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EndoAnchors Advance Treatment of Aortic Aneurysms: Experience in a Community Hospital

BY MAZIN FOTEH, MD

CONFRONTING THE COMPLEX ANATOMY OF AAAs AND THE LIMITATIONS OF EVAR

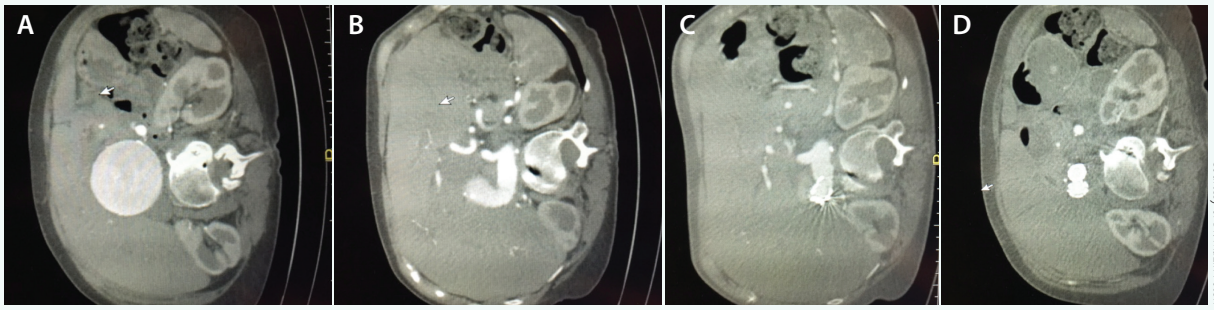
Even though endovascular aortic aneurysm repair (EVAR) has been embraced and widely adopted for being minimally invasive compared to open surgery, it has a number of shortcomings, as does open surgery. Both of these imperfect solutions may be appropriate to treat select abdominal aortic aneurysms (AAAs) and thoracic aortic aneurysms (TAAs). Evidence suggests open surgery may be a more durable long-term option compared to EVAR,[1-3] although reinterventions for open repair also carry a risk of mortality reported as high as 23%.[4] Yet, late complications are a persistent problem for EVAR, with a higher risk for rupture and reinterventions. Type Ia endoleak in hostile necks are too common both acutely and over time and must be managed, ultimately with either endovascular reintervention or conversion to open repair, possibly even explantation of the failed endograft. Despite technologic improvement in third-generation endograft design and decreased rates of type I and type III endoleaks, these problems continue in hostile neck anatomy. The crux of the problem is endograft sealing in challenging proximal aortic necks and maintaining that seal post-repair, even as aortic disease progresses.

In 2009, it was posited that no single approved endograft device would likely perform well in angulated necks.[5] At present, this may still be the case. For highly complex anatomies, there is a lack of durable, on-label, endograft-only solutions that can significantly ameliorate the problem of late complications with any graft generation.

Within the realm of infrarenal graft enhancements, active fixation appears to have had the greatest impact on long-term durability.[5-7] Data from the EUROSTAR registry, although reported in 2005, are still relevant to contemporary devices: active fixation using barbs in the infrarenal or suprarenal positions is associated with lower migration risk compared to devices without barbs.[8] While there are certainly applications for fenestrated and branched endograft systems, these devices carry an added dimension of complexity, not only in the number and types of components and their spatial endovascular deployment, but also in the time needed to deploy them. Procedure times are longer, which heightens risk for complications with greater doses of contrast, radiation exposure to the patient and physician, and their associated economic implications. After more than 2 decades, we are still faced with significant difficulty in resolving both early and late complications for hostile neck anatomy. For instance, the 2011 study by Schanzer and colleagues reported a large data set of 10,228 EVAR patients with sufficient preoperative and postoperative CT scans, of which 41% showed sac enlargement after 5 years. Of these, the rate of sac growth was significantly higher in patients treated outside the instructions for use (IFU). The authors concluded the use of endografts outside their respective IFUs was rampant, resulting in a high rate of sac enlargement and elevating concern for aneurysm rupture.[9]

EndoAnchor therapy has been reported as safe, feasible and effective in treating early and late type I endoleaks and augmenting the seal and fixation of stent grafts, as a prophylaxis for future seal complications.[10] This capability led to the approval of the Aptus™ Heli-FX™ EndoAnchor™ System to be used in approved endografts in both the United States and

CASE ONE



Courtesy of Dr. Mazin Foteh

EndoAnchors used as a prophylactic adjunct to address concerns for postoperative disease progression in a patient with complex aortic neck anatomy and large AAA with high-rupture risk. Preoperative CT demonstrates large AAA and high infra-renal neck angulation (A and B). One-year postoperative CT demonstrates aneurysm exclusion and significant sac regression (C and D).

Europe (listed previously in this supplement). Data from ANCHOR (Heli-FX Aortic Securement System Global Registry), the prospective, multicenter registry of patients undergoing EVAR adjunctively treated with EndoAnchor therapy, showed ANCHOR patients had notably more challenging neck anatomy than the general EVAR population.[11] When compared to EVAR patients described in the aforementioned 2011 paper by Schanzer and colleagues, ANCHOR patients had, on average, notably larger proximal aortic neck diameters and shorter neck lengths.[11] Speziale et al confirmed in a 2014 study that the presence of more than one proximal neck risk feature is associated with higher rates of complications and reinterventions.

Revision cases have become increasingly common in modern-day practices. As the general population ages, more time has passed from initial repair, allowing for greater aortic disease progression.[12] To say this more simply, patients are outliving their disease and repairs. Lastly, early graft failure with open conversion is not a benign risk. Ferrero et al reported in their single-center experience that early graft explanation carried a mortality risk of 50% and approximately 20% for late conversions.[13]

Lifestyle factors play a large role in the progression of aortic disease and aneurysm development, since it is well-known that persistent hypertension and smoking contribute to late changes in aortic disease progression.[14] High-risk anatomical factors are a marker for aortic disease progression and ultimate EVAR failure.[15] Likewise, multiple factors portend a risk of intraoperative type Ia endoleak. A recent study in 2016 showed that type Ia endoleaks were predicted with confidence by a lesser-known measure of aortic curvature along with the more well-known risk of significant aortic neck calcification. In fact, aortic curvature appears to be a better predictor of intraoperative type Ia endoleak than neck angulation.[16] Any improvements to bolster current EVAR techniques are clearly welcome and may mitigate late complications while improving outcomes.

Importance of Active Fixation

Just as the advent and adoption of active fixation found success in newer-generation stent grafts, EndoAnchor therapy presents a unique active fixation adjunct to endovascular endografting. In fact, the success of the open surgical anastomosis rests in the buttressed nature of hand-sewing the sutures to reach to the external layer of the aorta: the adventitia. In a similar fashion, EndoAnchors were designed to securely fix the endograft to the aorta's adventitial layer from within by penetrating the intima and media layers,[17] thus creating a series of functional anchors that provide both radial and axial support just as with sutures. As demonstrated in a human cadaver study in 2012, EndoAnchors provide the strength and stability equivalent to or exceeding that of a surgical anastomosis for withstanding large blunt hemodynamic and anatomically imposed forces.[18] The clinical experience of EndoAnchor therapy is approaching a decade of use and is broadly available in both the United States and Europe. Published reports show the rationale for EndoAnchor use, which includes improving proximal fixation of an endograft,[19] obtaining more complete graft apposition,[19,20] and overcoming graft nonalignment issues in TAAs to facilitate seal.[21]

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The Role of EndoAnchors in EVAR Practice for AAAs

Where might EndoAnchors fit in practice? Figure 1 illustrates one approach to treating complex AAAs. The most obvious situations where EndoAnchor therapy could augment and improve outcomes are in complex aortic neck anatomies. Hostile neck features run the gamut of short, highly angulated, and/or tapered configurations. However, less subtle findings, including thrombus and dense calcium deposition, are also predictors of early failure and ultimate rupture.[15] Prior to the advent of EndoAnchor therapy, more complex treatment options have included open surgical repair, fenestrated repair, or parallel endografting. Now, EndoAnchors in concert with a compatible stent graft are a viable option and promise a simpler procedure to consider for patients needing elective or emergency repair.[10,22-25]

Less obvious situations may include young patients who are not candidates for open repair and who need a permanent fix. If a patient is young, relatively healthy, and has a long-term life expectancy, but the patient has factors that preclude open repair or the patient refuses open repair, EndoAnchors with a standard EVAR approach may be an appropriate option. Furthermore, if the patient is of advanced age, has a short-term life expectancy, has numerous comorbidities, and is not a strong candidate for fenestrated endovascular repair (FEVAR), EndoAnchors with a standard EVAR approach may be an appropriate intervention.

After any aortic procedure, then the challenge of patient compliance to imaging surveillance protocols begins. A 2016 study by AbuRahma and colleagues reported that of 565 patients, 57% were noncompliant, a disconcerting result. It was notable that subgroups of patients were created to compare compliance between patients with hostile neck anatomy (neck angle exceeding 60°, n = 251 [48%]) compared to patients with favorable neck anatomy (275 [52%]). Noncompliance of patients with hostile neck anatomy was significantly higher compared to those with favorable neck anatomy (64% vs 50% noncompliance; $P = 0.0007$).[26]

There are several potential reasons for noncompliance in addition to patients residing in remote geographies relative to their aortic center. Patients may have ambulatory challenges, advanced age, cognitive decline and comorbid disease. There may be insufficient family and/or caregiver support. For patients identified to be potentially noncompliant to surveillance, EndoAnchor therapy applied in the primary repair may perhaps increase physician confidence in the durability of the procedure.

It must also be noted that there are also inherent risks with standard follow-up imaging surveillance, such as cumulative radiation exposure posing a risk for malignancy and the cumulative impact on renal function from contrast, particularly in the elderly and patients with renal insufficiency. A 2016 study reported risk factors associated with renal decline in 135 EVAR patients, of which 25 (19%) were recognized to have a

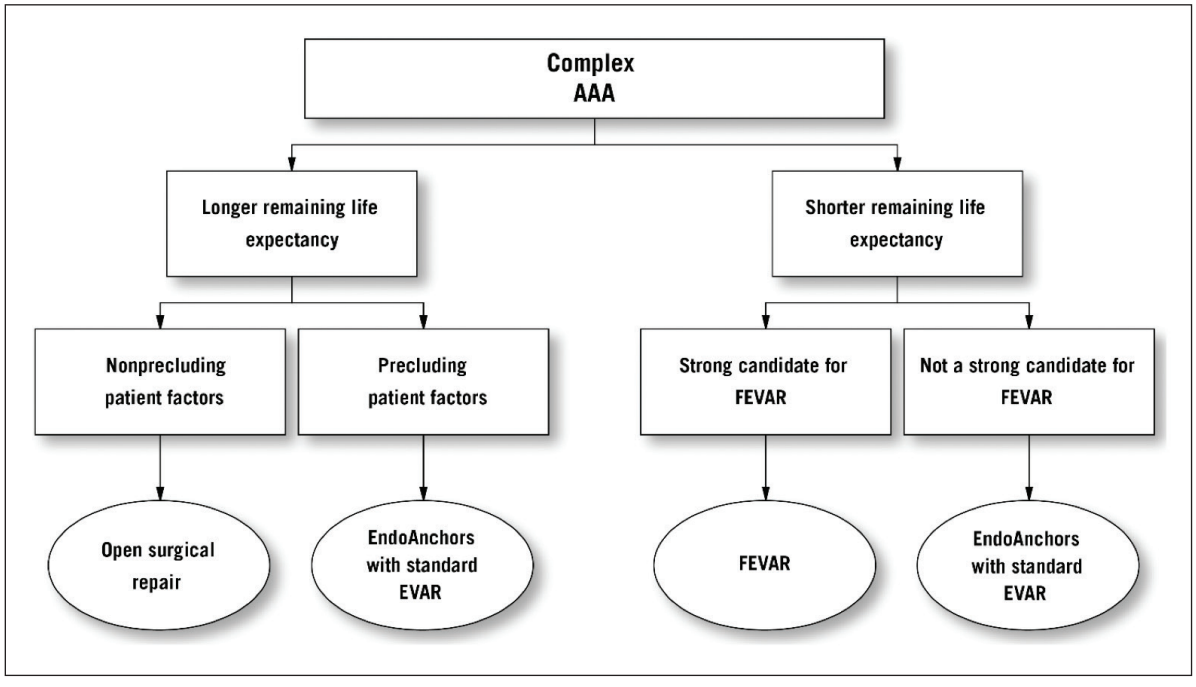
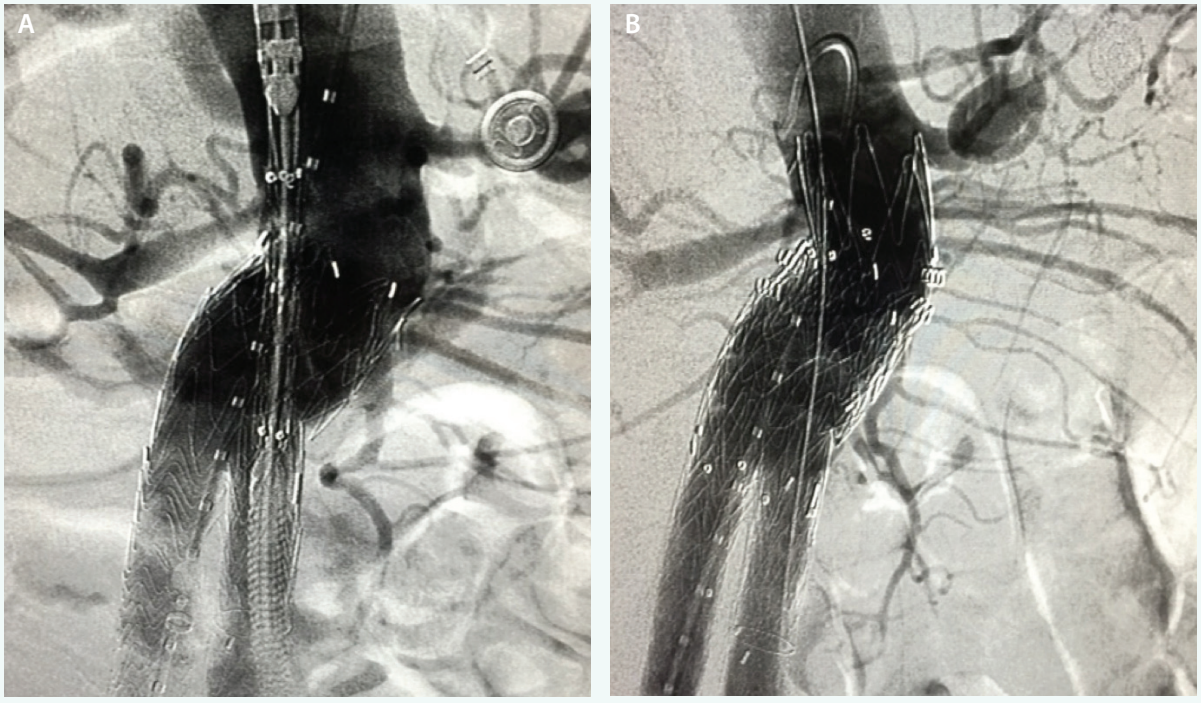


Figure 1. EndoAnchor therapy in the EVAR treatment algorithm.

CASE TWO



Courtesy of Dr. Mazin Foteh

EndoAnchors used to treat a late type Ia endoleak and enhance the durability to address concerns for further complications. Initial angiogram shows type Ia endoleak (A). Final angiogram demonstrates successful sealing of type I endoleak after implantation of cuff and EndoAnchors (B).

significant progression in chronic kidney disease. Independent risk factors for this decline included a diseased-thrombus laden aorta, lack of oral ß-blocker administration, renal insufficiency, and an elevated creatinine > 1.4 mg/dL.[27] A 2014 study of late rescue of proximal endografts reported that chronic renal impairment at the time of the procedure was an independent risk factor for late failure.[28] Less frequent imaging follow-up could likely be of benefit in these patients at risk for nephropathy.

ENDOANCHOR EXPERIENCE AT A COMMUNITY AORTIC CENTER

Cardiothoracic and Vascular Surgeons (CTVS), Austin, Texas

EndoAnchors are being used in the many cases at CTVS, a growing community aortic center in Austin, Texas. Because of their widespread use, our center was interested in tracking EndoAnchor cases and evaluating outcomes over time. Therefore, our institution initiated a site-based series of EVAR use with EndoAnchors independent of the ANCHOR registry. Imaging surveillance was site-reviewed by the author as primary investigator and a radiologist.

A total of 37 patients were treated with the Aptus HeliFX EndoAnchor Systems during abdominal or thoracic endovascular repair (EVAR/TEVAR) from April 2013 to March 2016. Of those 37 patients, 36 underwent EVAR for an AAA and 1 TEVAR case was performed for a TAA. An average of 5.6 ± 1.1 EndoAnchors were deployed for each case (range, 4–9). In 6 patients (16.2%), EndoAnchors were not initially planned but were used at the discretion of the operator. Our treatment algorithm has evolved over time. As our comfort with the device increased, its utility became more apparent. Now, our practice has evolved to include EndoAnchors in the planning phases for EVAR, particularly when we are treating patients with hostile neck anatomies.

Three revision cases were performed (8.1%). The first, a ruptured AAA with observed graft migration on May 1, 2013. The other two patients both presented with a type I endoleak and graft migration (August 1, 2013 and November 14, 2014). The mean age was 76.3 ± 7.9 years (range, 62–92; median, 77 years). The vast majority of patients had a history of coronary artery

disease (64.9%) and hypertension (97.3%); 27% had documented diabetes mellitus (27%). Mean creatinine values were 1.46 ± 0.44 mg/dL (range, 0.8–2.5 mg/dL).

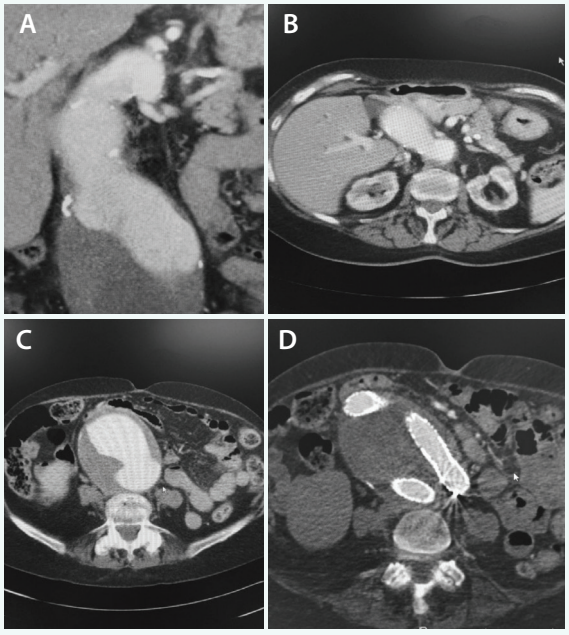
Among the entire cohort, notable anatomic characteristics were significant aortic calcification observed in more than half of patients (51.4%), ranging from 25% calcification to circumferential calcified aortas. A high-risk aortic neck was identified in 31 patients (83.7%), one case of which included a ruptured aneurysm. The most frequent indications for EndoAnchor use included a short neck in 10 patients (27.0%), high neck angulation in five patients (13.5%), and an intraoperative type I endoleak in four patients (10.8%). Average aortic neck diameter was 27.3 ± 5.5 mm (range, 18–38 mm).

We observed excellent early outcomes and over a mean follow-up of 6.5 months (N = 37). Technical success was achieved in all patients with no notable intraoperative complications and no endoleaks viewed intraoperatively or postoperatively over follow-up. All patients have had at least 1 month of follow-up and 24 patients have been followed for 6 months or more (maximum of 23 months). Over follow-up, there were no reinterventions or conversions to open surgical repair. Among all 37 patients observed over follow-up, there were no cases of aneurysm sac growth reported. Notable sac regression was observed in the majority of patients (56.8%), and sac size remained stable in the other 43.2% of patients. Overall, our experience with EndoAnchor use during EVAR has been overwhelmingly positive and corroborates with the overall findings from the ANCHOR registry. Long-term durability needs to be proven over time, and we plan to report follow-up of these patients and the addition of future primary and revision cases to document EndoAnchor use as an adjunct for EVAR and TEVAR.

EXPANDING THE CAPABILITIES OF COMMUNITY AORTIC CENTERS

The benefits in building a comprehensive aortic center include serving a greater number of patients who otherwise might not be treated at the community level, obviating the need for referrals to high-volume centers and potentially reducing the number of type I endoleaks and revision cases. Community centers are also closer to the majority of patients than regionalized centers, to which patients must travel longer distances for care. Bolstering the capabilities of community aortic centers, including adding EndoAnchors as part of the interventional armamentarium, can thereby provide local care to patients who would have otherwise been referred.

CASE THREE



Courtesy of Dr. Mazin Foteh

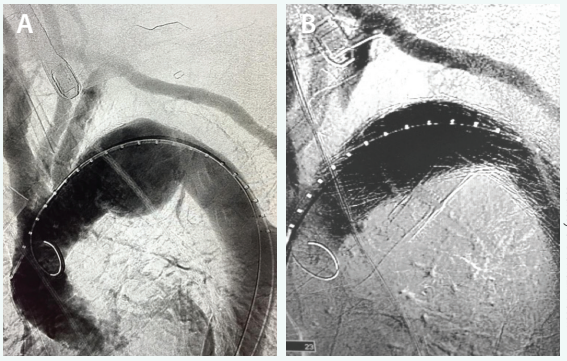
EndoAnchors used as a bailout for an intra operative type Ia endoleak in an emergency EVAR for ruptured AAA. Preoperative CT demonstrates ruptured AAA with large 9-cm aneurysm and complex aortic neck (A–C). EndoAnchors successfully treat type I endoleak, as demonstrated in postoperative CT (D).

There are many tools required in building a comprehensive aortic center, of which being EndoAnchor therapy-ready is but one consideration. It is a significant task with a large investment in time, expertise, and resources. At our institution, we are dedicated to institutional growth and expanding our aortic center services. We are currently pursuing expanding our services in the three following areas:

(1) Investments in infrastructure,
(2) Streamlining protocols, and
(3) Selectively expanding endovascular inventory.

On the infrastructure front, we are undertaking a hybrid suite retrofit to include a new Philips image fusion C-arm, which can fuse CT angiography with on-table fluoroscopy to allow us to treat more complex cases on the table while reducing radiation exposure to the patient and team. It will also allow us to do on-table three-dimensional CT scans for the diagnosis of acute type A and B dissections and ruptures. This advanced imaging will expedite care and improve outcomes. The patient can be moved directly from the emergency department to the hybrid operating

CASE FOUR



Courtesy of Dr. Mazin Foteh

EndoAnchors used as a prophylactic adjunct in complex TEVAR to enhance durability and address concerns for future complications. Initial angiogram shows complex proximal neck (A). Final angiogram confirms successful exclusion of TAA postdeployment of graft and EndoAnchors in proximal seal (B).

room suite to have CT scans performed expeditiously, which translates into faster "door-to-repair" times. It must be noted that a hybrid suite is not required to deploy EndoAnchor therapy (the topic for discussion of this issue) or a number of other endovascular techniques. There has been debate whether hybrid suites are a luxury or necessity.[29] As an institution, we have elected to invest in a hybrid suite retrofit of existing our OR space with guidance from the literature.[30,31] An updated hybrid suite will help advance our community hospital's capabilities at treating more complex anatomy, harness our multidisciplinary expertise, and be in a better position to improve patient and health worker safety.

With this infrastructure in place, CTVS is also streamlining structured protocols for acute aortic pathologies, including rupture. Adoption of such rupture protocols has been recognized to improve outcomes.[32,33] We have found EndoAnchor therapy is an important on-hand treatment option for emergent cases and bailout to prevent conversion to open repair.

We have also selectively increased our on the shelf inventory of endografts, not only increasing supply to match a greater demand, but also to allow us to perform more complex anatomic cases without needing a manufacturer representative to be present. Inventory management is necessary to maintain capabilities for effective elective and emergency aortic aneurysm repair. The Aptus Heli-FX and Heli-FX Thoracic EndoAnchor systems occupy an important place in our inventory since they are used in many cases with compatible endografts. Unlike most endograft components, Heli-FX is a single-platform technology designed to accommodate a large range of anatomies, making it conducive to judicious inventory management.

Expanding the capabilities of a community center can help treat more patients who may be otherwise referred to regionalized aortic centers of excellence. There is a tendency nationally for physicians to seek opportunities that keep patients for the obvious benefit of geographic proximity for the patient and ability for community practices to manage their patients locally. In my view, EndoAnchors can enable more physicians to treat not only simple, straightforward EVAR cases with a confident, potentially improved long-term result but also more complex cases.

Any community aortic centers can likely benefit from integrating EndoAnchor therapy into their interventional armament to improve their patients' health outcomes. Its ease of use and proven outcomes has generated confidence that this unique intervention can improve the durability of standard EVAR. The learning curve is low. It may take up to five cases to reach one's most comfortable familiarity and efficiency in deploying EndoAnchors. In the ANCHOR registry, average total deployment time has been reported at roughly 16 minutes, which includes a mean of five EndoAnchors implanted as a prophylactic adjunct to primary EVAR.[11] This is comparable to our center's experience. In training other physicians in EndoAnchor deployment, I've found physicians new to the therapy tend to want to use them first on a tough case, say a revision case, to rapidly gain experience similar to how surgeons new to pedal access may opt for tough cases first. Contrary to current adoption trends, I recommend finding the opportunity to use them in a relatively simple, straightforward case first to become accustomed to the device delivery system and deployment, and only then tackling a tougher case.

In our community center experience, EndoAnchors offer a simple option with ease of deployment that does not appreciably extend procedure time and improves results. EndoAnchor therapy can effectively enhance durability of a standard EVAR approach for complex cases that may have previously called for observation, open surgery, or more complex interventions. Overall, EndoAnchor therapy will complement and bolster a community aortic center's capabilities in providing more comprehensive care for patients, especially those with complex anatomies, and avoid the need for costly referrals. ■

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