“Successful management of a bleeding complication during transaxillary transcatheter aortic valve implantation: a case report.”

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- Draft manuscript preparation: P. Lauten, MD; M. Al-Jassem MD

All authors reviewed the results and approved the final version of the manuscript.

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Abstract

Background
The axillary artery is an alternative access route for transcatheter aortic valve implantation (TAVI) in patients who have unfavorable femoral arteries as well as comorbidities which preclude surgery. Transaxillary TAVI (TAx-TAVI), with a complete non-transfemoral approach, is a feasible and safe alternative even if complications like vascular closure device failure with bleeding occurs.

Case summary
We describe here a simplified non-transfemoral TAx-TAVI approach in a 71-year-old patient with pulmonary edema due to severe symptomatic aortic stenosis with a prohibitively high surgical risk (Society of Thoracic Surgeons Mortality 11.9%) and extensive peripheral artery disease that rendered the femoral arteries unsuitable for access. Importantly, this strategy also allows for successful management of bleeding events, particularly those associated with vascular closure device failure, by the use of a new covered stent device. The patient was discharged on Day 6 after admission in stable conditions. In short term follow-up (30 days) he is asymptomatic with normal left ventricular function.

Discussion
TAx-TAVI is a promising alternative to transfemoral TAVI approach. Patient safety, even during bleeding complications, can be guaranteed with appropriate preparation.

Keywords
Learning points

- Non-femoral TAVI using a transaxillary approach without surgical cutdown is safe and feasible after meticulous material planning
- Transaxillary cannulation requires detailed anatomic knowledge and is less standardized in comparison to transfemoral TAVI
- Radial/brachial access is safe with contemporary devices and materials.
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| **30 days – follow up** | - Normal left ventricular function  
- Improved quality of life (NYHA II)  
- Reduced level of NT-proBNP |
Successful management of a bleeding complication during transaxillary transcatheter aortic valve implantation: a case report.

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Introduction

Transcatheter aortic valve implantation (TAVI) is an established treatment for severe, symptomatic aortic stenosis in elderly patients across all risk categories. When the femoral arteries are unsuitable for this procedure, the thoracic (apex and direct aortic) and upper body (carotid and axillary) arterial routes are possible although they are associated with an increased risk and less favorable outcomes. (1-4) TAVI registries in United States and Europe report non-transfemoral access strategies in approximately 15% of TAVI patients. (5) Alternative access strategies typically require surgical involvement. However, some reports have described the feasibility of complete percutaneous transaxillary TAVI (TAX-TAVI) approaches.(6, 7) Here we report step-by-step a simplified approach for non-femoral TAX-TAVI in a patient with a prohibitively high operative risk and no suitable femoral artery access.
Case presentation

A 71-year-old man with highly symptomatic severe aortic valve stenosis (AS) and in acute heart failure with pulmonary edema and dyspnea was urgently admitted to our Heart Center. Transthoracic echocardiography (TTE) showed high gradient stenosis (Vmax 4.4 m/s, ΔPmean 49mmHg, AVA 0.6 cm²) and reduced left ventricular function (LVEF 32%) (Video1). Pulmonary hypertension was not documented. He had exertional angina, Canadian Cardiovascular Society Class II and one syncope. His past medical history included hypertension, paroxysmal atrial fibrillation, diabetes mellitus Type 2, chronic obstructive pulmonary disease GOLD III, and multiple prior percutaneous endovascular treatments with stents due to severe peripheral artery disease. At admission, his medical regimen included single antiplatelet therapy, atorvastatin, a beta-blocker, mineralocorticoid receptor antagonist, and bronchodilators. Upon examination, his blood pressure was 170/90 mm Hg. Baseline electrocardiography showed sinus tachycardia, left ventricular hypertrophy with strain pattern, and AV-Block 1st degree.

He had bilateral crackles at the lung bases and clinical findings of severe symptomatic AS. N-terminal pro-brain natriuretic peptide (NT-pro BNP) level at admission was 11 200 pg/ml (normal less than 125 pg/ml). After initial management with intravenous diuretics and recompensation on our intensive care unit (ICU), the patient underwent coronary angiography which revealed no significant coronary artery disease. Invasive assessment of AS showed a peak-to-peak and mean aortic gradient of 133 mm Hg and 44 mm Hg, respectively. Left ventricular end diastolic pressure was 35 mm Hg. Given his co-morbidities and surgical risk, he was deemed a candidate for TAVI by our Heart Valve Team. The pre-procedural multidetector computed tomography (MDCT) revealed unfavorable vessels for transfemoral access from both groins due to multiple prior stenting procedures and due to a severe calcified aortic valve with an aortic annulus perimeter of 76.8 mm and annulus area of 502.3 mm² (Figure1). Further calcification of the annulus was excluded. We evaluated the left axillary artery (9 mm) as an alternative access site and found it to be feasible for TAVI (TAx-TAVI) (Figure 2).

Procedure details

We obtained informed consent and regulatory body approval for performing this TAx-TAVI procedure under general anesthesia while using a completely non-femoral approach with a supra-annular, self-expanding TAVI Prosthesis (EvolutR 29 mm, Fa.Medtronic Inc., Minneapolis, MN).

Right radial artery access was obtained and a 6 French (Fr) pigtail inserted. Using ultrasound guidance, the left brachial artery was punctured and a 7 Fr sheath and safety wire (0.035 inch High-Torque Supra Core 300 cm., Fa. Abbott CA, USA ) was parked in the descending aorta with a mounted balloon (Mustang PTA Balloon Catheter 10x40 mm, Fa. BostonScientific MA, USA) (Figure 4 A,B).

This set up was established as a bail-out strategy in case of bleeding and the need to advance a covered stent (schematic overview Figure 3).

Using the overlay technique, the left axillary artery was punctured, two suture-based vascular closure devices (Proglide, Fa.Abbott CA, USA) were deployed, (Figure 4 A,B; Video) and a large bore sheath (Sentrant 14 Fr, Fa. Medtronic) was used for arteriotomy with a super stiff wire (0.038 in, Amplatz super stiff, BostonScientific MA, USA). A temporary pacemaker lead was deployed over a 6Fr sheath via the internal jugular vein. Pre-dilatation
was done with a 22 mm x 4 cm Z-MED Balloon (NuMED, Inc; Denton Texas USA) using a SAFARI2 Pre-shaped TAVR wire (Fa. Boston Scientific, MA, USA). The TAVI procedure itself was performed in accordance with the manufacturer recommendations (Figure 4 C, D; Video 2; Video 3). After valve implantation, the balloon that was placed in the aorta at the beginning of the procedure was advanced to block the subclavian artery. After device sheath removal, we observed a partial closure device failure with significant residual bleeding (Figure 4 F; Video 4). Due to relevant und unstoppable bleeding, we decided to advance a covered stent (7 mm x 39 mm, Viabahn VBX balloon-expandable endoprosthesis, Fa Gore) for arteriotomy closure with final expansion to 10 mm with an additional Balloon. Hemostasis was confirmed by selective angiography (Figure 4 G, H; Video 4). After removal of the brachial sheath, a plug-based closure device (Femoseal Vascular Closure Device 7Fr, Terumo Europe) was used for successful hemostasis. An echocardiogram one day later showed significant improvement of LV-Function (45% ejection fraction) and a mean transvalvular gradient of 10 mm Hg. Ultrasound of the left access site documented normal vascular parameters. The patient was discharged on Day 6 after uneventful clinical course. In short term follow-up (30 days) he was asymptomatic with normal left ventricular function, clearly improved quality of life (NYHA II) and significantly reduced level of NT-proBNP (2346 pg/ml).

Discussion

Evidence from recent studies and registries suggests that transfemoral access for TAVI is the safest vascular approach. (8) In this high risk patient, femoral access was challenging due to the presence of severe aortoiliac disease that had been treated by multiple interventions, and an alternative access site was needed. The subclavian/axillary artery are more elastic; whereas, the femoral artery is more muscular. Furthermore, histologically, the adventitia of the femoral artery is more fibrous and thicker than that of the subclavian artery. (7) Thus, there is reasonable concern regarding the risk of major bleeding or dissection associated with direct puncture of the axillary artery without surgical cutdown. In light of this, we used two suture-based Proglide devices, which prior comparative studies showed useful when turning to an axillary approach. (9, 10) In this case, we also used a covered, balloon-expandable stent because of significant residual bleeding at the puncture site and Proglide-failure. The most favorable characteristic of this stent, particularly for peripheral vascular interventions, is the wide size range of up to 11 mm with dedicated balloons and a 7 French sheath access. Thus, there is an increased likelihood of successful hemostasis.

In our practice, the transaxillary approach is considered a secondary percutaneous option for patients without a transfemoral option. With careful preparation, standardization of procedures, and Heart Valve Team experience this has proven to be a viable secondary option in these challenging, high risk TAVI patients. However, in unsuitable patients, different access routes have been shown to be safe and feasible. The challenge is to choose the best alternative access route for the individual patient based on their vascular anatomy and comorbidities, choice of valve and the local institutional skill set. If alternative access is considered, a vascular surgeon should be part of the heart team to identify potential risks associated with the access routes and assist in the decision-making (Figure 5).
Conclusion

When a patient has unfavorable femoral anatomy, the transaxillary route can be a safe alternative approach for TAVI. Even when bleeding complications occur as in this case, patient safety can be secured by appropriate preparation. Randomized data evaluating this approach is lacking and possibly represents an area for future study.

Consent

The authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from the patient in line with COPE guidance.

Conflict of interest: All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation. There are no conflicts of interest pertaining to this case report.
References


Figure 1 Computed tomography scan of ilio-femoral axes showing existing stents (undersized) and bilateral calcified stenosis.
Figure 2 planning computed tomography scan and angiography of the puncture site left axillary artery ideal puncture area (red dotted line) at a distance to the lateral border of the rib cage to prevent artificial puncture of the pleural cavity
Figure 3: Schematic overview for non-transfemoral TAx-TAVI from left axillary access with safety net devices.

Right axillary access
- 6F sheath
- Pacing lead

Left axillary access
- 14 Fr sheath
- Diagnostic catheter
- Crossing wire
- Guidewire
- Transcatheter Heart Valve
- Vascular closure device

Right radial access
- 6F sheath
- Pigtail Angioline
- Sideport use for Monitoring

Figure 4: Main procedural stages: ipsilateral balloon occlusion after sheath removal; ipsilateral covered stent implantation using safety wire concept.

A

B

C

D

E

F

G

H

Ipsilateral pigtail catheter

Ipsilateral blocking

Bleeding arteriotomy

Ipsilateral covered stent

0.035 inch safety wire