VISION and Its Role in the Study of Devices for Thoracic Endovascular Aortic Repair

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The need for postoperative surveillance does not end at 30 days, a previously accepted time point used by the American College of Surgeons National Surgical Quality Improvement Program (NSQIP). As vascular surgeons who use devices to treat complex disease processes in medically complex patients, there remains a need to follow patients in the long term, to study device failure, and to evaluate for areas of improvement to impact patient outcomes. The Vascular Quality Initiative (VQI), the embraced registry of the Society for Vascular Surgery, effectively extended the follow up time horizon for vascular surgery patients entered into registries, mandating one-year follow-up after various surgical and endovascular procedures. Further, Dr. Goodney's algorithm for matching patients in the VQI registries with Medicare billing data allows patients to be followed in perpetuity, by linking any subsequent admissions, studies, and reinterventions to the original operation while they are alive. This is the holy grail of registry research: high-quality, reliable data that extends for the lifetime of the patient.

The power of combining VQI data and Medicare matched datasets can be applied to diverse disease processes and procedures, including Thoracic Endovascular Aortic Repair (TEVAR). Utilizing the rich granularity of the TEVAR/Complex EVAR module, and combining it with Medicare matched long term data, we have the ability to study the outcomes of patients undergoing these procedures, defining modes as well as the timing of these modes of failure, and trends across the country in addressing these device failures. In this way, VISION (Vascular Implant and Interventional Outcomes Network) accomplishes what industry-sponsored trials do, and then some: large-scale inclusion of centers, patients, and surgeons performing these procedures with enhanced generalizability, and the ability to monitor outcomes for the foreseeable future.

In a recently published VQI-based paper, the overall rate of TEVAR reinterventions was 7.9%, with an in-hospital reintervention rate of 3.5%. The reintervention rate differed by the type of thoracic aortic pathology, with reinterventions most commonly performed for Type B dissection. As we continue to learn more about the long term consequences of TEVAR in patients with thoracic aortic pathology, it will be important to continue to stratify by the type of aortic pathology, as the frequency and nature of the reintervention does differ significantly based on the original indication for surgery. Further, these data will inform clinicians as well as regulators as to the relative success rates of TEVAR for differing pathologies over time, controlling for patient factors such as age and presence of comorbidities.

While industry has adopted type B dissection as an indication for the application of TEVAR, it is important to note the relevance of the IDEAL (Idea, Development, Exploration, Assessment, and Long term assessment) framework in the continual evaluation of devices, even after they have achieved FDA-approval. This framework underscores the importance of the continued study of devices in the post market approval setting, due to the known small but finite risk for device failure over time. This framework, while initially depicted as a type of "life cycle" where each stage is predicated on the last, has some flexibility in that one can return to earlier iterative phases to allow for smaller improvements, thus enhancing the evolution of the technology. VISION is thus the perfect vehicle for continued device study and development, as it is informed by real world data capture in real-time.

The role that observational registries play in the modern era of health care cannot be disputed. The clinical information that has been amassed under the VQI infrastructure has lent insight into patient outcomes that have previously been understudied. Women, in particular, have not been included in clinical trials with the same frequency that men have. When data from a large national registry can be culled for information regarding patient outcomes, it shows us the power of registries to transcend gender-based gaps in research.

References

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