VDM Vascular Disease Management

INTERVIEW

VQI Collaboration With the International Consortium of Vascular Registries: How Can It Better Evaluate Aortic Endograft Performance?

An Interview With Adam Beck, MD, FACS

Adam Beck, MD, FACS
UAB Medicine, Birmingham, Alabama

Keywords
Endovascular Aneurysm Repair
EVAR
Vascular Quality Initiative
International Consortium Of Vascular Registries

December 2023
ISSN 2152-4343

Adam Beck, MD, FACS
Vascular Surgeon
UAB Medicine, Birmingham, Alabama

VASCULAR DISEASE MANAGEMENT 2023;30(12):E221-E222

At the 2023 VEITH Symposium in New York City, Adam Beck, MD, FACS, from UAB Medicine in Birmingham, Alabama presented a session on "VQI Collaboration With the International Consortium of Vascular Registries (ICVR): How Can It Better Evaluate Aortic Endograft Performance." *Vascular Disease Management* spoke with Dr. Beck to discuss how these organizations are working together to improve endovascular aneurysm repair (EVAR).

Dr. Beck, before we talk about your presentation on aortic endograft performance, provide a quick overview of the VQI and ICVR.

VQI is short for the Vascular Quality Initiative, which is an international quality program overseen by the Society for Vascular Surgery. Over 1000 institutions participate in the VQI. Data is collected for 14 individual procedural registries, and over one million procedures have been collected thus far. One of those registries includes endovascular aneurysm repair (EVAR), which I'll talk about in just a moment. ICVR, or the International Consortium of Vascular Registries, is a collaboration between the VQI and VASCUNET, which is a similar quality-improvement organization from the European Society of Vascular Surgery that consists of 27 countries with independent quality registries.

How does this collaboration help evaluate aortic endograft performance?

Several years ago, we decided that we wanted to evaluate the use of EVAR in ruptured aneurysms. Although EVAR has become common practice for ruptured aneurysms internationally, the device labeling does not include rupture for any devices on the market. In fact, the labels on these devices specifically indicate that they haven't been evaluated in in ruptured aneurysms.

So, the ICVR worked with industry and with an organization called MDEpiNet (www.mdepinet.net) to evaluate these devices with the idea being that the data could be used to approach the FDA for a potential label change to include ruptured aneurysms, which would allow the companies to specifically teach clinicians to use EVAR devices for ruptures. Because this has not been done with registry data before, it is essentially a proof-of-concept project that will lay the groundwork for similar projects in the future. Device approval requires premarket evaluation often followed by post-approval studies after market approval by FDA. Post-approval studies can be a very costly and lengthy process and are often restrictive in their inclusion criteria, which ultimately makes them not align with how the devices are used after approval. Once devices are approved, we use them however we think is best for our patients, which is very often not the same way they were evaluated in a clinical trial. The ICVR provides us the opportunity to look at how the devices are actually being used in the real world internationally, and to potentially use those data for regulatory purposes.

What is the one takeaway that you wanted the audience at VEITH to get from your presentation?

I think that it's important to recognize that EVAR devices are being used in common practice for ruptured aneurysms in ways they were not studied in the clinical trials leading to their market approval. Although we believe EVAR is what is best for our patients with ruptured aneurysms, we need data collected from routine every day practice to evaluate their performance. The use of quality registry data in collaboration with industry and the FDA, provides a novel, efficient and low-cost method to evaluate these devices and satisfy this goal. If we are able to successfully achieve a label change through this project, this will allow industry representatives to specifically train physicians on the best techniques to treat ruptured aneurysms. The end result is to help patients. ■