Advances in Aortic Repair

A recap of important research from the past year and a look ahead to some crucial questions in aortic surgery.

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The past decade has produced some truly remarkable advances in endovascular aneurysm repair (EVAR). Through continued innovation from the industry as well as the ingenuity and creativity of many physicians, there is a larger armamentarium with which to tackle complex aortic pathology. This article reviews several of the most important papers from the past year and looks forward to 2020 and the decade to come, outlining some challenges that lie ahead.

Open Versus Endovascular Repair of Abdominal Aortic Aneurysm

Lederle FA, Kyriakides TC, Stroupe KT, et al. N Engl J Med. 2019;380:2126–2135.

This article by Lederle et al reports the long-term follow-up of the OVER clinical trial, a randomized controlled trial comparing endovascular versus open surgery for abdominal aortic aneurysms (AAAs). The OVER trial, much like the European trials EVAR-1, DREAM, and ACE, had previously confirmed an early survival advantage for EVAR over open surgical repair. However, when the 15-year outcomes from EVAR-1 were published in 2016, a late survival benefit was seen in the open surgical group, causing some to question the long-term durability of EVAR.

Lederle et al reported 14-year follow-up (mean, 8.4 years) outcomes of patients treated at United States Veterans Affairs hospitals. Essentially, no difference in overall mortality was found between EVAR and open surgical groups (68% vs 70%; hazard ratio, 0.96; 95% confidence interval, 0.82–1.13). These data contradict the EVAR-1 long-term follow-up data. The OVER trial did confirm an increase in secondary interventions among EVAR patients, consistent with the previously published data as well.

These data are extremely important in reinforcing the durability of EVAR, even when averaged across an entire group of multiple sites and varying devices and practitioners. Despite the increased need for reintervention, patients undergoing EVAR are surviving at similar rates to their open surgical counterparts. EVAR has been widely adopted as the standard of care for AAAs throughout the world, and this should continue to be the case going forward.

TOP HEADLINES IN AORTIC THERAPY

- **UK Physicians and Other Stakeholders Continue to Await NICE AAA Guidelines**
  After the circulated draft guidance was met with strong critiques, the United Kingdom's (UK's) National Institute for Health and Care Excellence (NICE) committee has been working on revisions to its final guidelines for AAA diagnosis and management that were initially anticipated by the end of 2018 but remain unpublished as of press time.
- **ESVS Offers Revised Clinical Guidelines for the Treatment of AAAs**
  In February 2019, the European Society for Vascular Surgery (ESVS) released their clinical practice guidance for the management of AAAs to assist physicians in selecting the best management strategy. These guidelines were a revision and expansion of guidance that had been published in 2011.
- **Continued Development in the Arch, Thoracoabdominal, and Dissection-Specific Devices**
  Ongoing national, regulatory, and physician-driven trials in complex aortic anatomies yielded largely favorable but also some mixed results for future treatment opportunities. Although initial data have shown promise for these devices, more long-term data are necessary to confirm the value of endovascular approaches. Progress was perhaps most notable in the dissection space, where the first pathology-specific platform gained United States approval.

Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the Manta Percutaneous Vascular Closure Device

Wood DA, Krajcer Z, Sathananthan J, et al. Circ Cardiovasc Interv. 2019;12: e007258.

The need for large-bore arterial access has risen in parallel with the development of more complex endovascular therapies and the desire to perform these procedures percutaneously. Surgeons and interventionalists have become more comfortable with percutaneous large-bore access, with the most common access and closure method being the "preclose" technique using two Proglide Perclose sutures (Abbott). The Manta vascular closure system (Teleflex) is a novel, collagen plug–based device that was approved for use in February 2019. According to the instructions for use, it is indicated for closure of arteriotomies ranging from 12 to 25 F. Wood et al report the results of the SAFE MANTA pivotal trial, a multicenter single-arm trial evaluating the safety and efficacy of the Manta device in patients undergoing transcatheter aortic valve replacement, EVAR, or thoracic endovascular aortic repair (TEVAR) via a transfemoral approach. Mean sheath size was 22 F, and technical success was achieved in 97.7% of cases. Major vascular complications occurred in 4.2% of patients, requiring either open surgical or endovascular repair for control of hemorrhage.

Many endovascular procedures involving large-bore access can be safely performed via a percutaneous approach. The preclose technique remains the tried-and-true standard and the technique with which most operators are most familiar. The Manta device shows promise in this controlled trial setting, with an advantage particularly in urgent or rupture scenarios where this is applied after large-bore access, but real-world outcomes are needed before ultimately settling on a recommendation for use.

Five-Year Results From the Study of Thoracic Aortic Type B Dissection Using Endoluminal Repair (STABLE I) Study of Endovascular Treatment of Complicated Type B Aortic Dissection Using a Composite Device Design

Lombardi JV, Cambria RP, Nienaber CA, et al. J Vasc Surg. 2019;70:1072–1081.e2.

Type B aortic dissection (TBAD) is perhaps the most challenging and complex pathology to treat in aortic surgery. Complicated TBAD, particularly involving visceral or extremity malperfusion, is now treated preferentially with TEVAR. Although this may resolve the immediate perfusion deficit by pressurizing the true lumen and attempting to induce thrombosis of the false lumen, there is still a question of how to manage the visceral segment given the mixed patterns of branch involvement. The STABLE I trial was a single-arm study that evaluated the use of the Zenith dissection endovascular system (Cook Medical) in patients with acute and subacute complicated TBAD. The system includes a proximal TEVAR component and a distal bare-metal stent to be placed across the visceral segment.

Lombardi et al report the 5-year results of the trial. For acute and subacute patients, these data demonstrate excellent freedom from overall mortality of 79.9% and 70.1%, respectively, and freedom from dissection-related mortality of 83.9% and 90.1%, respectively. The system also seemed to promote positive aortic remodeling, with most patients showing complete thrombosis of the false lumen and a concomitant increase in true lumen diameter and a decreased false lumen diameter. Freedom from secondary intervention was 65.5% and 71.2% for acute and subacute patients, respectively.

Based on the favorable results of this pivotal trial, the Zenith dissection system is now commercially available in the United States and is quickly being adopted across the country. The technique, which has already been popularized in Europe, is similar to the PETTICOAT or STABILISE techniques, depending on whether a balloon septal rupture is performed. Although long-term data are not available, the early trend toward positive aortic remodeling will hopefully lead to lower rates of late aneurysmal degeneration and the need for additional aortic intervention in the follow-up of TBAD patients.

Technical Aspects and 30-Day Outcomes of the Prospective Early Feasibility Study of the Gore Excluder Thoracoabdominal Branched Endoprosthesis (TAMBE) to Treat Pararenal and Extent IV Thoracoabdominal Aortic Aneurysms

Oderich GS, Farber MA, Silveira PG, et al. J Vasc Surg. 2019;70:358–368.

Total endovascular repair of thoracoabdominal aortic aneurysms (TAAAs) is one of the most exciting recent developments in aortic surgery. Although several devices are available for use in Europe and other places around the globe, the United States presently has no commercially available option for this pathology. The Gore Excluder thoracoabdominal branched endoprosthesis (TAMBE; Gore & Associates) is the first such device to enter the pivotal trial stage in the United States, largely based on the initial feasibility data presented by Oderich et al. This study enrolled 13 patients at five centers across the United States with pararenal and type IV TAAA. At 30 days, there was no mortality, aneurysm rupture, conversion to open surgery, need for dialysis, or spinal cord injury. The only major adverse events reported were blood loss in excess of 1,000 mL in four patients. Additionally, one patient had a renal branch occlusion from a dissection, and one patient had a type Ic endoleak from a renal branch, which was successfully treated.

Traditionally, open TAAA repair has been associated with high rates of perioperative mortality, spinal cord ischemia, and other complications. Having an endovascular option to treat these patients would represent a dramatic paradigm shift, especially if outcomes such as those demonstrated by Oderich et al can be achieved. Hopefully, these exceedingly positive outcomes with high technical success and low complication rates will continue in the TAMBE pivotal trial and in general practice thereafter. This will also presumably help expedite the approval of other endovascular TAAA devices, including both custom and off-the-shelf options.

CRITICAL QUESTIONS FOR THE DECADE AHEAD

Will Endovascular Devices Be Available to Treat TAAAs?

Total endovascular repair of extensive TAAAs remains a significant limitation. In the United States, there are currently no approved devices for this indication. Although reasonable results have been described using off-the-shelf components—including by our group using the "octopus" configuration[1]—and with physician-modified devices, having disease- and purpose-specific FDA-approved devices available will undoubtedly change the landscape. Progress has been slow, but the future appears bright.

The Gore TAMBE device demonstrated excellent results in early feasibility studies and has now begun recruitment in the United States pivotal trial phase. TAMBE is a four-branch device that can be used off-the-shelf for a range of visceral anatomic configurations. A similar concept is employed with the Valiant TAAA system (Medtronic), which recently received an FDA Breakthrough Device designation, and it hopefully will move quickly into the trial phase as well. This modular device is based on the Endurant platform (Medtronic), which again is designed to be adaptable to different anatomies.

What Role Will Custom-Made Devices Have?

In this era of personalized medicine, there is interest in creating custom devices for TAAA repair. Although there are certainly drawbacks to this approach, including specific anatomic limitations and production time, the benefits of a patient-specific approach are obvious. Custom programs are currently limited to physician-sponsored FDA individual device exemption (IDE) trials, which are being compiled by several physicians in the United States IDE Aortic Research Consortium and have reported good early results.

When Will These Devices Be Commercially Available?

This next decade will represent a sort of "aortic space race," with multiple companies racing for excellent outcomes, device approval, and market share. However, availability will generate additional questions that will be among the most important to answer for the future of aortic repair. These include whether these devices should be widely disseminated or stay centralized at the most experienced centers, if an off-the-shelf option will become standard or if there be a move toward custom repair for most patients, and what the role of open repair for TAAA will be, if any.

What Are the Long-Term Outcomes of Endovascular Treatment for TBAD?

Both standard TEVAR as well as PETTICOAT or STABILISE techniques have shown promise for improved aortic remodeling in the short term. However, once patients survive the acute phase, the Achilles heel of TBAD has been the formation of late aneurysms and persistent false lumen flow. These aneurysms can be exceedingly difficult to treat, especially with a thickened and fibrotic septum dividing the lumen. There are ways to tackle this problem, including endovascular septotomy ("cheese wire" technique), septal rupture, and other techniques. Still, an ounce of prevention is worth a pound of cure.

The availability of the new Zenith dissection stent system may be a game-changer in this regard. With the results of STABLE 1 suggesting that most patients have favorable remodeling, this may become standard of care for acute and subacute TBAD. Anecdotally, we have also had very good experience with this device and technique. It remains to be seen how durable this effect will be. If we can promote false lumen thrombosis and prevent late aneurysm formation, the future of aortic dissection treatment will be dramatically changed for the better.

Endovascular Treatment of Post Type A Chronic Aortic Arch Dissection With a Branched Endograft: Early Results From a Retrospective International Multicenter Study

Verscheure D, Haulon S, Tsilimparis N, et al. Ann Surg. Published online April 8, 2019.

The aortic arch, which involves the cerebral branches, is perhaps the last frontier for endovascular therapy along with the ascending aorta. Open surgery has been the only option for patients with pathology involving zones 0–2 of the arch or at minimum some type of hybrid approach with supra-aortic debranching and TEVAR. Branched and fenestrated technology, while initially conceived for use in the paravisceral aorta, has shown some early promise for use in the arch as well.

This multi-institutional European study reports outcomes of 70 patients with a previous open surgical repair for type A aortic dissection undergoing arch repair with the Cook A-branch device (Cook Medical). All patients in the study were considered unfit for open repair. The A-branch device is custom-designed with either two or three inner branches, as dictated by patient-specific anatomy. The device was landed in the prior ascending surgical graft for proximal seal, and the branches were cannulated by either arm or direct carotid access.

Three-branch devices were used in seven (10%) patients, and the remainder received two-branch configurations. Patients who received the two-branch device all underwent left carotid-subclavian bypass or transposition. Technical success was achieved in 94.3%. The combined in-hospital mortality and stroke rate was 4% (three patients), with one minor stroke, one major stroke, and one death from multisystem organ failure. Twelve patients required early reinterventions, primarily for access site complications. In the longer-term follow-up, the reintervention rate was 29% and overall mortality was 11%, with seven of eight deaths unrelated to the aorta.

Although these patients were considered high risk, the results of this study are encouraging. Endovascular interventions in the proximal aorta are certain to be afflicted by cerebrovascular and other complications, but the rates seen here are quite low and likely will improve with increasing surgeon experience. The rate of reintervention is high but not unexpected in this patient population. When type A repair includes only the ascending aorta, the remainder of the arch often remains dissected and at risk for late complications. Having a branched endovascular option to address this issue will be extremely valuable for these patients. Although more study is needed before these types of devices can be adopted as the standard of care, there is certainly potential.

CONCLUSION

Although the current state of EVAR is well ahead of where it was a decade ago, there is still tremendous room for growth. There will certainly be new unanticipated challenges ahead, but we should embrace those challenges and look forward to the resultant innovations. ■

1. Dua A, Lavingia KS, Deslarzes-Dubuis C, et al. Early experience with the Octopus endovascular strategy in the management of thoracoabdominal aneurysms. Ann Vasc Surg. 2019;61:350-355.

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