What Have You Learned From Long-Term Data Sets Beyond 10 Years, and How Will These Data Affect Your Practice?

Experts discuss key lessons from long-term EVAR studies and what they mean for the future.

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Overall, long-term data sets help clinicians determine appropriate patient and device selection. The information obtained from such studies helps improve device design and patient outcomes with endovascular aneurysm repair (EVAR). Without them, we would be doomed to repeat history and the mistakes of our predecessors.

Unfortunately, data are still limited on EVAR outcomes beyond 10 years. Although a recent small, single-center review of EVAR in 58 patients out to more than 10 years noted stable aneurysm exclusion in the majority of patients,[1] larger administrative data sets suggest outcomes that are much less durable. A 2015 article looking at 8-year outcomes in the Medicare population noted that 5.4% of patients who underwent EVAR experienced aneurysm rupture versus 1.4% who underwent open repair.[2] Interventions related to the management of the aneurysm or its complications were also more common after EVAR as compared to open repair. Another large multicenter registry describing the 10-year results of 1,736 patients noted a 97% rate of freedom from aneurysm-related mortality.[3] A closer look at the study reveals that the average follow-up was only 3 years, with 8% lost to follow-up. I am not sure we can necessarily claim long-term victory for EVAR yet. Large tertiary care institutions have all noted an increase in the need for conversion for failed EVAR.

Our previous report noted device failures out past 10 years, mainly due to progression of aortic disease and device integrity issues for all types of implants.[4] Continued device development has addressed some of the concerns related to earlier iterations of EVAR devices; however, some changes have not always been positive. An example of this was the risk of type IIIb endoleaks after a fabric change in the AFX device (Endologix, Inc.).

We are still not able to use complicated fenestrated or branch devices commercially in the United States. The use of chimneys and snorkels has risen to achieve successful EVAR outcomes in anatomically complex patients. The short-term results have been promising, but the problem of small persistent type I endoleak has not been solved, and the late risk of failure is still unknown.

I still believe that EVAR can achieve very low mortality and offer durable repair in patients with good anatomy. The long-term data sets hint at the need for caution in recommending EVAR for unfavorable anatomic situations in patients with longer life expectancies. The last

concern that we have not addressed is optimal surveillance and the cumulative radiation dose from serial imaging and the risk of cancer development. I remain bullish on EVAR for the right patient but believe open surgery in skilled hands remains appropriate in many instances.

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The long-term outcomes following EVAR continue to raise concerns about durability, but they should not radically change our practice and push us back toward an "open-first" approach. It is important to remember that our endovascular practices continue to evolve, as do the technologies available to us, both in terms of devices and imaging capabilities.

There are a multitude of factors that could be better used to predict long-term failure. It is very clear from the long-term outcomes data that we should be sticking more closely to the instructions for use for individual devices. Perhaps more importantly, we should be using patient-specific factors, in particular those related to aortic and iliac anatomy, to better personalize our interventions and surveillance programs and guide our reinterventions. The long-term data show that the short-term survival benefit is most stark in the older age group, but conversely, the longer-term outcomes are much worse. This needs closer investigation and stratification of long-term risk.

Finally, it is also time to consider alternative technologies for the aorta. The traditional bifurcated stent graft is always going to be subject to anatomic limitations that will preclude treatment of a reasonable proportion of patients, especially within instructions for use. "Sealing" offers a novel way of treating aneurysms and may also raise durability concerns, but it does represent different treatment modalities that may provide a better long-term solution for aneurysm exclusion. It is imperative that we as endovascular practitioners, work closely with engineers and industry to develop novel, durable endovascular solutions for the benefit of our patients.

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The long-term data from the Endovascular Aneurysm Repair Trial 1 (EVAR 1) are a little bit discouraging for the endovascular believers, especially due to the high reintervention rates seen in the endovascular group. In order to refute this evidence, endovascular believers can argue that current stent grafts are performing much better than previous-generation stent grafts that were used in EVAR 1. However, new technology should demonstrate this point. Unfortunately, there are no new ongoing trials or large registries, which is a concern because we are probably missing relevant information about durability.

In my opinion, EVAR durability is currently the major concern. There is still a lot of room for improvement in order to reduce the reintervention rate and lessen the cumbersome surveillance. It is clear that EVAR patients have better short-term outcomes, but this benefit disappears over the long term. Only with improved durability should experts agree that EVAR should be the first option for abdominal aortic aneurysm (AAA) treatment. Today, it is hard to say that; no guideline clearly recommends EVAR as a first-line repair for any AAA with suitable anatomy.

In my personal clinical practice over the last 5 years, we have become stricter in our anatomic criteria for regular EVAR patients and pay more attention to suboptimal cases for long-term durability. We look for regular and long necks when choosing stent grafts. Otherwise, if the patient is not a good candidate for open repair, we are increasingly using special designs, such as fenestrated stent grafts. Additionally, we are using more endoanchors, even in patients with regular anatomies and potentially long life expectancies (ie, > 10 years).

Finally, in the near future, we can't expect new randomized controlled trials in order to get more evidence about

the better performance of the new-generation stent grafts because they are excessively expensive and almost unfeasible. The alternative is encouraging stent graft companies to develop their own well-designed postmarket registries to collect good data so that we could compare the results with EVAR 1 results.

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Open repair had been the standard of care for AAA for decades before being challenged by EVAR. After its initial clinical description by Volodos et al and Parodi et al, EVAR has had a technologically rapid and diverse evolution. In addition, we have seen major paradigm shifts in the nature and scope of EVAR practice.

Application of EVAR in the elderly population at higher surgical risk has been justified time and again, and not much debate exists about its use in this setting in real-world practice.Because younger patients who develop AAAs have a significantly higher life expectancy, the long-term durability of stent grafts becomes an important consideration. Although EVAR is the accepted norm in the elderly population at high surgical risk, there is concern for younger patients due to their relatively longer life expectancy, as long-term follow-up data show relatively higher aneurysm-related mortality in the EVAR group. The perioperative survival advantage for EVAR is sustained for several years; however, rupture after EVAR remains a concern.

Recently published long-term results from EVAR 1 have shown that there is a greater risk of secondary aneurysm sac rupture beyond 8 years, resulting in significantly higher mortality in the EVAR group. Although

EVAR 1 is the only long-term randomized controlled trial available to compare outcomes, it must be remembered that first-generation EVAR devices were used in these patients.

Several recent, small, nonrandomized studies have shown a significant reduction in overall mortality after aneurysm repair—both endovascular as well as open repair. With newer devices, the incidence of type I and III endoleak is low. Long-term data on freedom from reintervention and rupture-free survival will take more time to become available, especially with the newer devices. Based on current data, where anatomically feasible, all AAAs in my practice are treated endovascularly. The currently available long-term data have taught me the following five lessons:

1. I still believe in the dictum, "Don't leave your hybrid OR without fixing a type I endoleak."
2. Stay current in your knowledge of your stent graft of choice.
3. Stay within the instructions for use. Learn about and make available all bailout hardware in your hybrid ORs.
4. Stay clued into any anatomic peculiarities that may predispose to limb occlusion or endoleak. Follow these patients closely.
5. Simplify follow-up, emphasizing use of abdominal x-ray and ultrasound Doppler, and reserve CT scans only for complex problems.

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Long-term data can have a significant impact upon one's practice in several areas, including patient and device selection, procedural technique, device durability, and overall effectiveness. One of the most difficult aspects of EVAR to both teach and learn is appropriate patient selection. Since the early use of EVAR in the mid- and late 1990s, a recurring pattern has been observed with each device introduced into the market. Initially, implantation occurs under strict patient selection criteria defined by the pivotal trial. This is followed by a period of aggressiveness, in which treatment beyond the instructions for use is attempted in order to assess how the device performs in adverse conditions. This evaluation and self-reflection also provides the impetus for improvements in devices over time and is an important aspect of device advancement. After experience has been gained, a more reasonable/less aggressive position is taken with respect to patient selection.

This process can be reflected in long-term data sets, as they currently involve devices approved from 2001 to 2006. Often, long-term data sets include early experience data that demonstrate the performance of the device under clinical trial conditions, which helps in determining the effectiveness of the therapy in optimal anatomy. Caution must be taken to avoid assimilating long-term data from these optimal environments to use outside these optimal conditions, as the results could be significantly different. Device performance can be evaluated in this fashion, and failure modes such as fabric integrity and migration have occurred. However, it must be noted that devices manufactured today have significant differences from their predecessors and have been developed with improved performance in mind.

Migration is time dependent and is rarely seen in short-term data sets. Therefore, its impact is most profoundly seen in more longitudinal studies. Although many early devices did not possess active fixation, most current devices incorporate this feature into their design. Additionally, long-term data sets have taught us about ineffective treatment strategies, such as limited iliac artery fixation length and treating patients with diseased proximal aortic necks. The former results in a higher type Ib endoleak rate, and as a result, vascular specialists now utilize the entire common iliac artery for fixation. In cases where the common iliac artery is diseased, extension into the external iliac is common, either by excluding the hypogastric artery or preserving an iliac branched component. Likewise, utilizing a diseased or enlarged proximal aortic neck for fixation results in proximal device failure and can be difficult to manage in some situations. Selection of an appropriately sized—and non-diseased—normal aorta is of critical importance in achieving long-term exclusion of the aneurysm and is currently one of the most common causes of device failure. This has significant implications with respect to durability when implanting fenestrated, snorkel, and branched devices. ■