Percutaneous Endovascular Aneurysm Repair: Current Status and Future Trends

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Abstract

Keywords

- ▶ percutaneous EVAR
- ▶ outpatient EVAR
- ▶ alternative access

Endovascular aneurysm repair (EVAR) is a common, safe, and effective method of treating abdominal aortic aneurysms. Traditionally treated via surgical cutdown over the common femoral arteries, many recent studies demonstrate percutaneous access techniques to avoid the surgical cutdown. Developing familiarity with these percutaneous techniques, including risks, complications, adjuncts, and alternative accesses, can help improve the outcomes and availability of EVAR. As these techniques become increasingly common, it is not unlikely that they can be practiced safely in select patients in an outpatient setting.

Endovascular aneurysm repair (EVAR) has become the most common form of treatment in the United States for abdominal aortic aneurysms (AAAs). First reported in 1991, EVAR involves placing an endoprosthesis into the aorta via imaging guidance to exclude an aneurysm and eliminate pressurization of the aneurysm sac. Multiple studies have been completed to compare the short-term and long-term outcomes of open surgical repair of AAAs versus EVAR. Data continue to suggest that EVAR is at least as safe and effective as open surgical repair in the long term, and likely more advantageous in the short term. Proven early benefits of EVAR include reduced operative times with decreased blood loss, decreased perioperative morbidity and mortality, and decreased ICU time and total length of stay.¹ The late complications of EVAR tend to be related to the development of endoleaks which require continuous surveillance and, often, additional procedures. This is a clear limitation of EVAR compared with open surgical repair in the long term, but some of these may be mitigated by newer devices.² A recent opportunity for further improvement in early EVAR outcomes has emerged with the advent of suture-mediated closure techniques allowing for fully percutaneous placement of endograft devices, potentially eliminating the need for arterial access provided by surgical cutdown.

Percutaneous Arterial Access and Closure

Traditional access for EVAR depends on a vertical or horizontal groin incision to be made over the common femoral artery

to provide open exposure. Via this open exposure, punctures can be made, large bore sheaths can be advanced, and the artery can be repaired under direct visualization after removal of the sheath. This can be done with the aid of vascular clamps to assist by temporarily limiting arterial blood flow to the site as needed. Previous studies have repeatedly demonstrated wound complication rates from open femoral access for EVAR to measure 14 to 22%.³ These comprise infections, hematomas, seromas, lymphoceles, thrombosis, dissection, nerve injury, and delayed healing. Real-world data from the NSQIP (National Surgical Quality Improvement Program) reviewed 14,868 patients who underwent common femoral artery exposure specifically for EVAR and demonstrated a 2.6% wound infection rate.⁴ Analysis demonstrated these complications occurred more frequently in patients who were younger, functionally dependent, smokers, female, of higher BMI, diabetic, or suffering from end-stage renal disease. Patients with wound infection had significantly longer length of stay, 7.3 versus 3.4 hospital days. Additionally, open femoral access has been shown to produce significant scar tissue potentially limiting future groin access for repeated interventions for endoleak treatment or further graft maintenance.⁵

The success of percutaneous EVAR (pEVAR) is excellent. Multiple studies suggest that there is no significant difference in technical success rate in EVAR procedures when comparing pEVAR to open femoral access. Success rates in both groups are expected to be in the 95% range.⁶ In pooled data, complication rates are demonstrably different. pEVAR

has a significantly decreased risk of wound infection, seroma, and lymphatic leak though, expectedly, an increased risk of pseudoaneurysm. No difference could be elicited in regard to hematoma, femoral occlusion, hemorrhage, or dissection.⁶ Recovery from completely pEVAR is also shorter with a significant difference in median length of hospital stay of 1 versus 2 days for open femoral access.⁷

Careful arterial access for pEVAR is of paramount importance. Access-related complications are the single leading cause of conversion from endovascular to open aneurysm repair.⁸ pEVAR is best initiated with a single-wall puncture of the anterior wall of the common femoral artery using real-time ultrasound guidance. Once the wire is upsized to a stiff 0.035-inch wire via micropuncture technique, a standard vascular sheath can be placed, generally a 6-Fr $\times$ 10 cm sheath will suffice. Given that upsizing to large sheaths will be necessary to permit the main body and contralateral limb delivery systems, "Preclose technique" is then employed to maximize the chances of a successful and safe percutaneous closure.⁹ Preclose involves the deployment of two Perclose Proglide devices (Abbott Laboratories, Abbott Park, IL) through a single arteriotomy; one footplate oriented to the 10 o'clock position and the second to the 2 o'clock position relative to the patient before firing the sutures. The sutures extending from the arteriotomy are identified and kept separate from each other during the remainder of the procedure. At the conclusion of the EVAR, as the sheaths are being removed, the devices are addressed in the order they were deployed, carefully tightening the sutures until hemostasis is achieved. Data suggest this is safe without heparin reversal,¹⁰ though some operators may choose to use protamine sulfate before sheath removal ($\rightarrow$ Fig. 1).

A key feature of this technique is the maintenance of wire access until both sutures are nearly completely tightened, which safeguards in case of failure. If bleeding persists, a third device can be deployed with the footplate remaining at the natural 12 o'clock position without any further rotation. Even with large sheaths, though, we have found the third device to be generally unnecessary. Further bailout options

at this point include the additional deployment of a plug-mediated closure device over the maintained wire access or contralateral access and careful deployment of a stent graft to cover the common femoral arteriotomy. Though deploying a stent graft in the common femoral artery clearly is not an ideal outcome, transradial, transcaval, and direct sac puncture methods are effective for treating subsequent type I and type II endoleaks if the common femoral artery is no longer accessible.^{11,12} The risks and benefits of these bailout strategies should be weighed against converting to surgical open femoral access and direct arterial repair.

Routine pEVAR access is via the common femoral arteries bilaterally. Close attention must be paid to the common femoral artery diameter. Small vessel diameter (< 5 mm) is associated with increased risk of procedure failure.¹³ The main body component delivery system can require up to a 24-Fr sheath; so, access sites for the main body and the contralateral limb sites must be appropriately evaluated. CT analysis data suggest that the best predictors of femoral artery access complications are the Sheath to Femoral Artery Area Ratio (SFAAR) and the Sheath to Femoral Artery Ratio (SFAR). Complications are more common when the SFAAR is greater than 1.35 or the SFAR is greater than 1.45.¹⁴ A 24-Fr Gore Dry Seal sheath (W.L. Gore, Newark, DE) has an outer diameter of 8.8 mm. Based on the ratio, complications may increase using this sheath in a vessel smaller than 6.1 mm. The mean and median CFA measurements for men are 9.9 and 9.7 mm, respectively, and both mean and median for woman are 8.2 mm, thus making it amenable to large bore percutaneous access. This measurement increases with age and body surface area.¹⁵ The size of the common femoral artery as well as its superficial location and easy compressibility make it an excellent access point for accommodating large sheaths.

Dealing with Heavy Calcium

Essential to any EVAR endograft planning is high-quality CT arteriographic images with postprocessing and three-

Fig. 1 (a). Demonstration of "Preclose technique" using the snare knot pusher devices from two previously deployed Perclose Proglide devices (Abbott Medical, Abbott Park, IL). (b) An image of bilateral large bore access sites for percutaneous endovascular aneurysm repair immediately after successful closure with the "Preclose technique."

dimensional reformatting. This proves just as crucial in planning for percutaneous access and closure. To minimize risk of procedural complication and maximize likelihood of procedural success, close attention must be paid to a size of the access vessel, anterior wall calcification at the proposed entry site, overall degree of vessel calcification in the path to the aneurysm, and iliac vessel tortuosity.

Care must be taken to avoid anterior wall calcification at the puncture site, as it is a known failure risk for the Proglide device.¹⁶ The suture is unable to be fastened to the arterial wall due to the inability of the needle to puncture the calcifications. Choosing a puncture location with the careful use of real-time ultrasound guidance should minimize access through calcified segments of the artery.

Heavy calcification of the iliac arteries also increases the risk of complication during EVAR. Major potential complications include rupture, thrombosis, distal ischemia, and dissection.¹⁷ Multiple techniques have been described to overcome the difficulties presented by these arterial calcifications. One such method described by Hinchliffe et al in 2007¹⁸ is the "paving and cracking" technique. If the common iliac arteries are not large enough to easily allow passage of the aortic stent graft, gentle balloon angioplasty is attempted to 10 mm. If this is unsuccessful, a 10-mm balloon-expandable stent graft is delivered to cover the diseased area of the common iliac artery extending distally to the external iliac artery, covering the origin of the internal iliac artery. Currently, VBX has become the most commonly used PTFE-covered stent graft (Gore, Flagstaff, AZ), but the iCast (Atrium, Hudson, NH) is also effective. The majority of patients who have such severely calcified iliac disease have highly stenotic or occluded internal iliac arteries, which can be covered without significant clinical sequelae. It is important to do so, however, as the most common point of rupture is the internal iliac artery bifurcation.¹⁸ The distal limb of the bifurcated aortic component can be extended into the iliac stent graft. The contralateral limb may or may not need a covered stent, as the delivery system is generally appreciable and smaller than that of the main body component.

A second method of overcoming heavily calcified iliac arteries involves the use of intravascular lithotripsy (IVL). Small retrospective studies¹⁹ and case reports²⁰ suggest that the use of Shockwave peripheral IVL balloons (Shockwave Medical, Santa Clara, CA) may safely and effectively dilate heavily calcified iliac arteries to allow passage of large bore aortic delivery systems through previously hostile iliac arteries. IVL is designed to create sonic pressure waves that pass through soft tissue to disrupt high-density calcium with significant shear stresses. This is done while a low-pressure angioplasty balloon is inflated to maintain contact with the arterial wall. Calcium is fractured in both the intimal and medial layers of the vessel which helps restore vascular compliance and mobility.²¹ Though early results are promising, further investigation is necessary to prove the benefit of this technique.

Alternative Arterial Access

Although the vast majority of pEVAR procedures can be completed via the common femoral arteries, occasionally

this is not possible. Additionally, some EVAR procedures necessitate additional accesses to address the unique anatomic challenges presented by certain aneurysms. Understanding the use of alternative arterial access sites is essential to have consistent success with entire pEVAR procedures.

Vatakencherry et al have shown that infrainguinal access can be safely and effectively performed with Preclose technique by puncturing an adequately sized superficial femoral or profunda femoris artery in cases of high femoral bifurcation.²² However, in some cases, upper extremity access may prove necessary. Brachial artery puncture can provide large bore access to the aorta from a cephalad approach. This can allow for more favorable catheterization angle for downgoing arteries, can be used to advance components for branches or snorkels in complex repairs, or to provide sturdy through and through wire access for extra support while advancing devices from femoral sheaths through diseased iliac arteries. Unfortunately, percutaneous brachial artery access is prone to complications. A retrospective series demonstrated a 6.5% complication rate for percutaneous brachial artery access which required 62% of those patients to return to the operating room for thrombosis, pseudoaneurysm, or hematoma.²³ Median nerve damage is an important and feared complication of brachial artery hematomas, but studies have shown it to be relatively uncommon occurring in 0.2 to 1.4% of brachial artery interventions.²⁴

It being imperative to minimize potentially serious complications of brachial artery access, the use of real-time ultrasound-guided access is essential. Left brachial artery access is almost always preferable, as it provides direct access to the descending aorta without crossing other arch vessels. Choosing a distal arterial access near the antecubital fossa allows for better control for eventual hemostasis. Ultrasound can help avoid puncturing a small radial or ulnar artery in this area in a patient with a high bifurcation. Micropuncture technique with a 21-g needle is recommended with subsequent upsizing to the appropriately sized sheath. Data suggest there is no difference in complication rates between 6 and 7 Fr sheaths in the brachial artery. The only proven independent risk factor for increased complication rate in brachial access is female gender.²⁵ Achieving hemostasis is most accomplished often via manual pressure. Using ultrasound-guided compression can help ensure adequate pressure is being applied directly over the arteriotomy site. Sheath removal can be done with or without reversing heparin depending on physician preference and ACT measurements. Multiple case reports and small series have been published which document efficacy of the use of arterial closure devices for brachial artery punctures.²⁶ These may save operating room time, but more rigorous studies will be necessary to prove acceptable safety for each proposed device. Understanding the mechanism of a particular device and using adjunctive ultrasound or fluoroscopy during deployment may increase the chance of a safe and effective closure.

With the increasing acceptance of the safety profile of radial artery access and availability of devices with longer

delivery systems and slimmer profiles, puncturing the radial artery rather than the brachial artery may be preferable for some pEVAR applications. Radial artery access allows for similar benefits of cephalad-oriented access as brachial artery access, but with lower risk of bleeding, easier hemostasis, shorter postprocedural monitoring times, and increased patient comfort. Of course, disadvantages of radial artery access exist and include limitations imposed by the smaller size of the access artery limiting sheath size and the increased distance from the aortic aneurysm reducing device options to those with sufficient delivery length. Failure to complete a planned intervention via radial access does occur in 1 to 5% of cases and generally due to unfavorable radial artery anatomic variations.²⁷ Transradial access is most favorable for body floss wire access or delivering smaller adjunct devices and stent grafts during adjunct EVAR procedures, such as while using snorkel technique²⁸ (► Fig. 2).

Similar to brachial access, the left radial artery is preferred due to the direct access to the descending aorta without crossing any other arch vessels. A theoretical risk of CVA does exist from this access technique, but large analyses have not shown there to be a significantly increased risk over transfemoral access.²⁹ Careful evaluation of the patient is crucial for radial access to limit complications including radial artery occlusion and hand ischemia. Fischman et al provided an outstanding review of radial artery access considerations³⁰ and conclude the only absolute contraindication for transradial access is Barbeau type D waveforms signifying an incomplete palmar arch with potential for digital ischemia. Bedside ultrasound can be used to follow the course of the radial artery in hopes of detecting radial artery anomalies, loops, or atherosclerotic changes that may increase the difficulty of the procedure. The use of smaller sheaths (5 vs. 6 Fr), the use of patent hemostasis, and, to a lesser degree, the use of anticoagulation have also been shown to decrease the risk of radial artery occlusion.³¹ The use of hydrophilic sheaths decreases the incidence of radial artery spasm and pain.³² The most commonly used sheath is the Terumo Slender Sheath (Terumo Interventional Systems, Somerset, NJ) given its hydrophilic coating and low-profile outer diameter while maintaining a large inner diameter. After ultrasound-guided single wall 21G puncture of the radial artery and placement of the sheath, a cocktail of drugs is typically given intra-arterially through the sheath to decrease spasm and potential risk of thrombosis. Different cocktail recipes exist, but generally contain nitrates, calcium channel blockers, and heparin. Fischman et al suggested 3,000 IU of heparin, 200 µg of nitroglycerin, and 2.5 mg of verapamil with ample hemodilution to reduce any painful burning sensation during the injection.³⁰ Patent hemostasis can be achieved via the TR band (Terumo Interventional Systems) which applies pressure to the arteriotomy via a balloon filled with air that can gradually be removed. This allows for maintaining patency of the radial artery while still providing adequate pressure for hemostasis at the arteriotomy site. Complications of radial access include hematoma, pseudoaneurysm, bleeding, radial artery occlusion, and distal embolization, but are rare.³³

Future Directions

Large devices used for TAVR (transcatheter aortic valve replacement) and TEVAR (thoracic endovascular aortic repair) have been introduced successfully via transcaval technique. This technique commences with femoral venous access when the iliofemoral arteries are not suitable for placement of large sheaths to deliver device components.^{34,35} Detailed preprocedural analysis is used to determine the location of a transcatheter puncture into the arterial system through which a large sheath can be laced and the intra-arterial procedure completed. The arteriotomy is then sealed with a nitinol cardiac occluder. A single trial of TAVR patients demonstrated success in 99 out of 100 patients with no failure or complication coming from the aortic tract site.³⁶ No reports have yet been published using this technique for EVAR, but it may allow certain EVAR procedures to be successfully and safely completed when otherwise impossible. Femoral vein punctures can be closed safely with the Preclose technique³⁷ or with prolonged manual pressure.

Device innovation in the aortic repair space is ongoing. Expandable sheath technology is promising when a slimmer profile is needed to traverse stenotic iliac arteries. Such a device would then expand safely expanding the iliofemoral arteries allowing for a larger straight path through otherwise tortuous or hostile arteries. The Solo Path (Terumo Interventional Systems) was an effective device, but was recalled by the Food and Drug Administration (FDA) recently. Undoubtedly, this device will reemerge, or similar devices will come to market. Comparing IFUs to patient demographics, further decreasing the profile of endograft components could increase the number of patients eligible for EVAR by 60%.³⁸ The FDA has approved two 14-Fr systems made by Cordis (Cordis/Cardinal Health, Dublin, OH) and Endologix (Irvine, CA), while the majority of other devices are at least 18 Fr.

Given the preponderance of evidence documenting the safety and efficacy of minimally invasive techniques for EVAR, potential exists for treating selected patients in an ambulatory surgical setting. A review of multiple recent publications demonstrates that patients can undergo elective short stay EVAR with a 70% success in achieving that plan. All major complications occurred within 6 hours of the completion of the procedure. Mortality rate was 0 to 1% and hospital readmission was 0 to 6%.³⁹ A study of 100 consecutive same-day outpatient EVAR procedures selected for asymptomatic patients who were expected to undergo minimally complex EVAR procedures and who live within 60 minutes of a hospital and had supervision at home for the first 24 hours. Four percent of this highly selected group ended up hospitalized for access vessel complications. Thirty-day readmission rate was 4% with zero 30-day mortality. Cost comparison demonstrated significant improvement in costs for the outpatient EVAR when matched against contemporary inpatient EVAR procedures.⁴⁰ These studies were completed outside of the United States as CMS (Center for Medicare and Medicaid Services) does not

Fig. 2 A 74-year-old man presents with an enlarging abdominal aortic aneurysm (AAA) and a pelvic kidney with the renal artery arising from the aortic bifurcation (a). Contrast injection demonstrates a large infrarenal aortic aneurysm (b). A patent renal artery is noted to arise just to the left of the aortic bifurcation (c). Percutaneous ultrasound-guided left brachial artery access was obtained and a 7-Fr sheath was placed (d). A wire was snared from via the brachial access (e) to achieve through and through wire access. The renal artery was selected from above with a wire and directional catheter (f). Final image demonstrates exclusion of the AAA with continued patency of the aberrant renal artery via use of a “snorkel” technique using VBX balloon-expandable stent grafts and a VIABAHN self-expanding stent graft (W.L. Gore, Newark, DE) (g). The brachial artery access was closed with “Preclose technique” in a similar fashion to the CFA access sites (h). The position of the footplate was monitored throughout the closure process with real-time ultrasound. The patient had mild asymptomatic ecchymosis the following day, but no hematoma or pseudoaneurysm on follow-up duplex ultrasound. Follow-up CT imaging 6 months later (i) demonstrates effective exclusion of the aneurysm with continued patency of the renal artery and brisk renal enhancement. The patient’s serum creatinine remained stable.

reimburse for EVAR procedures completed outside of the hospital, whether in an ambulatory surgical setting or an outpatient physician office setting.

Conclusion

Percutaneous endovascular access has been shown to be a safe and efficacious method of delivering the large bore sheaths necessary to treat AAAs. Careful preprocedural patient selection and planning, meticulous ultrasound-guided arterial access, and vigilant closure of the arteriotomy sites lead to excellent published results. Common femoral artery access is the standard route for percutaneous access, but a skilled vascular interventionalist should be familiar with multiple adjunct and alternate routes and the manner in which to employ them safely. As devices and techniques continue to improve and percutaneous access becomes standard, it seems reasonable that same-day ambulatory EVAR in an outpatient setting will become permissible and reimbursed by CMS for highly selected patients who fit strict safety criteria.

Conflict of Interest

The author has no conflict of interest to report.

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