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CASE REPORT
Other

Successful management of a bleeding complication during transaxillary transcatheter aortic-valve implantation: a case report

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Background The axillary artery is an alternative access route for transcatheter aortic-valve implantation (TAVI) in patients who have unfavourable 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 oedema 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 The TAx-TAVI is a promising alternative to transfemoral TAVI approach. Patient safety, even during bleeding complications, can be guaranteed with appropriate preparation.

Keywords Transcatheter aortic-valve implantation • Transaxillary TAVI • Aortic-valve stenosis • Self-expanding valve • Bleeding complication • Case report

ESC curriculum 4.2 Aortic stenosis • 6.2 Heart failure with reduced ejection fraction • 9.3 Peripheral artery disease • 6.1 Symptoms and signs of heart failure

Learning points

- Non-femoral transcatheter aortic-valve implantation (TAVI) using a transaxillary approach without surgical cut-down is safe and feasible after meticulous material planning.
- Transaxillary cannulation requires detailed anatomic knowledge and is less standardized in comparison with transfemoral TAVI.
- Radial/brachial access is safe with contemporary devices and materials.

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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 favourable outcomes.[1–4] Transcatheter aortic-valve implantation registries in the USA and Europe report non-transfemoral access strategies in approximately 15% of patients with TAVI.[5]

Timeline

Day 0	Urgent admission for TAVI at our Heart Valve Center: Patient in pulmonary oedema. Pre-screening for aortic valve replacement/recompensation on intensive care unit (ICU)
Day 1	Heart Valve Team Conference: Society of Thoracic Surgeons Mortality 11.9%; Logistic Euroscore I 26.01%: Patient not suitable for surgical aortic valve replacement or transfemoral TAVI
Day 2	Successful transaxillary TAVI (TAx-TAVI) with finally stenting of the access artery due to unstoppable bleeding
Day 3	Early mobilization on heart valve unit
Day 6	Discharge
30 days follow-up	Normal left-ventricular function Improved quality of life (NYHA II) Reduced level of NT-proBNP

Alternative access strategies typically require surgical involvement. However, some reports have described the feasibility of complete percutaneous 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 oedema and dyspnoea was urgently admitted to our Heart Center. Transthoracic echocardiography showed high-gradient stenosis (V_{max} 4.4 m/s, ΔP_{mean} 49 mmHg, aortic valve area 0.6 cm^2) and reduced left-ventricular function (32%; see Supplementary material online, *Video S1*). Pulmonary hypertension was not documented. He had exertional angina, Canadian Cardiovascular Society Class II, and one syncope. His 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 mmHg. Baseline electrocardiography showed sinus tachycardia, left-ventricular hypertrophy with strain pattern, and AV-block first degree.

He had bilateral crackles at the lung bases and clinical findings of severe symptomatic AS. *N*-terminal pro-brain natriuretic peptide (NT-proBNP) level at admission was 11 200 pg/mL (normal <125 pg/mL). After initial management with intravenous diuretics and recompensation on our 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 and 44 mmHg, respectively. Left-ventricular end diastolic pressure was 35 mmHg. Given his comorbidities and surgical risk, he was deemed a candidate for TAVI by our heart valve team. The pre-procedural multi-detector computed tomography revealed unfavourable 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 mm^2 (*Figure 1*). 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 anaesthesia, while using a completely non-femoral approach with a supra-annular, self-expanding TAVI Prosthesis (EvolutR 29 mm; Fa.Medtronic Inc., Minneapolis, MN, USA).

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 in High-Torque Supra Core 300 cm; Fa. Abbott CA, Abbott, Minneapolis, MN, USA) was parked in the descending aorta with a mounted balloon (Mustang PTA Balloon Catheter 10 × 40 mm; Boston Scientific, Marlborough, MA, USA; *Figure 4A* and *B*).

This set up was established as a bailout 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 4A* and *B*, Supplementary material online), 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; Boston Scientific). A temporary pacemaker lead was deployed over a 6 Fr sheath via the internal jugular vein. Pre-dilatation was done with a 22 mm × 4 cm Z-MED Balloon (Numed Inc, Denton, TX, USA) using a SAFARI2 preshaped TAVR wire (Boston Scientific). The TAVI procedure itself was performed in accordance with the manufacturer recommendations (*Figure 4C* and *D*, Supplementary material online, *Videos S2* and *S3*). After valve implantation, the balloon that was placed in the aorta at the beginning of the procedure was advanced to block

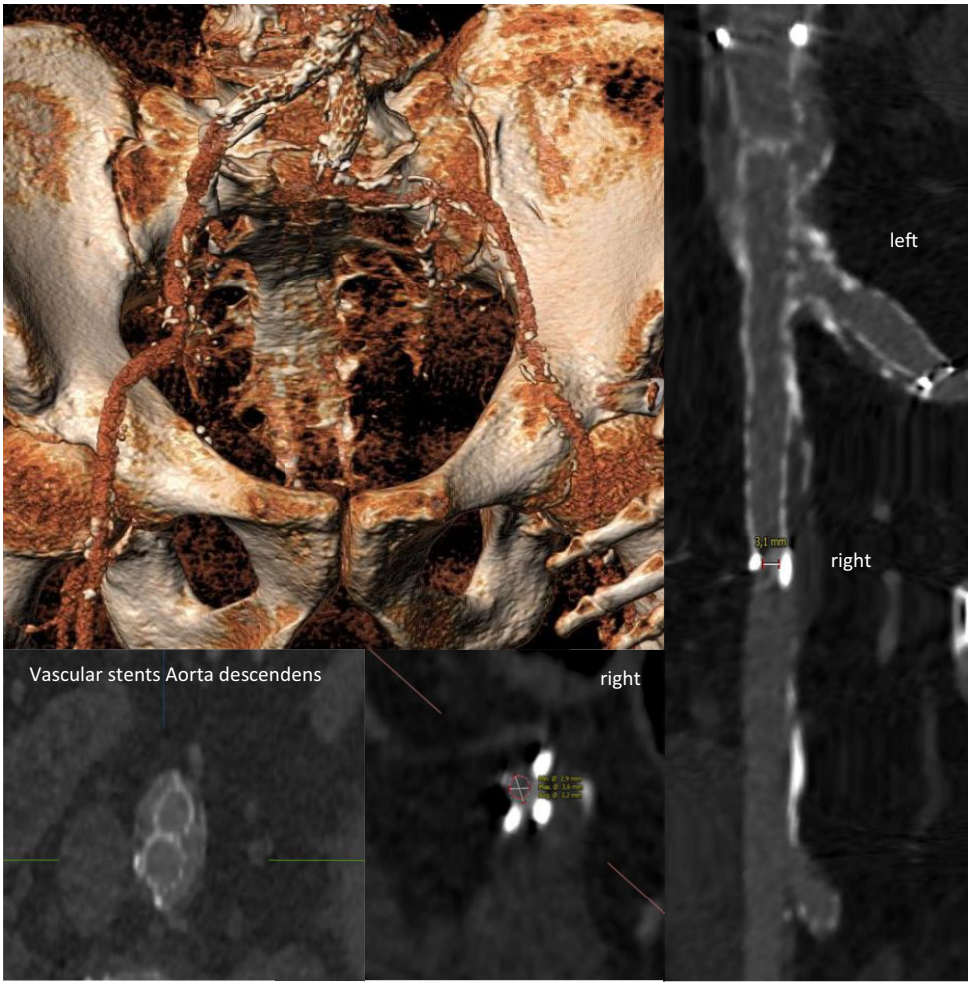

Figure 1 Computed tomography scan of ilieo-femoral axes showing existing stents (undersized) and bilateral calcified stenosis.

the subclavian artery. After device sheath removal, we observed a partial closure device failure with significant residual bleeding (*Figure 4F*, Supplementary material online, *Video S4*). Due to relevant und unstoppable bleeding, we decided to advance a covered stent (7 39 mm, Viabahn VBX ballon-expandable endoprosthesis; Fa Gore) for arteriotomy closure with final expansion to 10 mm with an additional Ballon. Haemostasis was confirmed by selective angiography (*Figure 4G* and *H*, Supplementary material online, *Video S4*). After removal of the brachial sheath, a plug-based closure device (Femoseal Vascular Closure Device 7 Fr, Terumo Europe) was used for successful haemostasis. An echocardiogram 1 day later showed significant improvement of LV function (45% ejection fraction) and a mean transvalvular gradient of 10 mmHg. 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 is 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 cut-down. In the 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, ballon-expandable stent because of significant residual bleeding at the puncture site and Proglide failure. The most favourable characteristic of this stent, particularly for peripheral vascular interventions, is the wide size range of up to 11 mm

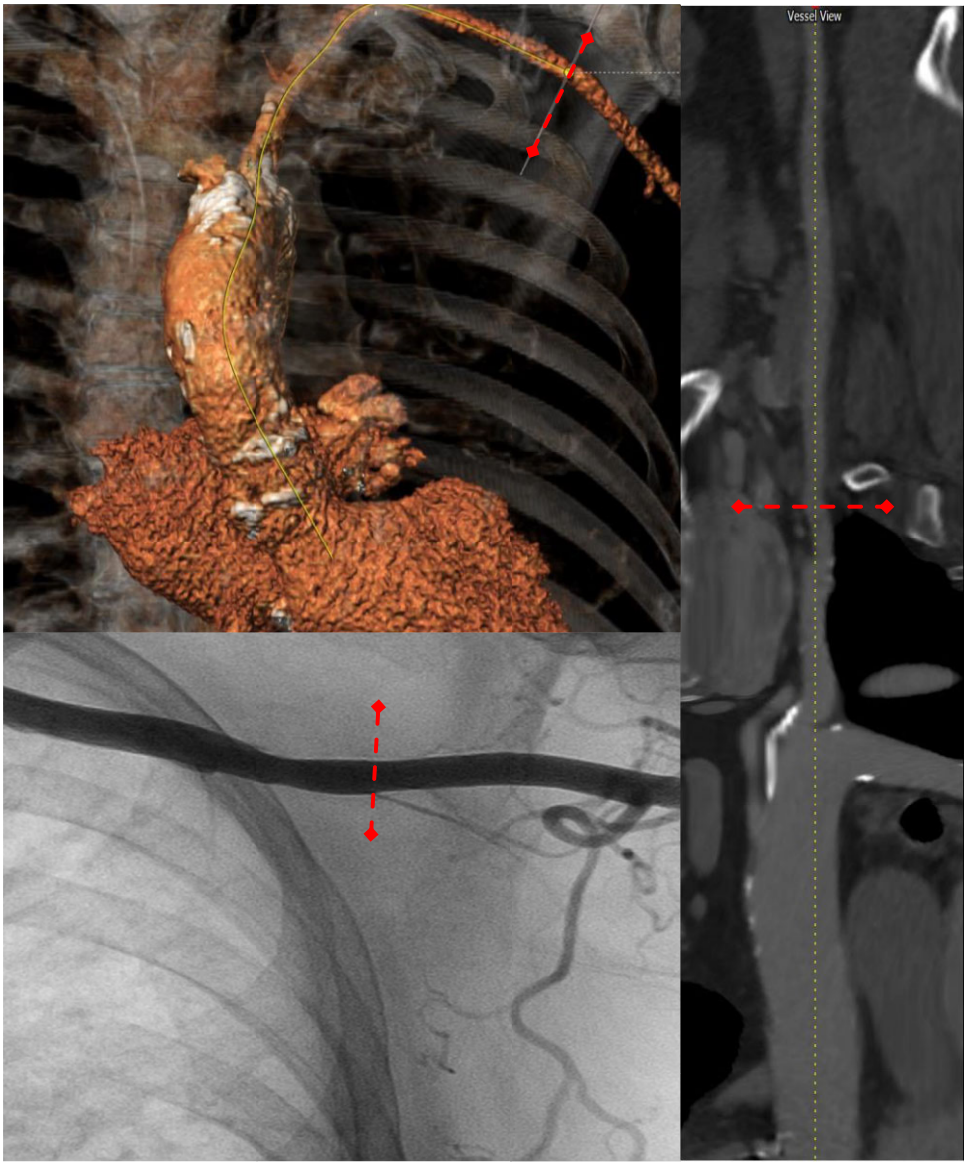

Figure 2 Planning computed tomography scan and angiography of the puncture site left axillary artery ideal puncture area (dotted line) at a distance to the lateral border of the rib cage to prevent artificial puncture of the pleural cavity.

with dedicated balloons and a 7 Fr sheath access. Thus, there is an increased likelihood of successful haemostasis.

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 proved to be a viable secondary option in these challenging, high-risk patients with TAVI. 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 unfavourable 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 are lacking and possibly represent an area for future study.

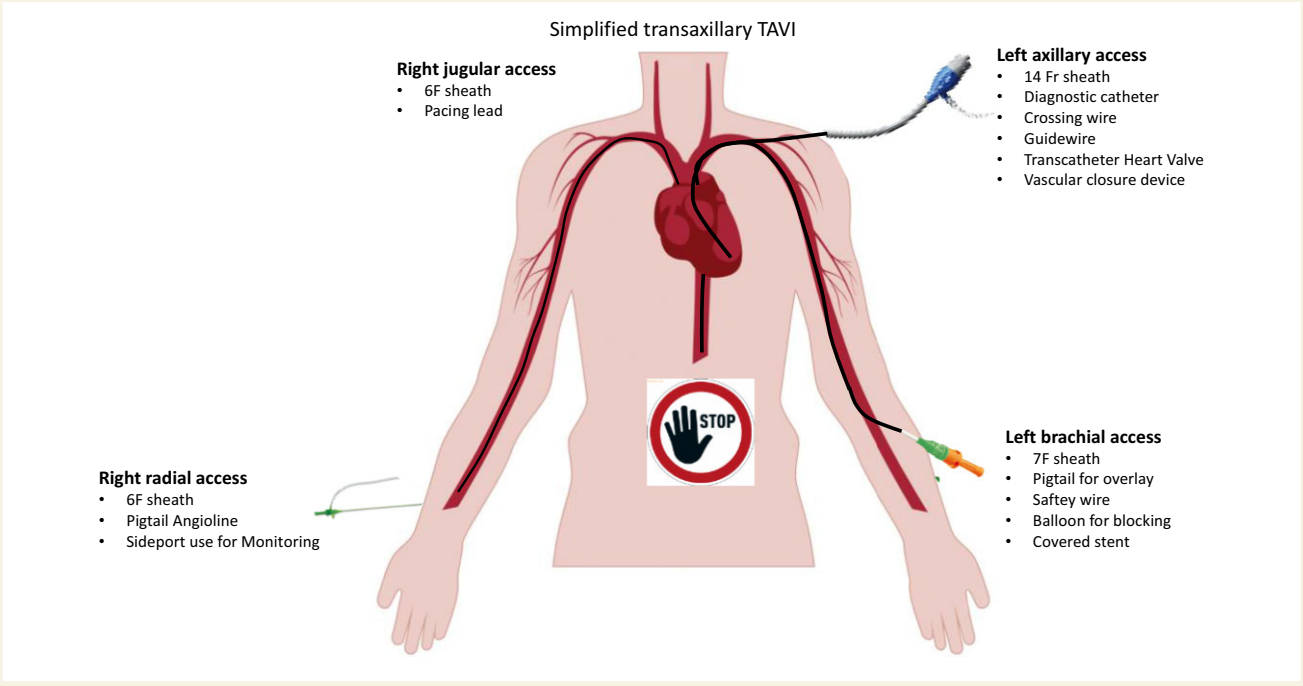

Figure 3 Schematic overview for non-transfemoral transaxillary transcatheter aortic-valve implantation from left axillary access with safety net devices.

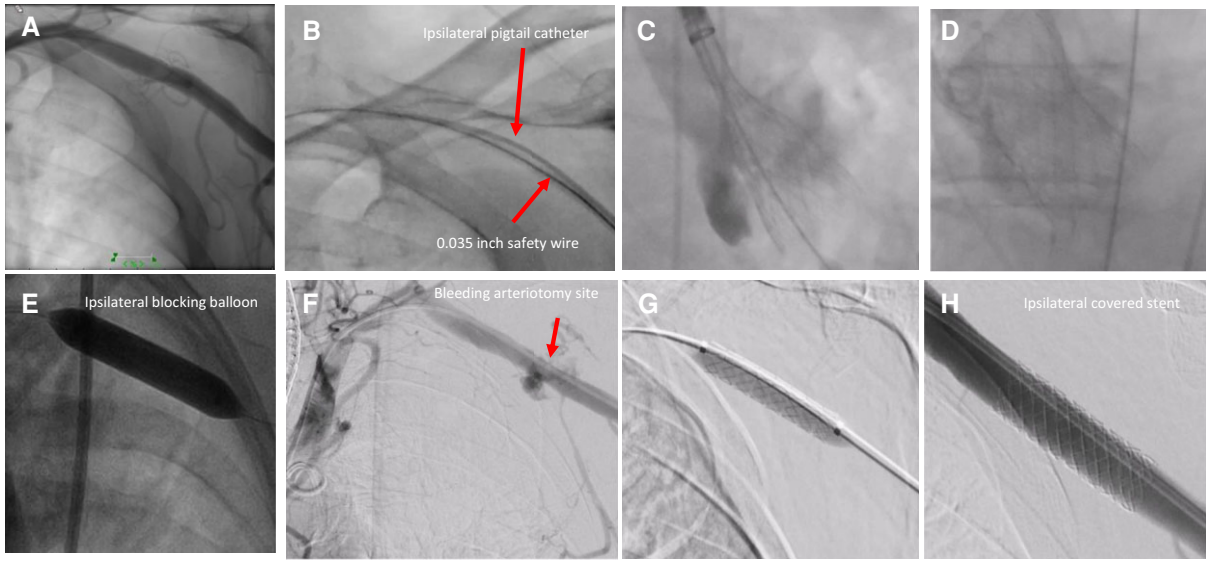

Figure 4 Main procedural stages: ipsilateral balloon occlusion after sheath removal; ipsilateral covered stent implantation using safety wire concept. (*A*) Angiography A. Axillaris, (*B*) Pigtail catheter from ipsilateral and safety wire, (*C*) EvolutR 29 3 cusp view, (*D*) fully implanted EvolutR 29, (*E*) blocking balloon after sheath removal, (*F*) residual bleeding after failure of 2 Proglides, (*G*) sucessful covered stent implantation, and (*H*) final angiography without residual bleeding.

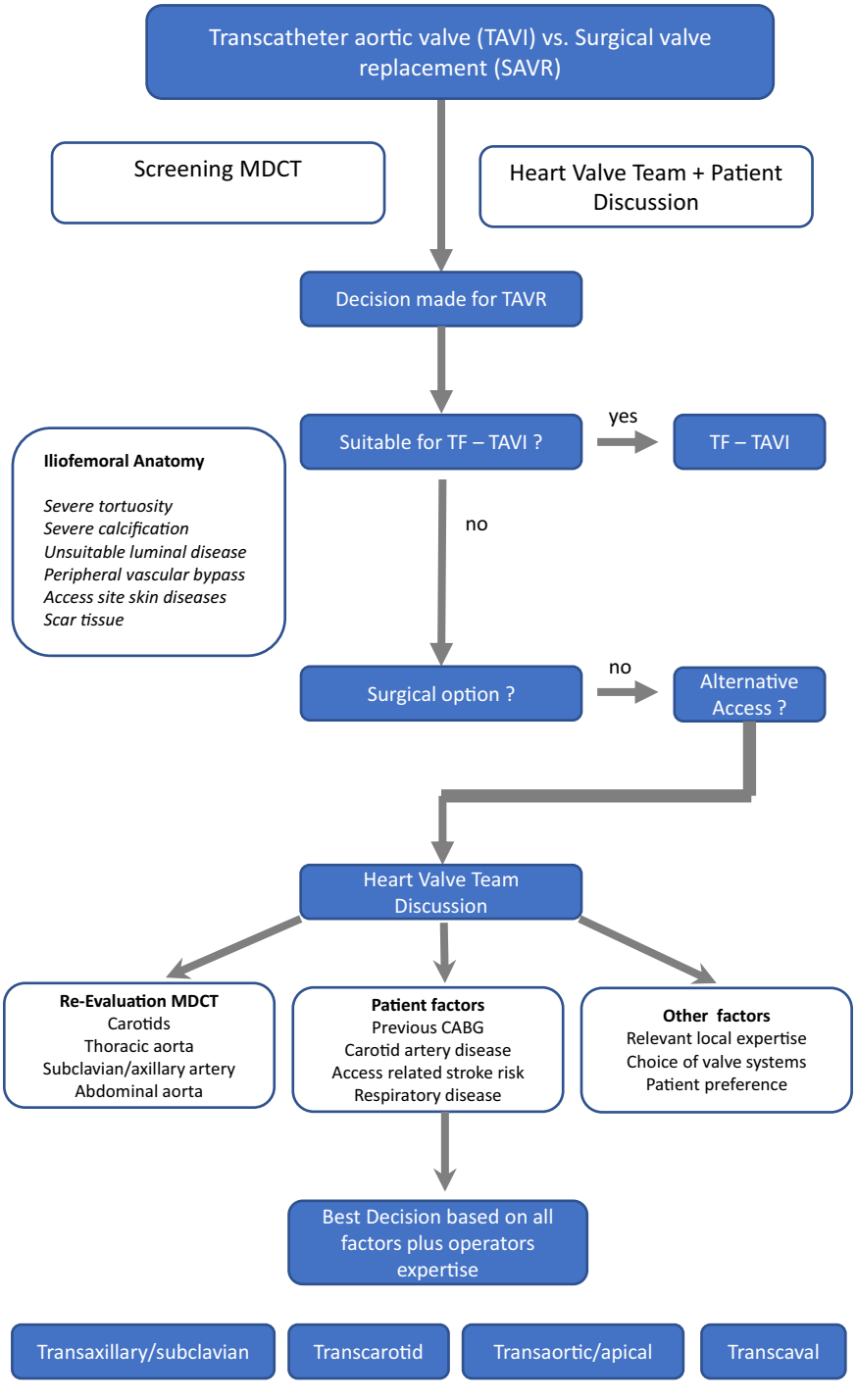

Figure 5 Algorithm for deciding access TAVI.

Lead author biography

Philipp Lauten is an interventional cardiologist at the Heart Valve Center, Bad Berka, Germany. Transcatheter heart valve therapy and coronary interventions were his main work focus under the mentorship of Prof. Mohamed Abdel-Wahab at Heart Center, Leipzig. Now he leads the structural and valvular disease programme as a senior consultant.

Supplementary material

Supplementary material is available at *European Heart Journal – Case Reports* online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

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.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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