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A Step-by-Step Guide to Fully Percutaneous Transaxillary Transcatheter Aortic Valve Replacement

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ABSTRACT

Transcatheter aortic valve replacement (TAVR) is now established as a viable therapy for the treatment of severe aortic stenosis. Though femoral access is used for the majority of cases today, this approach may be limited in cases of insufficient vessel caliber, tortuosity or severe iliofemoral disease. For such scenarios, a transaxillary (TAx) approach is appealing as this vessel appears to be far less frequently affected by atherosclerotic disease, even in the presence of significant iliofemoral disease. Though surgical cutdown has been the traditional method for the TAx approach, there has been a growing clinical experience with successful percutaneous transaxillary access in the setting of TAVR and mechanical circulatory support devices. In this review, we offer a step-by-step guide to TAx TAVR.

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KEYWORDS Alternative access; percutaneous; transcatheter aortic valve replacement; transaxillary

Introduction

Transcatheter aortic valve replacement (TAVR) is now established as a viable therapy for the treatment of severe aortic stenosis. Greater than 90% of cases in the United States today are performed via percutaneous access of the common femoral artery.^{1,2} Despite incrementally smaller TAVR delivery systems, femoral arterial access can be challenging or unacceptable due to diminutive vessel caliber, significant calcification and atheroma, or severe tortuosity between the arteriotomy and the native valve. For such patients, an alternative approach to TAVR is required. Multiple approaches have been described, including transapical, direct aortic, transcarotid, transcaval, transsubclavian, and transaxillary (TAx).^{3–6}

Percutaneous access of the axillary artery (AA) for large bore access is attractive as it requires relatively little additional equipment and is easy to monitor for complications. Thus, for those considering percutaneous TAx TAVR, we offer this step-by-step guide (Table 1).

Discussion

Planning

Planning percutaneous TAx access requires thorough understanding and careful assessment of the anatomy of the axillary vessel using multimodality imaging.

Anatomically, the AA begins as the subclavian artery, which courses above the first rib before taking an infraclavicular course, where it emerges from behind the clavicle as the AA. The AA then courses posterior to the pectoralis minor muscle toward the axilla. The first segment of the AA (distal to the clavicle and proximal to the superior border of the pectoralis minor muscle) is the optimal segment for percutaneous access due to a relative paucity of vascular branches. In this segment, the brachial plexus is also a discrete bundle lying cranial to the axillary without significant branches (Figure 1). Puncture here is also advantageous as it is compressible against the second rib when required (Video 1-available online). From the skin, this segment of the axillary artery lies inferior and lateral to the clavicle and medial to the deltopectoral groove on the chest, conceptually similar, though mildly cephalad, to where one would insert a permanent pacemaker or a subclavian central line.

Screening for AA suitability is best performed using the high-resolution computed tomography (CT) scan. Ideally, the CT window should be wide enough to capture both axillary arteries and high enough to screen the ostial or proximal segments of the left vertebral. Reformatting, as typically performed for the iliofemoral vessels, should be performed for the AA and subclavian. Take note that the typical TAVR CT protocol is performed with the arms raised above the head, which frequently creates the illusion of moderate stenosis, kinking, or tortuosity in the

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 Table 1. Step-by-step guide to fully percutaneous.

	Considerations
1. Planning	 (1) CT reconstruction of bilateral subclavian/axillary arteries if possible (2) Arterial duplex studies in the absence of CTA data (3) Consider: (a) vessel size, calcification, tortuosity (b) angle with the aortic arch (c) dependence on LIMA vs RIMA (d) angle of the aortic valve (e) patient handedness
2. Room setup	 Sterile table placed perpendicular to shoulder on chosen access side Radpads on chosen shoulder to limit radiation scatter Plethysmography probe distal to access site with signal visible to operator Monitors placed just cranial to sterile table facing patient's feet to allow operators to work side-by-side at perpendicular table
3. Access	 Obtain additional 6 Fr arterial access (ideally femoral) Position 0.018" wire to distal brachial across access site Position peripheral balloon in proximal subclavian for hemostatic control Fluoroscopic/ultrasound guided micro puncture access Pre-closure with two Perclose devices Re-establish access with an 8F sidearm sheath in the axillary
4. TAVR sheath insertion	 Cross aortic valve and measure hemodynamics Place exchange-length stuff wire into left ventricle Remove 8 Fr sheath Peripheral balloon inflations for hemostasis during dilations Insert TAVR sheath under fluoroscopy taking care around the subclavian flexure (Edwards E-sheath logo facing down) Deliver sheath into the ascending aorta (sheath will hang outside the body)
5. TAVR valve deployment	(Edwards SAPIEN 3 valve): (1) Load valve onto delivery balloon in ascending aorta
6. Closure	 Peripheral balloon for hemostasis during sheath removal Tighten Perclose sutures Strategies for inadequate hemostasis: (a) Additional Perclose device (b) Temporary balloon tamponade with peripheral balloon (c) Manual compression with protamine reversal (d) 8F Angioseal (use with caution) Bailout options: (a) Covered stent graft (7 Fr access for 0.018" Viabhan) (b) Surgical repair
7. Post-TAVR	 Plethysmographic monitoring of access arm Frequent neuro/vascular checks by Nursing Avoid vigorous physical exertion of access arm (sling as "reminder") Avoid raising arm above shoulder (x ~ 1 week) Avoid lifting > 10 pounds with access arm (x ~ 1 week)

second segment of the AA. In the absence of co-localizing calcification, this can be considered an artifact and is typically distal to where one would plan to enter the axillary artery in any event. Additionally, due to the proximity of the clavicle and second rib to the subclavian artery and proximal AA, automated reconstruction software may incorporate some of the co-linear bony structures into the vessel creating the impression of significant anterior calcification of this segment (Figure 2). Careful review of the CT should be performed if the calcification is disproportionately present at the level of the clavicle, or otherwise follows the course of the bony structures only. Duplex ultrasound can be used to clarify in situations of uncertainty.

If a CTA cannot be performed due to chronic kidney disease or did not sufficiently capture the subclavian and axillary arteries, arterial duplex ultrasound may be obtained to assess vessel caliber. Duplex will not provide the same level of detail, specifically regarding vessel tortuosity, or angulation with the aorta. Invasive angiography is another option. This method may underestimate calcification but is very good for assessing 2-dimensional caliber, tortuosity, and atheroma burden.

Choosing between right or left AA requires consideration of several factors. In general, the left AA is preferred as it allows for better co-axial orientation of the TAVR prosthesis in the aortic annulus. It also decreases the chance of carotid compromise relative to the right innominate artery. Other factors to consider include the aortic annular angle and the angulation of the takeoff of the subclavian/innominate artery from the aortic arch (both derived from CT analysis). An angle > 30° between the annular plane and horizontal axis (i.e. a "horizontal aorta") typically means a more difficult right-sided approach due to challenges achieving a co-axial approach. For similar reasons, patients with a type 1 arch, in which all three great vessels originate from the transverse arch rather than the ascending aorta, may be more difficult to



Figure 1. (A) Human cadaveric dissection of left axillary artery. (B) An enlarged view of the same anatomy showing the ideal target zone for micropuncture entry in the first segment of the axillary artery (proximal to the branch point of the thoracoacromial artery; blue circle).

approach via right-sided access (especially if the innominate originates distal on the arch). On the other hand, left-sided access may be more challenging if the left subclavian artery is retroflexed towards the descending aorta. Lastly, the patient's hand-dominance and/or dependence on internal mammary grafts should also be considered in the decision-making. In general, without significant prior experience, we would suggest the left axillary artery should be chosen preferentially as it more closely mimics transfemoral access. The remainder of the article will be written presupposing left-sided axillary access though can be mirrored for use during right-sided access.

Room setup

Appropriate room setup is essential to facilitating this procedure. Ideally, for left-sided access, a sterile table should be placed at the patient's left shoulder extending perpendicular to the bed with the fluoroscopic camera on the opposite side of the patient (Figure 3). RADPAD protective drapes (Worldwide Innovations & Technologies, Inc., Lenexa, KS, USA) are placed around the left shoulder area to block radiographic scatter. A plethysmography probe should be placed on the patient's left index finger and the waveform should be visible to the operators throughout the case. Ideally, the fluoroscopic monitors should be positioned above the patient's left shoulder facing the feet. This allows the operators to stand side-by-side at the perpendicular extension table as they would in a femoral access case. If the monitors cannot reach, positioning along the patient's right side is also feasible.



Figure 2. (A) Automated axillary CT reconstruction showing artifactual calcium detection in the left axillary artery (blue arrow). (B), (C) Curved reconstructions of right (B) and left (C) axillary arteries in the same patient showing minimal calcification in these vessels.



Figure 3. Ideal room setup for a left percutaneous axillary TAVR case.

Access

Initially, standard 6 Fr femoral access is obtained. An initial angiogram of the left axillary is performed if tolerable based on kidney function (Video 2-available online). We use a Judkins Right 4.0 to engage the ostium of the left subclavian and perform angiography. A 260 cm 0.018" Platinum Plus wire (or equivalent) is directed into the distal left brachial artery and the JR4 is removed leaving the wire in place. This step ensures vascular protection and also serves as a fluoroscopic marker for percutaneous puncture. In the absence of adequate femoral access, ipsilateral radial access may be obtained but is less ideal as retrograde angiography is less revealing and bailout strategies are restricted. Half dose heparin should be provided at this juncture. A metallic instrument on the skin is then used to outline the course of the artery relative to the 0.018" wire by fluoroscopy (Figure 4). Tracing a line on the skin along the instrument reflecting the course of the wire will help the operator remember to puncture with a cranial bias (typically towards the patient's contralateral ear). Micropuncture access is then performed using the modified Seldinger technique, with fluoroscopy and ultrasound guidance (Figure 5). Generally, skin puncture is performed just medial and inferior to the shoulder prominence in the deltopectoral grove.

A small, 5–6 mm incision is made at the access site and the subcutaneous tract is dilated with a hemostat followed by a 6F dilator. The arteriotomy can safely be managed using a vascular pre-closure technique. For this purpose, we use two ProGlide devices (Abbott Vascular, Abbott Park, IL, USA) to "preclose" the vessel (Video 3—available online) though the vessel rarely tolerates angulation of the Perclose devices into the "10 and 2 o'clock" positions and mild rotation is sufficient. Importantly, these Perclose devices are deployed with the 0.018" wire in place. Trapping this wire within the Perclose knots is possible though rare. Further discussion on this topic will be provided later. Advanced Perclose users will note that the vessel does not feel as "rubbery" on pullback after the footplate is deployed. Gentle manipulation of the Perclose device in the axillary is therefore recommended.

Between catheter and device exchanges, manual pressure should be held medial and superior to the arteriotomy (typically just below the clavicle). Additionally, a 6–10 mm, 0.035 inch-lumen peripheral balloon with \geq 130 cm shaft sized to match to the diameter of the subclavian 1:1 may be positioned in the proximal subclavian artery over the 0.018" wire and inflated at low pressure (1–3 Atm) during catheter exchanges to provide temporary hemostasis. We no longer find this step necessary for routine catheter exchanges given the efficacy of manual pressure. If balloon hemostasis is used, the



Figure 4. Fluoroscopic view with metallic scissors aligned with the left axillary artery (0.018" wire as fluoroscopic marker). The course of the left axillary artery is then marked on the surface of the skin by tracing alongside the clamp.



Figure 5. Fluoroscopic view showing micropuncture needle entry into left axillary artery. The tip of the needle is seen just lateral to the border of the 2nd rib. Puncture at this location is advantageous for manual compression if needed. A puncture too proximal to the clavicle can create a difficult transition under the clavicle and above the rib in thin individuals.

plethysmographic waveform can be monitored for obliteration to ensure an adequate occlusion when inflating the angioplasty balloon.

TAVR sheath insertion

Following access and pre-closure, an 8 Fr sheath is then placed in the arteriotomy through which a standard catheter (AL1, JR4, etc.) is used to cross the aortic valve. We prefer crossing the aortic valve prior to TAVR sheath or delivery catheter insertion as these sheaths are relatively long for this access point and will hang outside the body (making preceding steps ergonomically challenging for operators). After crossing the aortic valve, standard hemodynamics are measured, followed by placement of a stiff wire in the left ventricle.

The 8 Fr sheath is then removed and the axillary arteriotomy is dilated to prepare for placement of the TAVR sheath or delivery of the Evolut system sheathless. A peripheral balloon may be used here to provide temporary hemostasis as described above. Sheath insertion must be performed carefully under fluoroscopy to avoid trauma at the subclavian flexure. In case of the Edwards E-sheath, the logo is faced towards the patient's head (sidearm towards the bed) per company recommendations to orient the seam towards the primary curvature of the subclavian, though this does not appear to be critical. The sheath should be delivered into the ascending aorta (Video 4-available online). The dilator may be removed while carefully leaving the wire in place. Kinking of the sheath at the subclavian curvature following dilator removal is possible though not common and easily overcome during valve delivery using a "push-pull" technique. For Medtronic Evolut-R, a sheathless insertion is recommended with special attention paid to

ensure the nose cone does not separate from the capsule around the flexure of the subclavian, a scenario that can increase the risk of subclavian injury (Video 5—available online). Valve delivery using the Medtronic Sentrant sheath is arguably more controlled but at 18F or larger, may be too large for the axillary artery.

TAVR valve deployment

Device deployment is relatively unchanged compared to transfemoral access with the exception of loading the valve on the balloon in the case of the Edwards SAPIEN 3 valve. This step is performed in the ascending aorta. At the point at which the valve is seen to exit the tip of the sheath under fluoroscopy, the nose cone of the delivery system is likely to already be across the native aortic valve (Video 6—available online). This does not appear to cause significant issues and loading of the balloon into the valve will draw the nose cone back into the ascending aorta. To create more room for valve loading, the E-Sheath may be drawn back into the proximal subclavian ostium but only after the valve has been advanced into the ascending Aorta. Valve deployment proceeds in usual fashion from this point forward (Videos 7 and 8—available online).

Closure

Following satisfactory valve deployment, the delivery system is removed. The peripheral angioplasty balloon should be advanced to the proximal subclavian and inflated during sheath removal for "dry field closure" (Video 9—available online). The Proglide sutures should be cinched after the sheath is completely removed. After the perclose sutures are cinched down, we perform final angiography of the vessel through the end-hole of the peripheral balloon with the wire still in place by adding a Co-Pilot to the end of the balloon and injecting through it after tightening the valve on the end of the Co-Pilot in clockwise fashion (Video 10—available online).

Complication management

If complete hemostasis is not achieved, as with femoral access, further options include deployment of a third Proglide device, endovascular tamponade across the arteriotomy site with the peripheral balloon (typically for 3-5 minutes), or external manual compression in combination with protamine administration. If the peripheral balloon cannot be advanced to the access site, consider that the 0.018" wire may have been trapped under the perclose suture (since it was in place during deployment). A buddy wire should then be advanced past the access point to the brachial artery and ready delivery of the balloon to the arteriotomy on the second wire confirms that the first wire is trapped under the Perclose suture and should be removed (we have found this to be quite rare). If these options are ineffective, stent grafting (our preference of a 0.018" Viabhan system requires femoral sheath upsizing to 7 Fr) or open surgical repair may be pursued. Covered stent graft durability in this location may be rightly questioned as compression between the second rib and clavicle can ultimately lead to fracture or stenosis though

its immediate efficacy is quite good. This option should therefore be reserved for worst-case scenarios. In the setting of surgical repair, balloon tamponade should be maintained to provide the surgeon with a dry field to minimize the possibility of inadvertent injury to the brachial plexus.

We have not yet seen a case of thrombus formation in the AA during TAVR, but this has been noted following prolonged in-dwelling mechanical circulatory support device removal. Should it occur, if the thrombus is non-occlusive, conservative management with a heparin infusion (goal partial thromboplastin time [PTT] 60-80 seconds) for 48 hours is typically sufficient. If the thrombus is occlusive, restoration of flow is required and is often most readily achieved with angioplasty. We favor the use of a relatively long but modest caliber balloon (roughly 60% of the vessel diameter) for angioplasty in this setting so as to not "watermelon seed" the thrombus down the arm. Following restoration of flow, anticoagulation with heparin for 48 hours and close monitoring is typically sufficient given distal pulses are present. We have not seen lack of antegrade flow in the AA due to an antegrade dissection flap but such a scenario would presumably require angioplasty with a more aggressively sized balloon and/or tacking up the flap with a stent.

Post-TAVR

Post-procedure, plethysmography is monitored on the subtended hand while the patient is in the hospital to ensure vascular patency. The bedside nurse is also instructed to perform frequent pulse and neuro checks of the upper extremity for 6-12 hours post procedure. The patient is instructed to avoid pushing/pulling with the access arm while repositioning himself in bed, to avoid lifting his arm above shoulder height during the immediate post-procedural period, and to not lift anything over 10 pounds using that arm for 2 weeks (initially a sling may be used as a reminder as needed, though that is not our standard practice). We have noted one late bleeding complication and one pseudoaneurysm in patients immediately restarted on anticoagulation and currently try to avoid therapeutic anticoagulation for at least 1 week post-procedure based on these anecdotes though there are no data to support this decision.

Conclusion

Fully percutaneous TAx TAVR is an attractive alternative access option in situations that preclude standard transfemoral access. Large bore TAx access may be feasible in these scenarios in part due to the observation that the AA is far less frequently affected by atherosclerotic disease, even in the presence of significant iliofemoral disease^{7,8} and thus it is frequently a potential conduit when other vascular beds are inhospitable. It is, however, not a particularly large vessel^{7,8} and frequently will not accommodate a sheath 18 or 20 French in diameter. Historically, surgical exposure has been the predominant technique employed when utilizing the AA perhaps due to unfamiliarity with the thoracic upper extremity vessels, the misconception that the axillary artery is not compressible, or concerns regarding proximity to the brachial

plexus. Nevertheless, there are no convincing data supporting the superiority of surgical exposure for TAVR access in general.⁹ A small but growing clinical experience with successful percutaneous TAx access in the setting of TAVR and mechanical circulatory support devices has been demonstrated^{8,10-15} and serve as the basis for the increasing popularity of this approach. Apart from the transcaval technique, this is the only other fully percutaneous alternate access technique that has thus far been described. Both options have potential benefits and limitations and can be considered in the absence of femoral access. As with all alternative access, the percutaneous TAx technique requires careful consideration, planning, and execution to be successful.

Disclosure statement

James M. McCabe is a consultant for Edwards LifeSciences and Boston Scientific. The other authors have nothing to report. The authors received no extra-mural funding for this project.

References

- Jolly SS, Amlani S, Hamon M, Yusuf S, Mehta SR. Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: A systematic review and meta-analysis of randomized trials. *Am Heart J.* 2009;157(1):132–140. doi:10.1016/j.ahj.2008.08.023.
- Mehta SR, Jolly SS, Cairns J, et al. Effects of radial versus femoral artery access in patients with acute coronary syndromes with or without ST-segment elevation. J Am Coll Cardiol. 2012;60 (24):2490–2499. doi:10.1016/j.jacc.2012.07.050.
- Modine T, Sudre A, Delhaye C, et al. Transcutaneous aortic valve implantation using the left carotid access: feasibility and early clinical outcomes. *Ann Thorac Surg.* 2012;93(5):1489–1494. doi:10.1016/j.athoracsur.2012.01.030.
- Greenbaum AB, O'Neill WW, Paone G, et al. Caval-aortic access to allow transcatheter aortic valve replacement in otherwise ineligible patients: initial human experience. J Am Coll Cardiol. 2014;63(25):2795–2804. doi:10.1016/j.jacc.2014.04.015.
- Bapat V, Khawaja MZ, Attia R, et al. Transaortic transcatheter aortic valve implantation using Edwards SAPIEN valve. *Catheterization Cardiovasc Interventions*. 2012;79(5):733–740. doi:10.1002/ccd.23276.
- Walther T, Simon P, Dewey T, et al. Transapical minimally invasive aortic valve implantation: multicenter experience. *Circulation*. 2007;116(11Suppl.):I–5. doi:10.1161/ CIRCULATIONAHA.106.677237.
- Tayal R, Iftikhar H, LeSar B, et al. CT angiography analysis of axillary artery diameter versus common femoral artery diameter: implications for axillary approach for transcatheter aortic valve replacement in patients with hostile aortoiliac segment and advanced lung disease. *Int J Vasc Med.* 2016;2016:1–5.
- 8. Arnett DM, Lee JC, Harms MA, et al. Caliber and fitness of the axillary artery as a conduit for large-bore cardiovascular procedures. In press.
- McCabe JM, Huang P, Cohen DJ, et al. Surgical versus percutaneous femoral access for delivery of large-bore cardiovascular devices (from the PARTNER trial). *Am J Cardiol.* 2016;117 (10):1643–1650. doi:10.1016/j.amjcard.2016.02.041.
- Nakamura K, Krishnan S, Mahr C, McCabe JM. First-in-man percutaneous transaxillary artery placement and removal of the impella 5.0 mechanical circulatory support device. *J Invasive Cardiol.* 2017;29(5):E53–E59.
- 11. Schäfer U, Deuschl F, Schofer N, et al. Safety and efficacy of the percutaneous transaxillary access for transcatheter aortic valve implantation using various transcatheter heart valves in 100

consecutive patients. *Int J Cardiol*. 2017;232:247–254. doi:10.1016/ j.ijcard.2017.01.010.

- 12. Schäfer U, Ho Y, Frerker C, et al. Direct percutaneous access technique for transaxillary transcatheter aortic valve implantation: "the Hamburg Sankt Georg approach". *JACC: Cardiovasc Interventions.* 2012;5(5):477–486.
- Mathur M, Hira RS, Smith BM, Lombardi WL, McCabe JM. Fully percutaneous technique for transaxillary implantation of the impella CP. *JACC Cardiovasc Interventions*. 2016;9:1196–1198. doi:10.1016/j.jcin.2016.03.028.
- 14. Tayal R, Barvalia M, Rana Z, et al. Totally percutaneous insertion and removal of impella device using axillary artery in the setting of advanced peripheral artery disease. *J Invasive Cardiol.* 2016;28:374–380.
- Lotun K, Shetty R, Patel M, Arain SA. Percutaneous left axillary artery approach for Impella 2.5 liter circulatory support for patients with severe aortoiliac arterial disease undergoing high-risk percutaneous coronary intervention. *J Interven Cardiol.* 2012;25:210-213. doi:10.1111/j.1540-8183.2011.00 696.x.