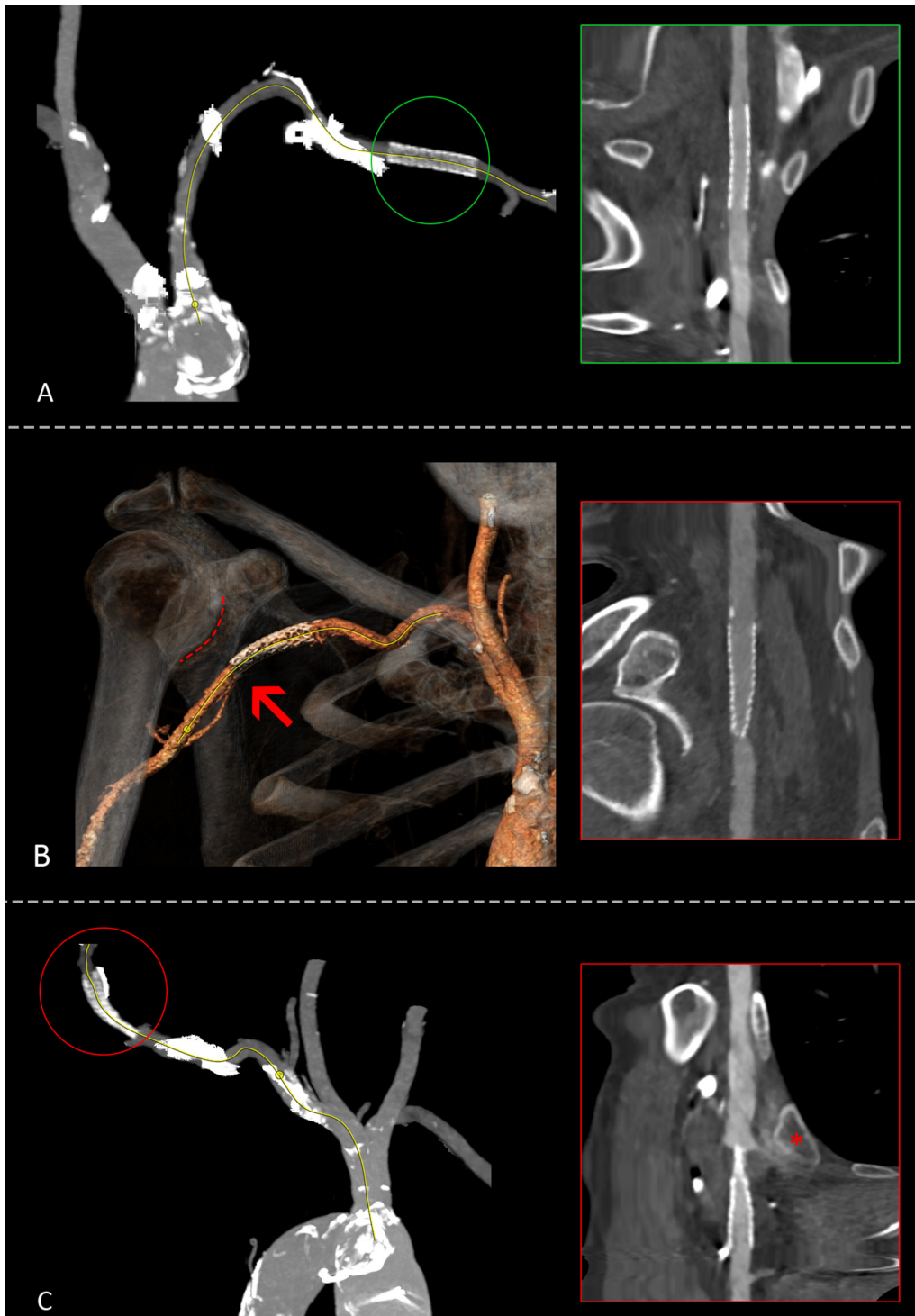| Post procedural CT assessment of axillary stent	No. (%) ($n = 11$)
Days to follow-up CT-scan	205 [2–440]
Stent stenosis	
- Due to deformation	2 (18.2)
- Due to thrombus	0
Stent occlusion	0
Strut fracture (any)	0
Stent patency	9 (81.8)

Fig. 3. CT-assessed axillary stent patency post TAx-TAVR. (A) Patient 1, stent patency: frontal view of the aortic arch and branches (calcium settings) with a clear view of the stent in the left axillary artery (green circle). Stent structure appears intact without any deformations or stenosis. The stretched vessel image of the stent does not show any signs of intra-stent obstruction (green cadre). (B) Patient 2, no stent patency: frontal view of the brachiocephalic trunk and right axillary artery (contrast/bone settings). The distal stent edge has been compressed (direction of red arrow) against the glenohumeral joint (dotted red line). Significant distal lumen loss is shown on the stretched vessel (red cadre) with contrast present in the distal part of the vessel. The patient was symptomatic and treated with postdilataion. (C) Patient 3, no stent patency: frontolateral view (simulated C-arm angles: RAO40, CAU22) of the aortic arch and branches with the stent in the axillary artery highlighted (red circle). The proximal part of the stent is deformed. Significant proximal lumen loss is shown on the stretched vessel (red cadre). Bending of the stent over the distal part of the first rib (red asterisk) might have caused the stent to be pinched. Contrast is present in the distal part of the vessel and the patient was asymptomatic. *Images were obtained using 3Mensio software* (*Pie Medical*, *Maastricht*, *The Netherlands*). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

of brachial plexus injury and stent deformation. This underscores the importance of appropriate covered stent apposition and expansion including postdilatation if needed to obtain immediate complete hemostasis and avoid the need for additional manual compression.

5. Limitations

This single center study has several limitations. First, most patients qualify for transfemoral TAVR. Therefore the sample size is relatively

limited. Second, multiple patients did not present at the outpatient clinic at one year follow-up, resulting in an inability to report on VARC-II defined adverse events beyond 30 days. Third, not all patients with a covered stent had a follow-up CT available which might have led to underreporting of asymptomatic stent deformation. Fourth, timing of follow up CT varied, precluding a comparison of axillary stent performance over time.

6. Conclusion

In patients with high or prohibitive surgical risk and no suitable femoral access site, simplified TAx-TAVR under local anesthesia offers a valuable alternative for transfemoral TAVR but requires advanced access site management techniques including covered stents. Our data suggest an unmet clinical need for dedicated TAx closure devices.

Declaration of competing interest

Professor Van Mieghem has received a research grant support from Boston Scientific, Edwards Lifesciences, Abbott Vascular and PulseCath B.V. which were received for activities outside the submitted work. Dr. Daemen received institutional grant/research support from Astra Zeneca, Abbott Vascular, Boston Scientific, ACIST Medical, Medtronic, Pie Medical, ReCor Medical and PulseCath, and consultancy and speaker fees from ACIST Medical, Boston Scientific, ReCor Medical, Pie Medical, Medtronic and PulseCath. The other authors have no conflict of interest to declare.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2020.11.025.

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