Contemporary Assessment of Alternative Access Routes for TAVR

A summary of alternative access options to transfemoral access for TAVR procedures.

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Transfemoral (TF) access is the most comprehensively studied access route for transcatheter aortic valve replacement (TAVR) and is considered the gold standard. TF access is associated with excellent outcomes, including a high procedural success rate and a low rate of complications in contemporary studies. When compared with alternative access, TF access has been associated with lower 30-day and 1-year mortality.[1] Furthermore, TF access has been associated with improved early mortality when compared with surgical aortic valve replacement in intermediate- and high-risk patients.[2]

Multiple advancements have been made in the last several years that have expanded TF access to a larger population of patients who previously had been considered for alternative access. Delivery system profiles have improved, allowing transcatheter valves to be delivered through 14- to 18-F sheaths in vessels with minimum diameters of ≥ 5 to 6 mm depending on the valve size. As a result, the rates of TF access have increased while the rates of alternative access have declined.

Despite the dominant role of TF access, TAVR centers (especially larger ones) must maintain proficiency in alternative access options because they encounter a significant proportion of cases in which femoral access is not feasible for transcatheter valve delivery. The 2018 American Association for Thoracic Surgery, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons (STS) Expert Consensus Systems of Care Document for Operator and Institutional Recommendations and Requirements for TAVR cites the need for complex access as a reason for referral to high-volume centers.[3]

Nonfemoral access has historically been associated with inferior outcomes in patients undergoing TAVR. This is not surprising given the sicker patient populations in the early TAVR trials and the use of transapical or transaortic sternotomy access. It is unclear whether the procedure itself or the patients' comorbidities have driven these outcomes. Furthermore, advances have been made in alternative access, expanding options for access from extrathoracic sites. More contemporary data suggest that access from extrathoracic nonfemoral sites may have similar outcomes to TF TAVR.[4-6] This article summarizes the various transthoracic and extrathoracic alternative access sites for TAVR.

ALTERNATIVE ACCESS OPTIONS FOR TAVR

Transthoracic Routes

In the early days of TAVR, two transthoracic options (transapical and transaortic) quickly emerged as alternative access sites for TAVR, facilitating transcatheter valve implantation in patients with prohibitive iliofemoral access. The obvious advantages of these approaches include a direct route to the aortic valve annulus and the ability to accommodate large sheaths. However, primary drawbacks are secondary to hemisternotomy or thoracotomy exposure. Patients require general anesthesia, have increased postoperative pulmonary dysfunction, longer lengths of stays, and increased morbidity and mortality when compared with TF access.[7-10] For completeness, we review transthoracic options but strongly advocate against the use of transthoracic approaches in the modern era of TAVR given the increased risk of morbidity and mortality.

Transapical access. Transapical access, first reported in 2005,[7] is an off-pump procedure performed via a small, anterolateral minithoracotomy. The initial attraction to transapical access included the ability to deliver a larger delivery system without regard for the iliofemoral system or aorta, a coaxial delivery of the aortic valve via an antegrade approach, and the avoidance of traversing the aorta for valve delivery. Drawbacks include respiratory depression associated with a rib-spreading thoracotomy, direct myocardial injury, and access site complications. Transapical access has been associated with higher mortality and procedural complications when compared with TF access.[8,9] Although still feasible, the use of transapical access has continually declined due to access site complications at the apex and the introduction of lower-profile devices that have expanded the use of TF access and other alternative accesses.

Transaortic access. The first transaortic access was performed in 2009[7] and emerged as another viable site for alternative access for TAVR. However, like transapical access, the overall use of a direct transaortic approach has declined with the availability of superior options. Transaortic TAVR is an off-pump procedure performed via a small, right anterior minithoracotomy (if anatomy is suitable) or via a midline ministernotomy. Advantages are similar to transapical access while adding an approach that is familiar to cardiovascular surgeons; however, transaortic access is associated with less respiratory compromise (given lack of entry into the pleural space) and absence of direct myocardial injury. A minimum distance of 5 cm is required from the access to the aortic valve. Other anatomic limitations include a severely diseased or porcelain aorta or significant chest deformities. Compared with TF TAVR, transaortic TAVR is associated with a higher rate of 30-day all-cause mortality, stroke, and life-threatening or major bleeding, but a lower rate of major vascular complications.[7,10]

Extrathoracic Routes

Much like TF access, the use of nontraditional, extrathoracic sites for alternative access has increased over the last decade given the advancements of smaller sheaths and delivery systems for TAVR.

Transaxillary (transsubclavian) access. Transaxillary access for TAVR was first reported in 2008.[7] It is thought that most reported cases of transsubclavian TAVR occur below the clavicle and, therefore, represent transaxillary access. Advantages include a short distance from the access site to the aortic valve and the use of a peripheral vessel for access that is familiar to cardiovascular surgeons.[4,7] The axillary artery is frequently of adequate size for TAVR access (with a mean minimum luminal diameter of 6 ± 1.1 mm) and less likely to have severe stenosis or calcific disease than the iliofemoral system, making it an attractive option for alternative access.[11] Observational data suggested that 1-year survival is similar in patients undergoing TAVR via TF access compared with transaxillary access even though patients with transaxillary access had a higher EuroSCORE.[5,12] In the largest cohort reported to date, there was a lower rate of mortality, fewer new cases of onset atrial fibrillation, fewer new patients needing dialysis, and lower readmission at 30 days in patients undergoing transaxillary TAVR as compared with transapical or transaortic access.[4] However, the rate of stroke at 30 days was significantly higher in the transaxillary group versus TF group (6.3% vs 3.1%; $P = .0002$),[4] raising concerns about the effect of the delivery system traversing the left vertebral artery (with the left transaxillary approach) or right common carotid (with the right transaxillary approach). Overall, transaxillary access remains a well-studied alternative access technique with reliable results. Unfortunately, in practice, there remain patients who are not suitable for this access secondary to small friable subclavian arteries, tortuosity, potential patent internal mammary graft compromise, or other factors. In addition, this approach and exposure can be very difficult in obese patients.

Transaxillary access also offers the potential for a completely percutaneous alternative access. The feasibility and safety of this approach have been demonstrated in 100 consecutive patients in which hemostasis was achieved using preclosure with two Perclose ProGlide devices (Abbott).[13] In an analysis by Dahle et al, 19% of patients underwent a percutaneous transaxillary approach. There was slightly lower fluoroscopy use in patients undergoing surgical transaxillary access and longer intensive care unit length of stay in patients undergoing completely percutaneous access in this series; importantly, no other differences in procedural outcomes were reported.[4]

Transcarotid access. Transcarotid access, first performed in 2009,[7] is typically performed via direct cut-down to the carotid artery superior and medial to the sternocleidomastoid muscle (Figure 1). A percutaneous approach with local anesthesia has also been reported. Typically, duplex ultrasonography and CT are used to ensure the suitability of the carotid and to plan access. Intraoperative monitoring is performed via a neurologic exam (in awake patients), electroencephalography, and/or cerebral saturation monitoring. After cut-down is performed, cross-clamping can be performed to evaluate for cerebral ischemia. If ischemia is observed, femoral-to-carotid shunting may be initiated. Initial reports of transcarotid access came from observational reports from the French transcarotid transcatheter aortic valve implantation registry.[6,14,15] In the largest series, there was a 100% success rate but a 5.7% rate of cerebrovascular

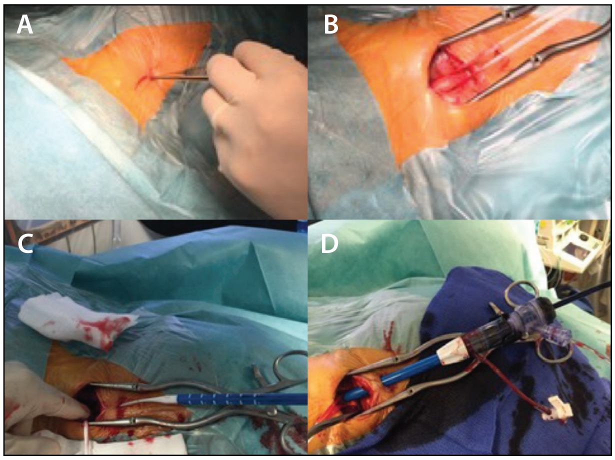

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Figure 1. Transcarotid incision along sternocleidomastoid (A). Exposure and isolation of right common carotid with vessel loop (B). Placement of delivery sheath through small cranially counter incision (C). Advancement of device and deployment through sheath (D).

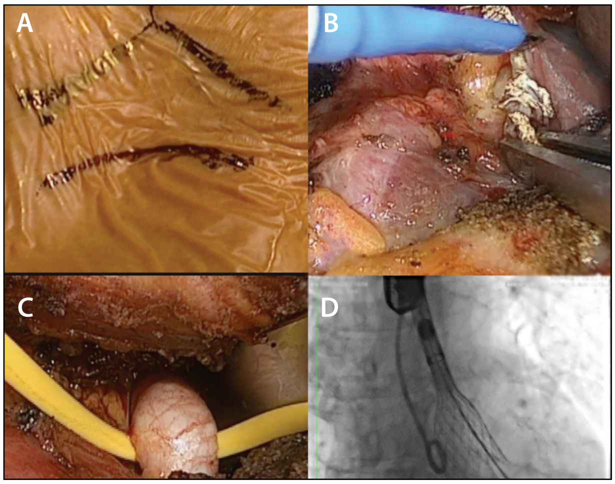

Figure 2. Suprasternal access. Curvilinear suprasternal incision (A). Division of the sternal-thyroid muscle off the right lateral aspect of the trachea (B). Isolation of the innominate artery with a vessel loop (C). Deployment of TAVR valve from suprasternal access (D).

events. However, in a more contemporary series from the United States, the stroke rate was 2.4% (similar to the rates seen in patients with transapical or transaortic access) with lower overall mortality than those with transapical or transaortic access.[16] A recent analysis of the TVT registry compared transcarotid with transaxillary access and found that transcarotid access was associated with significantly shorter operative and fluoroscopy times, shorter length of stay, lower volumes of contrast use, and a trend toward fewer strokes in the transcarotid group (4.2% vs 6.4%; $P = .07$).[17]

Transcarotid access serves as a very practical approach, with an exposure that most surgeons are comfortable and facile with. There remains a question of cerebral vascular events because the site of access is close to the carotid bifurcation, which is a typical site of atherosclerotic disease.

Suprasternal (transinnominate) access. Suprasternal access, first reported in 2011,[7] is performed through direct cut-down with direct delivery of the sheath or delivery system into the innominate artery. Although initially described using dedicated mediastinoscopy equipment,[18] suprasternal access may be performed directly via an incision just above the sternal notch (Figure 2).[19] Similar to the axillary artery, the innominate artery is typically spared from severe atheromatous disease. In the largest series reported to date, there was a 100% success rate, a 30-day survival of 98%, a low rate of reexploration for bleeding (3.6%) and major bleeding (1.7%), and no stroke or transient ischemic attack (0%).[19] Importantly, this was done with no prior workup with cerebrovascular MRI and with only intraoperative noninvasive cerebral saturation monitoring. As with other access sites, CT imaging is crucial for screening. Suprasternal access is not recommended for patients with anatomic exclusions such as aortic arch or innominate pathology, patients with distances of < 7 cm from the expected site of access to the valve plane, and those with severe kyphosis or large thyroid masses that limit exposure. Notably, patients with a previous sternotomy, tracheostomy, mediastinoscopy, or significant carotid disease are not excluded and can benefit from this approach.[19] We advocate this as our primary alternative access given its ease of exposure, almost universal applicability, and excellent results.

Modified TF Access Routes

Transcaval. Transcaval access, first performed in 2013,[20] is an innovative access technique in which percutaneous femoral venous access is achieved and used to again access the descending aorta via the inferior vena cava (IVC) using an electrified stiff coronary guidewire. After the creation of an IVC aorta communication, a stiff wire is inserted into the abdominal aorta, over which the delivery sheath is inserted. At the end of the procedure, a nitinol occluder device is used to occlude the aortic entry site.[7] Transcaval access has been met with significant excitement given the option of an alternative femoral approach. Planning with CT before the procedure ensures a > 1-cm area that is free from calcification or severe atheroma, suitable for crossing from the IVC into the aorta, and an adequate distance from the iliac bifurcation (> 1.5 cm). The rapid pressurization of the retroperitoneal space and shunting of blood from the aorta into the IVC is thought to explain the hemodynamic stability seen in the short period after sheath removal or in cases of persistent shunt.[7] The feasibility of this technique has been demonstrated in a cohort of 100 high-risk patients (mean STS score, 9.7%) in whom the technical success rate was 98%. Despite the high rate of technical success, procedural complications were high, raising some concerns for the safety of this technique. The overall rates of major vascular complications, life-threatening bleeding, and major bleeding were 19.2%, 12.1%, and 6.1%, respectively. The rates of these complications that were directly linked to the transcaval access were 13.1%, 7.1% and 5.1%, respectively.[7,20] Currently, on-site proctoring is recommended, and significant institutional experience may be required to consistently perform the procedure safely. Additionally, prospective data are needed to demonstrate the true learning curve, as well as more reassuring safety and outcomes data that may strengthen or weaken the utility of this procedure. There are also concerns about procedural cost, length, radiation exposure, and unknown natural history of the percutaneous large vessel closure and/or persistent shunting in patients being treated for aortic stenosis.

Intravascular lithotripsy. The introduction of intravascular lithotripsy (IVL) to facilitate TF access for TAVR has also emerged as a potentially disruptive technology, further increasing the rate of TF access use. IVL may allow femoral access in patients with calcific peripheral artery disease who were previously thought to have prohibitive stenosis (ie, 4–5.5 mm) in the femoral or iliac vessels.[21] However, the routine use of IVL in TF access cases requires a note of caution. Unlike traditional TF access, IVL has not been prospectively studied in large cohorts and robust outcomes data are lacking. Until these data are available, it remains unknown how IVL-assisted TF TAVR compares with either traditional TF access or other alternative access options for TAVR and, therefore, cannot be considered the standard approach.

A CONTEMPORARY APPROACH

Multidisciplinary valve referral centers should have expertise in at least one alternative access site. Current evidence demonstrates that extrathoracic access is strongly preferred to thoracic access; therefore, the roles of transapical or transaortic access are diminishing and outdated in contemporary TAVR practice. Reports of transaxillary access have been robust and have demonstrated similar outcomes when compared with TF access in patients with more comorbidities. However, similar outcomes have been demonstrated with transcarotid and suprasternal access, which are likely to grow if favorable data continue to accumulate. Based on the evidence presently available and our own experiences, we strongly favor suprasternal and transcarotid access in our practice given its reliability, simplicity, and broad applicability.

Alternative TF approaches are also evolving. Transcaval access is feasible, but there remains a significant learning curve, concerning data regarding bleeding risk, and an unclear natural history of residual large-vessel shunting. The role of IVL-assisted TF access may prove disruptive if prospective studies can demonstrate acceptable outcomes.

As operator experience and the body of evidence grow, we expect alternative access techniques to become further refined. As a result, more percutaneous access options will emerge. We would also expect to see simultaneous evolution toward a “minimalist alternative approach” to TAVR in patients with severe peripheral artery disease that precludes femoral access and necessitates an alternative approach. ■

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