AN INTERVIEW WITH…

# Brant W. Ullery, MD, FACS

Dr. Ullery discusses his approach to challenging EVAR scenarios, improving post-EVAR surveillance, and thoughts on the current CLI landscape.

**How great a role does challenging vascular anatomy play in your decision to undertake endovascular aneurysm repair (EVAR)? What techniques do you use to overcome these challenges when EVAR is otherwise considered to be the best option for the patient?**

With the growing armamentarium of newer-generation devices, procedural adjuncts, and increasing comfort and acceptance of off-label techniques, I believe the issue at hand is not simply whether we *can* perform EVAR in a particular patient but rather if we *should* do it. For the overwhelming majority of patients who are plagued by limited life expectancy due to concomitant comorbidities, the answer to that question is a resounding "yes" in support of EVAR. Physiologic reserve (most often a function of comorbid burden) and acuity of presentation are far more influential in my decision matrix of whether to pursue an open or endovascular repair for patients with abdominal aortic aneurysms (AAAs) than challenging vascular anatomy alone. Elective open repair remains an excellent option for medically fit patients, particularly given the superior long-term data.

In patients with hostile iliofemoral access anatomy who are not open surgical candidates, I have a low threshold for placement of endoconduits and have found these to virtually eliminate the need for iliac conduits in my practice. Narrow distal aortas (< 14 mm) and high-grade iliofemoral stenosis generally prompt me to further interrogate the limbs of conventional aorto-bi-iliac stent grafts to minimize the risk for limb occlusions. Intravascular ultrasound (IVUS), with or without the addition of arterial pressure gradients, is universally employed in such cases. I also ensure that completion angiography is performed without stiff wires in place (replacing these for floppy wires or catheters) to restore the native anatomy as much as possible. Reinforcing stents may be required within the iliac limbs to achieve suitable diameter (I generally aim for a minimum limb diameter of 7 or 8 mm as measured by IVUS). In addition, bends or kinks in the mid or distal limbs may require extension using either covered or uncovered stents to "soften" the arterial angle (akin to extending covered renal stents with self-expanding bare-metal stents during fenestrated EVAR cases with acute bends of the renal artery).

With regard to challenging neck anatomy, this remains an exciting area in our field. I personally straddle the fence on the fenestrated versus chimney/snorkel debate. Although, in general, on-label techniques are always preferred, both of these established techniques have clinical merit and have shown no difference in short- or midterm outcomes to date. The ongoing dichotomous debate is too simplistic in my view. The harmonious attributes of both techniques should be appreciated in complex suprarenal and thoracoabdominal cases where combined fenestrated and chimney approaches assist in overcoming many of the limitations of each individual technique. Growing real-world application of physician-modified endografting and the relatively recent FDA approval of Heli-FX EndoAnchor implants (Medtronic) for short-neck AAAs adds further dimension to the treatment approach to patients with complex AAAs.

In those for whom an endovascular approach is deemed most suitable despite the presence of challenging vascular anatomy, several anatomic and patient-related variables guide me as to the optimal treatment strategy, including renal artery orientation, access anatomy, acuity of presentation, baseline renal function, life expectancy, infra- and suprarenal aortic angulation, renovisceral ostial occlusive disease, and status of the thoracic aorta and upper extremity arterial tree.

**How does the finding that caudally directed renal arteries have a lower risk of endoleak after chimney EVAR affect your clinical decision-making and follow-up? What techniques might be done to overcome high takeoff angles within the seal zone to lower the risk of early type Ia endoleaks?**

My Stanford colleagues and I have previously interrogated many of the procedural components, as well as some of the perceived long-term failure mechanisms of the chimney technique. We confirmed that caudally directed renal arteries are not only more procedurally efficient with regard to ease of antegrade cannulation but they also result in more favorable polar geometry (cranial-caudal) with respect to gutter-associated type Ia endoleak risk. In fact, we found that chimney grafts traversing > 90° in polar angle within the seal zone have an

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11-fold higher odds of type Ia endoleak on initial postoperative CT scan compared with chimney grafts oriented more cranial-caudally. We opine that greater polar angle trajectories within the seal zone lead to improper mating between the chimney graft fabric and the fabric/struts of the main body endograft. Therefore, improving the molding step of the procedure (eg, triple-kissing balloon angioplasty) may be one critical area to refine.

In recent years, I find myself universally employing the "eye of the tiger" technique for all chimney stent configurations, whereby my final balloon molding step is performed using a balloon in the parallel stents that is 1 to 2 mm smaller in diameter relative to the original size of each balloon-expandable chimney stent. This added step is intended to make the cross-sectional configuration of the chimney stents more elliptical, thereby reducing the residual area between the parallel stents and corresponding risk of gutter-related proximal endoleak. In addition, I recommend oversizing at least 20% to 30% of the aortic main body to further optimize the mating between parallel stent grafts and decrease the potential for gutters. For patients with cranially directed renal arteries who are not anatomic candidates for fenestrated EVAR, one can consider elongation of the chimney stents (so-called neck lengthening) or reinforcement of the chimney stents with self-expanding stents to maximize the mating between the parallel stents and potentially overcome the increased risk of gutter endoleak in these anatomies.

Our previous work demonstrated that the natural history of gutter endoleaks may be more benign than originally thought, as evidenced by the fact that nearly 90% of gutter-related endoleaks in our early experience spontaneously resolved within 18 months. Nevertheless, we continue to maintain a rigorous surveillance imaging protocol for all of these patients, which includes cross-sectional and duplex imaging of the aorta and chimney stents, as well as serum creatinine levels.

## Can you describe your treatment algorithm for patients with AAAs and various levels of renal impairment?

It is widely believed that preoperative renal impairment is associated with increased risk of postoperative acute renal function decline. Given that postoperative acute renal failure is associated with higher perioperative mortality, treatment for patients with AAAs who have concomitant baseline renal impairment requires special considerations.

A paucity of data exists regarding the optimal methods to prepare patients for open or endovascular AAA repair. In emergency cases involving ruptured or symptomatic AAAs, there is no specific role for such preventive measures. The presence and severity of renal function decline often serves as one of several important variables to consider when deciding whether to offer treatment and has important implications with regard to technical considerations during repair. A surprisingly common scenario is an unstable patient with an AAA who has baseline renal impairment and hostile neck anatomy. The internal debate for the surgeon is whether to "go for the gold" with complex EVAR in hopes of both successfully excluding the aneurysm and maintaining renal artery patency (which increases operative time, contrast usage, and potentially prolongs the period of hemodynamic lability) or, alternatively, focus primarily on rapid exclusion of the aneurysm even at the potential cost of sacrificing one or more renal arteries to obtain adequate proximal seal. Every case is unique, but my primary goal is always rapid aneurysm exclusion in these cases. Younger, more independent patients with less severe baseline renal impairment are those in whom renal artery preservation more strongly permeates my operative objectives. For emergent infrarenal and juxtarenal AAAs, open repair is exclusively reserved for treating refractory intraoperative type Ia endoleaks in my practice. Thankfully, this situation is exceedingly rare.

In the more common elective setting, multiple proactive steps can be taken to minimize risk of exacerbating baseline renal issues in patients undergoing EVAR. These easiest initial steps are ensuring adequate perioperative hydration, avoiding hypotension, refraining from all potential nephrotoxins, and minimizing contrast usage. I personally use 50% diluted contrast in all patients, regardless of baseline renal function, and also have a low threshold to incorporate IVUS or selective wire catheterization to guide device deployment by marking the renovisceral and/or hypogastric arterial origins. These maneuvers alone provide the opportunity to generally use a total of 15 to 30 mL or less of contrast volume for most conventional EVARs. In select cases involving patients with severely impaired renal function who require either intentional coverage of an accessory renal artery or complex EVAR (ie, fenestrated or chimney), I consider stenting one or both of the main renal arteries at the index operation if there is concomitant renal arterial occlusive disease or, more commonly, I do this in a separate setting prior to EVAR. Reasons to selectively perform these adjunctive procedures are many and may include temporally separating the inherent increased contrast volume demands in these patients, partially offsetting the potential deleterious effects of accessory renal artery coverage by optimizing perfusion to the main renal artery, and to facilitate efficient renal artery cannulation during subsequent complex EVAR by treating ostial disease and marking the renal artery origins with stents.

**What do you say to patients to motivate them to return for all necessary follow-up imaging after EVAR?**

Multiple reports have shown that annual follow-up compliance after EVAR in the United States is significantly below recommended levels, most often cited at ≤ 50% at 5 years. This is particularly worrisome given that the late failure modes in EVAR (eg, delayed rupture) generally occur 6 years or more after EVAR. I believe both patient and referring physician education is paramount to achieve improvement in these figures. Even among patients who do return for scheduled follow-up, some arrive at the clinic very anxious because they have been told by their primary care provider or radiologist that their supposedly treated aneurysm is "leaking." The "endoleak" nomenclature is still not a widely recognized or fully understood concept across the broader medical community. I think this is a ripe opportunity for vascular interventionalists to educate patients and referring physicians starting at the initial clinical encounter.

In some ways, my tone in describing the disease process and risks/benefits of EVAR is similar to that for patients undergoing arteriovenous access procedures for hemodialysis. The general message for both is that these are safe and effective procedures, but both require close clinical surveillance due to a variety of early and late failure modes. Clearly defining these expectations up front to the patient, family, and referring physicians sets the foundation for a long-standing relationship rather than a simple transactional one that terminates at hospital discharge after the procedure.

It is important to note that elderly patients and those undergoing urgent or emergent EVAR are at greatest risk for being lost to annual follow-up imaging. Such patients are less likely to gain from the aforementioned benefits of a preoperative visit due to lack of social support or acuity of presentation. The lack of consensus regarding the perceived benefit of regular surveillance after EVAR in elderly patients adds additional complexity to achieving compliance with follow-up standards. Moreover, those undergoing nonelective EVAR are often treated outside of their established health care network. These two target patient populations invite an important opportunity for national quality improvement efforts to enhance care coordination across providers and health systems, as well as to incentivize appropriate follow-up imaging among those at highest risk for being lost to follow-up.

**As one of the Principal Investigators for the TRANSCEND trial studying paclitaxel drug-coated balloon use for peripheral artery disease (PAD), what are your thoughts on the changes made to the trial based on FDA recommendations? Have you personally changed your approach to treatment in this population since the long-term mortality signal was reported?**

Following the updated FDA report in March, Surmodics temporarily paused recruitment efforts for the TRANSCEND trial. Surmodics and trial leadership reached out to the FDA directly to seek guidance on these recommendations and their potential impact on the TRANSCEND trial. In response to the agency's recommendations, Surmodics took several actions, including communicating FDA recommendations to all trial investigators, updating the patient informed consent form, continuing its regular data safety review, and establishing increasingly aggressive patient follow-up programs for both newly randomized patients and those already enrolled in the trial.

The statistical warfare that has transpired in response to the Katsanos et al meta-analysis is a healthy one, and I believe it will make our field better in the long term. In an era of increasing scrutiny regarding treatment options, cost containment, and emphasis on value-based outcomes, all interventionalists regardless of specialty should welcome this debate to better define the best treatment paradigm for our patients with PAD. Personally, I have not yet significantly changed my overall approach to this population since the meta-analysis was first reported late last year. The rebuttal with independent patient-level data is only now surfacing in the literature and, thus far, supports the clinical benefit observed by most interventionalists in real-world practice, and I anticipate such data will increasingly support current treatment paradigms. Nevertheless, I do think it is important to heed the recommendations by the FDA, particularly as they relate to highlighting the present uncertainties of a late mortality signal with paclitaxel-based treatment options during the informed consent process and continuing diligent postoperative surveillance in those treated with paclitaxel-coated balloons or paclitaxel-eluting stents.

**Although many challenges still remain in critical limb ischemia (CLI) treatment, what areas do you see that point to progress in terms of treatment options and the ability to provide improved patient outcomes?**

The adoption of retrograde tibiopedal access over the last several years has prompted rapid acceleration of advanced percutaneous techniques to revascularize both the tibioperoneal and inframalleolar arterial segments. Historically, I think the interventional bar was set at a point where the primary goal was simply to achieve

inline flow to the foot via one or more infrapopliteal vessels. Over time, technologic improvements and experience has allowed us to raise this bar further such that there is now growing appreciation for the importance of attaining a patent pedal arch in many patients with CLI. Retrograde transmetatarsal, transplantar arch, or collateral vessel access approaches for foot salvage remain early in their development but serve as an exciting step forward for all patients with CLI.

Despite this progress in recanalization efforts, much work remains regarding the optimal treatment option for this small vessel arterial tree, which is notoriously prone to recurrent disease and a corresponding need for secondary interventions. The application of antirestenotic therapies for these small vessels, including drug-coated balloons or stents, is on the horizon and preliminary trial data are promising. Evidence of the added benefit of stem cell therapy and bioresorbable vascular stents is also eagerly anticipated but further on the time horizon.

## What recent nonmedical technologic innovation most fascinates you?

Among many shifts toward environmentally friendly technologies, the electric car industry has fascinated me since I trained in the Tesla hub of Silicon Valley. Since moving to the Pacific Northwest, I have fully embraced the stereotypical environmentalist stance of my local and regional community. I firmly believe that electric cars and other alternative energy sources will be increasingly important in our lifetime and beyond. I am inspired by many, including my anesthesia colleague here in Portland, Dr. Brian Chesebro, who empower themselves to make changes for the greater good. He is at the center of a campaign in his field to reduce the environmental footprint of anesthesiologists simply by changing from desflurane to sevoflurane (desflurane is 20 times more potent of a greenhouse gas than sevoflurane and lasts for 14 years in the atmosphere, whereas sevoflurane breaks down in just 1 year). I have no doubt that similar environmental-based initiatives can and will be pursued within the surgical community in the years to come. ■

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