ROUNDTABLE DISCUSSION

Utility of Registry Analysis of Long-Term EVAR Trends

Moderator Jack Cronenwett, MD, asks a group of expert panelists about improving EVAR follow-up across patient populations, advantages and limitations of registry data to evaluate devices, efforts to link data across registries, and how to support future study efforts.

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In November 2021, an FDA-convened panel expressed concern that current devices for endovascular aneurysm repair (EVAR) may not outperform open surgery in the long term due to higher need for reintervention or other complications. The panel agreed that real-world surveillance is needed to assess mortality, aneurysm-related mortality, aortic rupture, and reintervention up to 10 years after initial EVAR. In addition, they recommended that imaging data should be analyzed to evaluate endoleak, aneurysm size change, and device patency, integrity, and migration. Finally, they recognized the burden of such data collection and the need to develop a supported but cost-effective solution.

Dr. Cronenwett: It is challenging to obtain annual follow-up in patients after EVAR, particularly when there have been no complications or complaints. Medicare data suggest that late imaging occurs in a minority of patients from both urban and rural areas. How can we improve long-term surveillance imaging for all patients after EVAR?

Dr. Wang: Long-term follow-up for EVAR in the Society for Vascular Surgery Vascular Quality Initiative (VQI) registry falls far short of 100%. Distance travelled to urban medical centers for follow-up, lack of health literacy regarding the importance of follow-up, and the organization needed to ensure that an imaging study is obtained during the follow-up appointment are all contributors. A specific protocol is required to identify patients who have missed their follow-up appointments, which is the first step to allow further outreach measures. Longitudinal follow-up can be especially problematic if "everything looked fine" on prior visits. Thus, patient education regarding the importance of continued surveillance is critical. Finally, if patients cannot travel, it is possible to obtain the CT scan or ultrasound locally, with the images sent to the original surgeon for review. This requires coordination with local physicians and ideally a mechanism for reimbursing the original surgeon for the work of reviewing and comparing images, without an office visit.

Dr. Brooke: For patients living in remote rural areas, there are both economic and geographic barriers to follow-up after EVAR. This includes the travel costs that patients must incur to obtain follow-up as well as limited technology and resources within low-population regions in the United States and abroad. Even the ability to conduct virtual telehealth follow-up can be compromised when patients live in rural areas with limited broadband coverage or cell phone reception. It is simply not practical to expect that all rural patients will obtain follow-up imaging at the medical center where their EVAR was performed. The surgical team will often need to identify community medical centers closer to the patient's home where surveillance imaging can be obtained with less cost to the patient. These studies can be sent electronically for review by the vascular surgery team, followed by a telephone call or telemedicine visit. All of this requires a protocol in place and staff to facilitate the visits and communications and a system that provides alerts if patients miss follow-up visits.

Health care systems and their providers must employ a combination of patient education and reminder strategies to reinforce the need for follow-up after EVAR. Vascular surgeons should focus on improving the health literacy of their patients about the risks of not following up at the point of care, and hospitals should utilize automated technology to provide reminder messages to patients following discharge. This includes leveraging the electronic medical record (EMR) to identify patients who underwent EVAR and sending out electronic prompts via email or the patient's personal EMR portal (eg, MyChart [Epic Systems Corporation]), as well as making phone calls to schedule appointments at defined time points after surgery. Centers that have implemented specific protocols and track follow-up rates have been able to show substantial improvement.

Dr. Goodney: Although we all agree that long-term follow-up after EVAR is ideal, it is important to set realistic goals. Some patients may not wish to continue follow-up if their general health concerns make it burdensome for them. As such, society and federal quality metrics will have to consider which patients want follow-up, which patients can obtain follow-up, and what their follow-up participation records have been. In many ways, the likelihood of follow-up represents a true "patient-centered" quality outcome measure.

Dr. Cronenwett: The most cost-effective method for obtaining late follow-up data would be to use existing administrative data sets for billing, such as Medicare claims. What are the advantages or limitations of using claims data to evaluate specific EVAR devices?

Dr. Brooke: The advantage of administrative claims data such as Medicare is that it is available for all defined

beneficiaries, includes patients from all regions, and can be used to capture claims for death, aneurysm rupture or aortic reinterventions, or imaging after EVAR, even if performed in different hospitals. The main limitation of using administrative claims is the reliance on diagnosis or procedure codes for billing purposes that may be inaccurate or not granular enough to capture a specific clinical condition or complication. Furthermore, claims data are generally limited to a specific population, such as Medicare beneficiaries, and thus do not usually include all patients being treated.

Dr. Schermerhorn: The biggest issue using Medicare data alone to evaluate device outcomes is that the claims data do not contain specific device identifiers. Further, reliance on ICD coding alone yields suboptimal accuracy for identifying specific reinterventions or identifying rupture after EVAR. Use of CPT codes increases accuracy of identifying a specific procedure but incurs added expense. Various algorithms can be implemented to improve the accuracy of coding and the relation to a prior aortic procedure, but these need validation.

One potential work around for the current inability to identify the endograft and other anatomic and procedural characteristics for patients not included in a registry such as VQI would be to require endograft manufacturers to supply a limited data file to FDA or a third party for linkage to Medicare claims data that would allow long-term follow-up and evaluation of these grafts outside of the VQI. Although the VQI continues to represent an increasing proportion of abdominal aortic aneurysm (AAA) repairs in the United States, it is still not universal and outcomes outside of the VQI may not be the same as those in it. Given the VQI's experience working with these data (procedural and Medicare-linked follow-up), it makes sense for the VQI to handle these analyses and couple them with the VQI-VISION data set for more complete coverage and analysis (www.vqi.org/data-analysis/blinded-datasets). Data sets from other insurers (private and Veterans Affairs) could be linked as well. All manufacturers currently collect these limited data files and would potentially be willing to share them with FDA if requested. It is likely that these manufacturers collect these same data for patients undergoing EVAR in other countries, and it may be possible in some countries to link these limited data files with administrative data for long-term follow up as well.

Dr. Goodney: The other disadvantage of "bland" claims data, that is without linkage to clinical registries such as VQI, is that Medicare data tells us about practice a year or two ago. Because of the time periods necessary to process and prepare claims-based data sources, it does not represent real-time feedback. Better results for quality improvement would evolve if the data were real-time and practice-integrated. Methods need to be developed to reach this goal, using tools such as the Virtual Research Data Center at the Centers for Medicare & Medicaid Services (CMS).

Dr. Cronenwett: Society-sponsored registries such as the VQI collect specific data about EVAR treatment, including device identifiers, but struggle with long-term follow-up. Linkage of such registry data with subsequent claims data looks promising. What is the current status of such efforts in various countries?

Dr. Goodney: The VQI and the Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION) is a coordinated registry network, formed in 2012, which has collected patients from registries such as VQI, industry trials, and other sources and linked their information to Medicare claims data to obtain long-term follow-up for events identifiable in claims data.[1] More than 500,000 VQI patients overall have been matched to Medicare claims in this FDA-funded effort, and at our last audit, 46,285 patients treated with EVAR in the VQI have been successfully linked to Medicare claims. Several thousand patients in VQI have also been linked to under age 65 data sets, such as the New York State Statewide Planning and Research Cooperative System and industry-based clinical trial data sets.[2]

In VISION, the initial details about patients, procedures, and devices that are recorded in the VQI registry are married to long-term outcomes at the patient level, using validated measures for reintervention, death, aneurysm rupture, surveillance imaging, and cost.[3-7] These data sources allow long-term evaluation of patient outcomes within the registry with very high rates of follow-up—essentially 100% for death, reintervention, and aneurysm rupture. This is possible because Medicare claims are reported by every hospital, even if it was not the hospital where the initial EVAR was performed. This process occurs at a fraction of the costs of clinical trials, and these methods have allowed us to study the effect of devices and treatment types on long-term outcomes. We can then provide these long-term outcomes to individual centers for feedback and quality improvement (survival, reintervention, and surveillance reports). Importantly, such information can be provided to device manufacturers to meet regulatory requirements. Because nearly 80% of patients treated with EVAR are Medicare beneficiaries in the United States, this offers nearly complete follow-up. When patients treated at a younger age reach age 65 and Medicare status, additional follow-up becomes available.

Dr. Mani: Cross-linkage of data from surgical quality registries (eg, VQI in the United States or Swedvasc in Sweden) with national administrative registries for evaluation of long-term events can be a very powerful combination. In Sweden, the presence of a unique personal identifier facilitates such cross-linkage and allows for monitoring of events that result in contact with any health care facility (eg, reinterventions), as well as survival and cause of death, with close to 100% capture of events. The downside of the claims-based method is that it depends on correct coding. Although this can be reliable for reinterventions and reoperations during follow-up, claims data will not capture details such as endoleaks not requiring intervention or aneurysm sac expansion. Additionally, when it comes to late aortic ruptures post-EVAR, there is the obvious risk that some of the fatal cases are coded erroneously as cardiac events in patient who do not undergo autopsy after sudden death. An important potential solution to this problem is to use the initial registry to investigate specific late events during long-term follow-up in the specific cases identified by claims analysis. Although this requires additional work/expense, it is much more efficient than having to follow all patients in a registry for many years. Meanwhile, it is important to acknowledge the need for ethical and legal considerations when linking registries using unique personal identifiers; personal integrity laws in some countries may limit the possibility of performing cross-linkage studies.

Prof. Varcoe: Registry-claims linkage studies have several advantages over clinical trials. They can accumulate a large sample of real-world patients, reducing risk of type 1 error, and will have very few subjects lost over longer follow-up periods when linked to death registries, thus reducing ascertainment bias. In that way, they can complement randomized trials and, as stated by FDA, may be the best and most cost-effective method of determining late differences in survival between EVAR and open repair.

We used the Australasian Vascular Audit (AVA), a prospective registry of specified vascular surgical procedures and compulsory for surgeons to retain membership in the Australian and New Zealand Society for Vascular Surgery. Like the VQI, AVA data fields capture demographic information, risk factors, procedure types and specific surgical details, including the operative site, indication, perioperative complications, and technical specifications for any device used. We performed a study where we applied data linkage between the AVA and administrative data sets (Admitted Patient Data Collection [index and subsequent ICD-10 codes], Register of Births Deaths and Marriages, and Cause of Death Unit Record File) over a 9.5-year (2010-2019) follow-up period to determine rates of mortality (all-cause and cause-specific), subsequent aneurysm rupture, and reintervention (aortic and non-aortic) rates between EVAR and open repair.[8] After propensity score matching, findings demonstrated increased rates of mortality in the EVAR group beyond 1 year of follow-up, which became more pronounced beyond 4 years. This was associated with an increased risk of secondary aortic interventions and subsequent aneurysm repair in the EVAR group, suggesting that reduced durability may have been the cause.

We are planning to perform a similar analysis on patients receiving EVAR and open repair for ruptured aneurysms and have recently finalized results from a similar study that directly compared contemporary endograft devices. These results can certainly be applied to evaluation of individual EVAR device types.

Dr. Cronenwett: What resources are needed to support these efforts? Is there an opportunity for international collaboration among countries that use the same devices?

Dr. Goodney: Our work in VISION thus far has been supported by the FDA, other federal grants, as well as resources from the VQI registry and industry partners. However, there are many things to consider going forward. First, resources for growth will need to be identified from stakeholders and collaborators who care for patients with AAA. These efforts will need to be linked to regulatory guidance, and FDA will be a key partner to help determine what follow-up should entail, when it should happen, and how it should be measured. Second, many believe remuneration for surveillance efforts needs to be considered in the "global" cost of EVAR, and patients should not shoulder the burden alone. And third, surgical societies should coordinate their surveillance recommendations and outcome assessments so that each device is measured with the same "measuring stick"—this will ease comparisons across all devices. It won't be beneficial to have each device followed using slightly different metrics. Device dashboards could provide these elements in a systematic and transparent fashion to help inform patients, physicians, quality assurance organizations, and regulators about the long-term outcomes of EVAR in real-world practice.

Dr. Wang: It is clear that successful EVAR requires both a properly conducted index operation, as well as assiduous postoperative monitoring, given the not infrequent reintervention rate. Therefore, the work needed to continue this surveillance should be properly reimbursed. There should be continued efforts to educate patients and providers about AAAs and endovascular repair and the potential need for reintervention. We should also ensure that these issues

are discussed at our national societies—and included in guidelines to emphasize how important follow-up is given the finite risk of device failure, which has been highlighted in device trials as well as clinical registries. Large clinical registries exist in many countries, and device-specific databases exist as well. Linking data sets across companies as well as countries can enable patterns of outcomes to be detected sooner, which can in turn inform practice in a more real-time way than clinical trials can.

Dr. Mani: International collaboration between vascular surgical registries results in a wealth of data. Significant efforts have been made over the past years by the International Consortium of Vascular Registries (ICVR) to harmonize data collection in quality improvement registries in vascular surgery worldwide, which is the basis for such collaborations. Although differences in practice between countries, for example regarding follow-up, can result in variations in outcome, international benchmarking also introduces a unique opportunity to identify best practice. Key challenges for future efforts in this field include the need to achieve reliable registration of device information in vascular registries internationally and ensuring comparable long-term data. Additionally, transatlantic data collaboration needs to be adjusted to the regulatory laws such as GDPR. These are important focus areas for international registry collaborations such as ICVR and VASCUNET.

Prof. Varcoe: International collaboration to combine clinical registries from countries with similar aortic practice is the holy grail. Such a "global" registry could be used to standardize reporting metrics, drive best practice in follow-up, and inform decision-making by providing a large, real-world cohort of cases that link clinical data to databases, which capture repeat interventions and death. However, I can foresee several challenges, not the least of which would include issues of data ownership, patient privacy, and cost. Although it may be tempting to put that cost back to device manufacturers, that may be poorly received if they see little incentive to fund a program, which may result in movement toward a greater proportion of open repair at a time when bottom lines are already being eroded by payers. It is my view that governmental and surgical society funding should be the source. Governments and societies represent the patients, and the patients have the most to gain from such endeavors.

Dr. Schermerhorn: Long-term imaging follow-up is crucial for successful EVAR. Late rupture is much more common after EVAR than open repair. More than half of EVAR patients are lost to imaging follow-up by 5 years according to Medicare data and VQI/VISION data. It is likely that many ruptures could be avoided with close follow-up and minor reintervention. This was not anticipated at the time of the introduction of EVAR. Despite an increasing awareness of this, there has been little improvement in long-term follow-up. A coordinated effort on the part of physicians (both those performing EVAR and primary care), industry, vascular surgery societies, patient advocacy groups, and regulatory/funding agencies would have the greatest potential to improve EVAR outcomes. International data coordination would substantially increase the patient numbers and allow broad generalization of results. There may be regulatory hurdles coordinating data from different countries or different payers. A regulatory mandate would likely be needed for industry to provide limited data files for linkage to payer-based long-term outcome files. Funding these efforts could potentially come from device manufacturers who would likely put this cost into the initial cost of their endograft. Centralized data collection and independent analysis would reduce overhead compared to individual industry-based analyses of their own data, which would then minimize the additional costs to be borne by hospitals/insurers. ■

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