



The Society for Vascular Surgery thoracic endovascular aortic repair guidelines support thoracic endovascular aortic repair as the primary therapy for the treatment of thoracic aortic aneurysms

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In the Society for Vascular Surgery clinical practical guidelines on Thoracic Endovascular Aortic Repair (TEVAR) for thoracic aortic aneurysms (TAAs),¹ the authors have provided multiple useful and important recommendations derived from contemporary best evidence. The guideline is presented in a relatively straightforward fashion moving from epidemiology and clinical presentation to medical management of patients with TAAs. Other aortic pathologies, exclusive of aortic dissection, are also briefly touched on as TEVAR has been used in these multiple settings. The majority of the guideline focuses on the multifaceted management of performing endovascular repair of TAAs, including many of the adjunct maneuvers, like management of the left subclavian artery, spinal cord ischemia, and access, required to deliver a “successful” TEVAR. Finally, the guideline describes follow-up and hospital privileging required to perform TEVAR.

Notable in the present guideline is the known lack of validated level 1 data in the form of randomized clinical trials focused on TEVAR. Guidelines such as this typically summarize in a rigorous way all available evidence published to date using randomized clinical trials as the pinnacle of truth. The data are then stratified according to evidence level based on the grade and strength of a recommendation. Given the overall lack of randomized-controlled trials surrounding TEVAR for TAA, the present TEVAR guidelines used a combination of large institutional, single-center trials, meta-analyses, and large administrative databases. It is important to

acknowledge that the “gap” in evidence focused on TEVAR for TAA likely will never be addressed in a level 1 fashion. This evidence conundrum for TEVAR and TAA parallels the questionable need for comparing open and endovascular abdominal aortic aneurysm repair for ruptured aortic aneurysms. Do we really need such a trial? Who could ethically sign someone up for such a trial when other significant and high-quality “non”-level 1 data point to such a significant benefit from EVAR compared with open repair, as well as TEVAR over open TAA repair. Guidelines focused on TEVAR for TAA, while likely never winning the “evidence race,” are important because they provide us with “best practice” clinical algorithms. Similar to the present guideline, the European Society of Vascular Surgery (ESVS) guideline on the management of descending thoracic aorta diseases reported that none of their recommendations were supported with “A” level evidence. Yet, 21 of the 80 (26%) recommendations were at the “I (1)” level, suggesting that the writers felt strongly about the strength of their recommendation even though the data were not of the highest quality.²

Despite this apparent lack of high-quality evidence, TEVAR has functionally replaced open repair over the last decade as the primary paradigm by which TAAs are repaired. This technically has often been accomplished by performing TEVAR “outside of the instructions for use (IFU)” setting, because IFUs are habitually based on randomized controlled trial (RCT) studies and/or feasibility trials, which include superselected patients based on ideal anatomy and significant surgeon experience. Although offering at most “B” level evidence, post-market registries have been established to track aortic diseases.^{3,4} Furthermore, real-world experiences offered by registries, even with their structural and selection bias, provide guidance for daily practice. Although not derived from RCTs, rather from large single-center experiences and multicenter registries, the recommendations of the present guideline still provide robust results and conclusions.

In addition to TAA, this registry provided some guidance for rarely treated aortic diseases, such as aortoenteric fistulas, mycotic aneurysms, and aberrant subclavian arteries. These pathologies are typically so rare that they can only be collectively addressed through case series and then meta-analyses. Multiple efforts are

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being made to collect data, most notably through the vascular low-frequency disease consortium and the National Registry of Genetically Triggered Thoracic Aortic Aneurysms and Cardiovascular Conditions (GenTAC), in an attempt to make broader recommendations regarding these rarer aortic conditions.^{5,6}

Guidelines such as these on TEVAR help to clarify what is the best available treatment at any given point in time. Clearly, although TEVAR is now the primary paradigm by which TAAs are repaired, we need to continue to monitor our outcomes, especially when endografts are used outside of instructions for use. It is also paramount to concentrate continued efforts on developing other instruments to improve the quality of our future recommendations. In clinical scenarios such as this without level 1 data, health care professionals, vascular societies, and health care companies should promote well-designed, fair, and honest studies, providing full disclosure of conflicts of interest especially when proposing novel treatment recommendations. Only in this way can registries and others non-RCT research provide us with stronger evidence, assuring that we can make both rigorous *and* high-quality recommendations.

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