VIVA Foundation Convenes Vascular Leaders Forum on Endovascular Repair for Aortic Aneurysms

With a focus on endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms (AAAs) and thoracoabdominal aortic aneurysms (TAAAs), The VIVA Foundation convened a Vascular Leaders Forum (VLF) on April 5, 2025, in Washington, DC. VIVA Board Members Drs. Sean Lyden, Niten Singh, and Parag Patel led the forum. VLF sessions aim to bring together experts and key stakeholders from a variety of backgrounds to focus on a singular topic, working in collaboration to advance the field of vascular medicine and intervention. Recent sessions have covered chronic limb-threatening ischemia (2024), deep venous disease practices (2022), and paclitaxel safety (2019).

"As with prior VLFs, we focus on areas where uncertainty exists. In the aortic space, new devices to treat complex pathology are being investigated, and there are now some available," noted Dr. Singh to *Endovascular Today*. Dr. Lyden continued, "These new FDA-approved devices are very expensive and many times cost more than the hospital is paid for the DRG [diagnosis-related group]. Questions regarding who should be implanting these devices and the implications of new technology can lead to unexpected issues."

This year's VLF included a full day of presentations and panel discussions involving physicians from across specialties as well as industry. Regulatory expert Dorothy B. Abel, BSBME, presented and shared perspectives from her 30-year tenure at the agency with specific focus on aortic disease and devices and her current role as a consultant.

STANDARDIZING METRICS

The first session of the day focused on standardizing metrics for EVAR outcomes, with presentations exploring optimal metrics, differences between United States and European recommendations for surveillance, how reintervention affects outcome reporting, and designing attainable post-EVAR surveillance goals. During the panel discussion, participants emphasized the need for prospective studies and debated the best way to address issues of patient compliance with surveillance imaging.

PHYSICIAN-MODIFIED ENDOGRAFTS AND CUSTOM-MADE DEVICES

Drs. Singh and Patel moderated sessions on physician-modified endografts (PMEGs) and custom-made devices (CMDs) for TAAAs, respectively. Presentations during the PMEG session included how to share knowledge and standardize training for their use, a debate as to whether PMEGs are a benefit versus a problem for future care and if they will always be necessary, and how FDA can improve knowledge sharing from PMEG investigational device exemption (IDE) trials. The main focus of the panel discussion centered on the underreporting of outcomes by low-volume centers and how to monitor those outcomes, as well as the lack of funding for and access to physician-sponsored IDEs. The difficulty in sharing knowledge through the medical literature without an IDE was noted.

The participants then went on to discuss CMDs, focusing primarily on the path to commercialization and its challenges, with dialogue volleying back and forth as to whether CMDs should be available to all centers or only IDE centers with additional certification or volume. The majority agreed that to produce the best outcomes, systems need to have the resources and infrastructure to support CMD implantation; these outcomes are not just volume specific and need to be better defined. With some devices now FDA approved, centers of excellence and accredited centers will be areas of growth.

REGULATORY CHALLENGES

Panelists took time during the regulatory session to discuss the current state of reimbursement for AAA devices, highlighting reimbursement challenges from NTAP (New Technology Add-on Payment) and that lack of payment in general has a major effect on innovation. Participants stressed the importance of clear communication with FDA and the Centers for Medicare & Medicaid Services (CMS) and education of how EVAR devices impact patients, with costs, data, and endpoints as major drivers for that conversation.

OFF-THE-SHELF SOLUTIONS

With Dr. Singh as moderator for the session on off-the-shelf solutions, participants engaged in discussion on how to manage patients who do not qualify for an IDE, the role of CHIMPS (chimney, periscope, snorkel), solutions with commercial TAMBE (Gore Excluder Thoracoabdominal Branch Endoprosthesis, Gore & Associates), and hybrid solutions with ZFEN (Cook Medical) and laser in-situ fenestration. Panelists and partici-

pants agreed that CHIMPS is now rarely utilized in favor of other techniques. Data from the 1-year TAMBE pivotal trial are anticipated.

ENDOLEAKS AND ENDOLEAK DETECTION

There has been ongoing debate surrounding the term "endoleak," with participants noting that it invokes concern among patients and is often misunderstood by practitioners as an emergency. Presentations during this session covered whether the term is a detriment to patient care, when type II endoleak is a concern, use of contrast-enhanced ultrasound for endoleak detection, and differentiating occult type I/III endoleaks from type II endoleaks.

Participants almost unanimously voted for a change in terminology and considered how endoleaks would be further classified while taking natural history into account. VIVA members are taking this as an action item for further discussion and a potential white paper.

Dr. Lyden told *Endovascular Today*, "The terminology 'endoleak,' which was created in the '90s as a way to describe perigraft flow, is a poor term. The 'leak' portion of the term has caused physician, patient, and family alarm." Dr. Singh continued, "This has led to unnecessary transfers between facilities. With current access by patients and families to their electronic medical records and the ability to view radiologic reports, this creates fear and anxiety of having a leaking aneurysm." "The course of a 'type II endoleak' is often benign, and the terminology should likely be changed so that other providers and patients do not think of an endoleak as a "leaking aneurysm" with impending rupture," both noted to *Endovascular Today*.

The session's panel discussion closed with a detailed conversation regarding use of contrast-enhanced ultrasound for endoleak detection, with cost of setup, staffing, learning curve, and reimbursement noted as important considerations.

ARTIFICIAL INTELLIGENCE AND THE FUTURE OF DETECTION AND SURVEILLANCE

Dr. Patel moderated the final session of the VLF on artificial intelligence (AI) and its potential role in detection and surveillance. Presentation topics included available options, designing technology assessment models to determine feasibility within systems, and opportunities and challenges to implementation of AI. With increasing patient demands, presenters noted that scalable solutions are needed. Challenges warranting further discussion included how to protect data and privacy and getting buy-in from all stakeholders. Some agreed that the best use of AI currently is to improve workflow and efficiency rather than for detection of AAAs.

Dr. Lyden offered closing remarks for the VLF, thanking participants for their insights and thoughtful discussion. "When you get experts in the field together, it helps push societies out of the gate for change. We have a couple of opportunities [as a result of this VLF], and we thank everyone for their time and their effort."

In comments to *Endovascular Today*, Dr. Singh noted, "We would like to continue the strong tradition of multidisciplinary exchange of ideas to improve the care of patients with AAA." Dr. Lyden echoed those sentiments, adding, "We always intend to gather world experts from all disciplines involved in vascular care. We look forward to when FDA and CMS representatives are once again able to attend."

Regarding next steps, the VLF leadership told *Endovascular Today* they will be creating a white paper on the unmet needs in complex AAA repair, as well as another paper calling attention to the urgent need to remove the term "endoleak" from the lexicon and creating a new term that has more clinical applications and less fear associated with it. ■