

Clinical competence statement on thoracic endovascular aortic repair (TEVAR)—multispecialty consensus recommendations

A Report of the SVS/SIR/SCAI/SVMB Writing Committee to Develop a Clinical Competence Standard for TEVAR

INTRODUCTION

Thoracic endovascular aortic repair (TEVAR) is a minimally invasive alternative to open surgical reconstruction that is being incorporated into vascular surgery, cardiothoracic surgery, interventional radiology, interventional cardiology, and vascular medicine practices. Contemporary techniques for TEVAR were developed by multiple specialists, primarily vascular surgeons, interventional radiologists, and cardiothoracic surgeons, who often worked together to combine their complementary skills.¹⁻⁹ Transferring technology, operative and interventional skills, and adjunctive medical therapies developed in their abdominal aortic aneurysm and peripheral vascular experience, these specialists demonstrated the feasibility and subsequent efficacy of TEVAR.¹⁰ This report delineates the skill set and knowledge base necessary to successfully perform TEVAR according to a consensus of opinions of experts who have been pioneers in developing the technology, have had national leadership roles in clinical trials, and have trained physicians who have developed new centers of excellence in TEVAR.

TEVAR: THE PROTOTYPICAL HYBRID PROCEDURE

TEVAR, as its name states, is first and foremost an endovascular procedure, but it is one that cannot be performed without adjunctive surgical participation. The relatively large size of the thoracic aorta and the physical limits of compression of thoracic endografts will for the foreseeable future render TEVAR a procedure that requires surgical access to the vascular system. Even if advances in percutaneous closure devices for large femoral arterial punctures make access site closure feasible, the marginal diameter of many external iliac arteries renders this a moot point, because the surgical creation of an iliac conduit will be required. Although iliac conduits have been uncommonly required to provide vascular access for abdominal aortic endografting (EVAR), up to one quarter of patients may require them for TEVAR, primarily as a result of the requisite diameter of the delivery systems, which are typically in the 24F to 28F range. Given the more frequent need for both iliac conduits and access vessel repair, securing vascular access for TEVAR is clearly more complicated than for EVAR. Additionally, to extend the applicability of TEVAR, the endograft is commonly placed over the orifice of the left subclavian artery, and many patients require extraanatomic surgical revascularization or subclavian-carotid transposition. Consequently, unless or until technological advances render these ancillary surgical procedures unnecessary, the need for a surgeon with training and expertise in these less common exposures and revascularization procedures is readily apparent.

On the interventional side, TEVAR requires the full endovascular skill set needed to catheterize and treat any of the vessels in the endograft delivery pathway, including those the endograft delivery system must be advanced through or past, as well as those the deployed endograft may encroach upon: primarily the brachiocephalic and mesenteric vessels. TEVAR requires far more in the way of endovascular skills than simple passage of a guidewire into the aorta, and expertise with the full range of endoluminal instrumentation (including large-bore sheaths, guiding

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catheters, stiff guidewires, angioplasty balloons, stents, snares, embolization coils, and, of course, endografts) is required to ensure a safe and successful procedure. Selective catheterization skills are needed to optimize precise graft deployment, and endoluminal intervention skills are needed to restore perfusion to inadvertently covered or embolized vessels. Expertise with fluoroscopic guidance, radiographic technique, acquisition projections, and image postprocessing will ensure optimal endograft placement and recognition of relevant complicating factors. These interventional skills are standard elements of the training curricula of the interventional specialties involved in TEVAR: vascular surgery, interventional radiology, interventional cardiology, and interventional vascular medicine.

The aforementioned surgical and endoluminal skills aside, successful TEVAR has a knowledge base requirement—not just of the nature of thoracic aortic pathology, but also of the complications attendant to its treatment, such as spinal cord ischemia, mesenteric ischemia, stroke, and renal insufficiency. Although this knowledge base is incorporated into vascular surgery and cardiothoracic fellowship training, it is not a standard component of training in the other interventional fields. Nonetheless, unlike surgical skills, the possession of which relates to one's medical heritage, the knowledge base necessary for competence in the management of TEVAR cases and their complications is something that can be acquired by any of the involved specialties through continuing medical education (CME) activities. Another knowledge requirement for TEVAR is that of computed tomographic (CT) and angiographic interpretation of thoracic vascular pathology to properly diagnose the condition, determine its suitability for endoluminal repair, perform proper TEVAR measurements and planning, and interpret post-TEVAR imaging studies to determine the ongoing success of the procedure. These skills are less specialty specific because they relate more to one's previous experience with EVAR or TEVAR than to one's medical heritage. As EVAR has become a standard component of all the interventional specialty training programs, and TEVAR will likely also, new graduates may be expected to gain this experience in their fellowships. To ensure uniformity in the interim, all those seeking TEVAR credentials will have to document their previous EVAR or TEVAR experience.

ASSEMBLING THE SKILL SET

As detailed previously, safe and successful performance of TEVAR requires diverse knowledge and technical skills not usually vested in one physician at the present time. This explains why most procedures are performed collaboratively between surgeons and interventionists. The former provides the surgical expertise, typically needed for managing vascular access and performing adjunctive revascularizations, while the interventionist performs the endoluminal instrumentation. Because thoracic aortic disease has historically been a surgical condition, the surgeon on the team, usually being the most knowledgeable about common perioperative problems and their management, has typically provided the perioperative care. However, other involved

specialists may acquire the necessary knowledge to assume this role, just as surgeons may acquire the comprehensive endovascular skills necessary to safely and independently perform the endoluminal instrumentation.

Although many contemporary vascular surgeons and a few cardiothoracic surgeons have acquired comprehensive peripheral endovascular interventional skills and can perform TEVAR independently, most cardiothoracic surgeons, who often have large referral bases for thoracic aortic disease, will need to team up with an interventional specialist to safely perform TEVAR. The tendency to minimize the complexity of the endoluminal instrumentation or presume that TEVAR experience alone qualifies as comprehensive endovascular training and entitles independent performance of TEVAR cannot be allowed to prevail over consensus standards of care designed to ensure patient safety and optimal outcomes. Therefore, although privileges to independently perform the endoluminal components of TEVAR can be obtained by vascular or cardiothoracic surgeons, who could then perform TEVAR independently, accepted multispecialty consensus criteria for peripheral endovascular interventional privileges should be followed to ensure that they are qualified to perform all needed endovascular maneuvers and address all likely complications. There are presently two multispecialty endovascular credentialing documents in common use: the recently published American College of Cardiology/American College of Physicians/Society for Cardiovascular Angiography and Interventions/Society for Vascular Medicine and Biology/Society for Vascular Surgery (ACC/ACP/SCAI/SVMB/SVS) clinical competence statement on vascular medicine and catheter-based peripheral vascular interventions¹¹ and the American Heart Association training standards for physicians performing peripheral angioplasty and other percutaneous peripheral vascular interventions.¹² These documents are similar in the numbers of procedures required for credentialing for general endovascular diagnostic and interventional procedures, and either of these would be considered currently accepted credentialing standards for unrestricted general endovascular competency.

PRINCIPAL REQUIREMENTS FOR INDIVIDUAL PHYSICIANS OR TEAMS OF PHYSICIANS

The purpose of this document is to provide standards regarding physician training and credentialing for TEVAR to facilitate the safe and orderly dissemination of this new therapy into clinical practice. This consensus document should be considered to represent minimum requirements for training and preparation to perform TEVAR. Although industry training program requirements may add to these, they will not lessen or substitute for any component. Given the diversity of knowledge and skills required, as well as the multitude of specialties participating, these requirements have been crafted to allow all interested disciplines to participate in TEVAR, although this will often require collaboration with physicians with complementary skills.

All physicians applying for TEVAR privileges should possess the highest level of certification (or eligibility) available in their specialty:

1. American Board of Radiology Certificate of Added Qualifications in Vascular and Interventional Radiology.
2. Board Certification in Vascular Surgery by the American Board of Surgery.
3. American Board of Internal Medicine Certificate of Added Qualifications in Interventional Cardiology.
4. Board Certification in Thoracic Surgery by the American Board of Thoracic Surgery.
5. American Board of Internal Medicine Board Certification with additional certification in endovascular medicine through the American Board of Vascular Medicine.

To ensure the safe and effective application of TEVAR, the following four knowledge and skill-set requirements must be vested individually or collectively in the physician or physicians performing every TEVAR procedure.

1. Familiarity with selecting patients; interpreting CT scans and 3-dimensional reconstructions; measuring; planning; and performing endovascular aneurysm repair, as evidenced by successful performance as the primary operator of 25 abdominal endografts in the previous 2 years or of 10 thoracic endografts in the previous 2 years.

The procedure most technically similar to TEVAR is EVAR, which is routinely performed by vascular surgeons, interventional radiologists, interventional cardiologists, or interventional vascular medicine physicians, acting independently or collaboratively. Skills with CT interpretation and measurement of vascular dimensions, proper sizing and selection of endoprostheses, techniques for delivering large-diameter devices through large (18F to 24F) sheaths, and endograft delivery systems and deployment mechanisms are common to both procedures. Correct device sizing and selection are required to avoid type I endoleaks, migration, and device failure. Reducing the risk of iliac artery injury (rupture or dissection) and rapid recognition and treatment of these injuries are critical for optimal patient outcomes. Familiarity with the long-term follow-up of endografts, reassessment for morphologic changes and device failure, and late complication management is necessary to match the outcomes of the pivotal clinical trials. These skills are developed with significant experience with abdominal and thoracic aorta endovascular repair, hence this requirement.

2. Peripheral intervention skills to perform aortography, bail out covered side-branch vessels, and treat access artery injuries, as evidenced by competency in catheter-based peripheral intervention, as defined by successful performance of the specified number of endovascular procedures in either of the two commonly adopted endovascular credentialing standards:

- A. The ACC/ACP/SCAI/SVMB/SVS clinical competence statement on vascular medicine and catheter-based peripheral vascular interventions.¹¹

- B. The American Heart Association training standards for physicians performing peripheral angioplasty and other percutaneous peripheral vascular interventions.¹²

TEVAR is first and foremost an endovascular procedure, and comprehensive endovascular skills are necessary for its safe and effective performance. Fundamental to TEVAR are technical and interpretative skills of thoracic and visceral aortic angiography, as well as of selective brachiocephalic and mesenteric angiography. Adjustment of gantry angles, optimization of injection rates and image-acquisition parameters, and application of postprocessing functions are essential skills that optimize precise deployment near critical side branches. Furthermore, in the case of device maldeployment with critical side-branch vessel compromise or device collapse, knowledge of the wide array of endoluminal instrumentation and facility with advanced endovascular techniques can effect an endoluminal resolution to what might otherwise require surgical intervention and, possibly, result in severe or fatal complications. Even routine TEVAR cases can require advanced endovascular diagnostic and interventional skills, such as intravascular ultrasonography, intravascular snaring, coil embolization, and side-branch angioplasty and stenting. Although most recent graduates of vascular surgery, interventional radiology, interventional cardiology, and vascular medicine fellowships can be expected to have had sufficient peripheral endovascular training to be qualified as peripheral interventionalists, the same cannot be said for earlier certificate holders. Consequently, physicians from all specialties applying for TEVAR credentials will be expected to document their cases and outcomes to qualify under the guidelines of one of the aforementioned multispecialty consensus documents.

3. Knowledge of thoracic aortic pathology; its diagnosis, natural history, and management options; and recognition and treatment of common complications, such as spinal cord ischemia, renal failure, stroke, myocardial ischemia, and atheroembolization, as evidenced by one of the following:

- A. Board Certification in Vascular Surgery by the American Board of Surgery.
- B. Board Certification in Thoracic Surgery by the American Board of Thoracic Surgery.
- C. Attendance at a minimum of 20 hours of CME specifically devoted to endovascular repair of thoracic aortic pathology in the previous 2 years.

Regardless of surgical board certification, all physicians participating in the team should have completed a minimum of 10 hours of CME specifically devoted to endovascular repair of thoracic aortic pathology within the previous 2 years. A comprehensive understanding of the indications for intervention on the various thoracic aortic pathologic processes that can be treated by TEVAR is required to ensure appropriate application of this new therapy. Although the morbidity associated with TEVAR can be significant, it is typically less frequent and severe than with the open surgical alternatives. Nonetheless, it is important to

be familiar with the diagnosis and management of complications commonly encountered in thoracic interventions, such as stroke, paraplegia, microembolization, and renal failure. Furthermore and ideally, clinicians committed to the diagnosis and treatment of thoracic aortic pathology can be expected to develop specific programs that optimize the clinical care of these patients. In the initial stages of program development, formal CME for all team members demonstrates this commitment and would be expected to be repeated every 2 years. A minimum volume of 10 TEVAR procedures over 2 years would be considered to be the minimum necessary to maintain an active TEVAR program.

4. Capability to obtain and repair access to the vascular system at the brachial, common femoral, or common iliac artery levels and to perform brachiocephalic transposition or extra-anatomic revascularizations, as evidenced by one of the following:

- A. Board Certification in Vascular Surgery by the American Board of Surgery.
- B. Board Certification in Thoracic Surgery by the American Board of Thoracic Surgery.

Although 75% to 85% of patients will have external iliac arteries of adequate size that are sufficiently free of problematic tortuosity or calcification to allow TEVAR from a common femoral site of access, even these will require its surgical exposure, at least for the foreseeable future. Furthermore, in all larger series of TEVAR, aortoiliac exposure and conduit construction have been required with significant frequency: 15% in the first pivotal trial of an approved device in the United States.¹⁰ In this same investigational trial, 20% of TEVAR procedures involved planned covering of the left subclavian artery, all of which underwent mandated brachiocephalic revascularization. Although not all of these would require revascularization in standard clinical practice, the need for brachiocephalic revascularization will be present in a sizable number of patients. Considering the issues associated with obtaining, maintaining, and repairing vascular access vessels, as well as the not-infrequent need for brachiocephalic revascularization, the participation of a qualified vascular or cardiovascular surgeon in all TEVAR procedures is imperative.

Although fear of the need for an acute surgical conversion prompted many to perform their early TEVAR procedures in the operating room under portable fluoroscopic imaging, this has proven to be an extremely rare occurrence, thus opening the door to the advanced imaging options available in dedicated angiographic facilities, such as rotational angiography and intraprocedural CT imaging. Testimony to the safety of this procedure comes from the Gore TAG trial,¹⁰ the basis for the first Food and Drug Administration approval of a thoracic aortic endograft, which reported no acute surgical conversions or intraprocedural ruptures in any of the 142 patients enrolled. Preliminary (unpublished) data from the VALOR trial of a Medtronic thoracic aortic endograft are similarly encouraging, revealing only 1 acute surgical conversion out of 150 TEVAR procedures (a rate of 0.7%) in their high-risk arm.

Therefore, although any alternative facilities should still have to meet surgical standards of sterility and have tables and lighting suitable for the commonly required access and revascularization procedures, just as for coronary angioplasty, they need not be ideal for performance of a thoracotomy and open thoracic aortic repair in view of the rarity of the need for this. Similarly, again as for coronary, carotid, or renal angioplasty, there is no justifiable requirement for a surgical suite or operating team to be held on standby during performance of routine TEVAR procedures. This demonstrated safety of TEVAR is testimony not only to the engineering that has gone into these devices to enhance their deliverability and performance, but also to the outcomes that can be expected when qualified interventionists are performing the procedure.

MAINTENANCE OF CERTIFICATION

Because TEVAR is a relatively new procedure, the requisite annual volume a physician needs to perform to maintain clinical competence is unknown. Considering the typical team approach, members of which may vary, and the fact that the requisite surgical skills are part and parcel of a standard vascular or cardiovascular surgery practice and the requisite endovascular skills are fundamental to an active endovascular interventional practice, maintenance of certification may be more appropriate for the TEVAR program rather than for its individual physicians. Individual physicians would be expected to maintain certification and privileges in their respective core disciplines and to participate in 10 hours of CME specifically devoted to TEVAR every 2 years, the combination of which would be believed to be sufficient for maintenance of their individual TEVAR privileges. For the program as a whole to be sufficiently active to warrant continuation of TEVAR, it would be expected to have successfully performed at least 10 TEVAR procedures over the previous 2 years. Having an active EVAR program could conceivably decrease the TEVAR requirements because of the similarity of the two procedures.

CONCLUSIONS

Endovascular repair of thoracic aortic pathology has emerged as an alternative to open surgical repair that has been associated with reduced morbidity and more rapid recovery. This therapy was developed in most centers by teams of physicians with the complementary skill sets necessary to address the surgical and endovascular challenges of the procedure. In a few centers, exceptional individual physicians have acquired all of the necessary skills to provide TEVAR independently, although this is not the usual situation. When the multidisciplinary approach is used, significant continued participation of every member of the team is necessary to maintain the desired results of the program. Undoubtedly, this technology will mature, and just as the techniques and skills required to competently perform the procedure will evolve, so should these standards. Hospitals and physicians seeking to provide this new therapy should assemble and support a program staffed by surgeons and

interventionists who individually or collectively possess all of the requisite clinical competencies.

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APPENDIX

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