Unmet Needs in…
Thoracoabdominal Repair

Thoracoabdominal disease management of the future should prioritize better understanding of patient selection, optimization of equipment, regulatory approvals, and improved access to care.

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Over the past 2 decades, endovascular repair has become a viable treatment option for thoracoabdominal aortic aneurysm (TAAA). Standardized, off-the-shelf branched stent grafts have been developed and customized, and patient-specific devices have evolved with the use of combinations of fenestrations and different types of directional branches to optimize individualized tailoring. Improved ancillary equipment, including sheaths and wires, are now available to allow for totally percutaneous transfemoral repairs of these complex aneurysms. In addition, pre- and intraprocedural imaging techniques using advanced processing and reconstruction software have vastly improved procedural planning and TAAA implantation, resulting in better outcomes.

Despite all these developments, there are still several unmet needs in the field of TAAA.

Indication for repair of TAAA is extrapolated in studies from less complex, infrarenal aneurysms that heavily rely on "simple" diameter measurements. We need to develop and use better criteria to help identify both those in need of repair and who among those will do well with such a repair. This involves improved imaging techniques that are more dynamic and better predictive of outcomes. We also need to better define patients with extensive aortic disease who do not need repair based on anatomy, biology, genetics, and comorbidities and who are at high risk of developing serious complications, such as spinal cord ischemia or stroke. All this is so we can better guide patients to the right decision regarding their disease.

Although planning of complex procedures has improved significantly, it still relies heavily on static imaging—not considering in vivo deployment, positioning of devices, or individual physician experience. Using automated image analysis and artificial intelligence might make planning more precise and less expert dependent, while also providing actual biomechanical, intraoperative feedback on the optimal graft design and plan.

Intraoperatively, the equipment used needs to be further developed and studied for these treatments specifically. Dedicated and tested sheaths, guidewires, and bridging stents are needed to ease procedures and improve outcomes. Most of the current ancillary equipment is generic at best and, in many cases, developed for totally different settings. Clearly, this is suboptimal.

Perioperative imaging currently relies heavily on radiation-based techniques. Although new C-arms, fusion image guidance, and better understanding of x-ray protection have likely reduced radiation exposure to patients and staff, the goal must be to remove the radiation altogether. The introduction of radiation-free navigation systems like FORS (Fiber Optic RealShape, Philips) and the IOPS intraoperative positioning system (Centerline Biomedical) not only provide this but also allow live three-dimensional navigation to improve stent graft procedures.

For complex aortic procedures, postoperative follow-up is still reliant on cross-sectional imaging techniques, primarily CT, to evaluate the outcomes. This is costly and uses radiation and contrast, which is potentially damaging to the patient. Despite this, we know that most routine imaging does not benefit the patient. Better identification of which patients need imaging follow-up is needed. In addition, using more noninvasive techniques such as ultrasound after endovascular repair of TAAA to evaluate graft integrity and end-organ function will lift some of the burden of follow-up from patients and health care providers.

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Many challenges exist in the management of TAAA, including optimizing device design for female patients, reducing spinal cord injury, and selecting the patients who will benefit most from repair, to name a few. However, access to commercially available off-the-shelf endovascular devices and the resulting disparities in the treatment of thoracoabdominal disease remains the greatest unmet need in the treatment of TAAA in the United States. Research among patients treated with this technology in the last decade has demonstrated endovascular repair to be safe and effective, with < 3% mortality at high-volume centers with access to custom fenestrated/branched endovascular aortic repair (F/BEVAR) devices.[1] Moreover, endovascular treatment at high-volume centers is likely safer than open repair for most patients with TAAA, particularly given the complex comorbid conditions found in this population.

Despite the growing body of literature, no commercially available devices for TAAA are approved in the United States today, leaving this proven technology inaccessible to patients in much of the country. Although I am fortunate to use these devices routinely in my practice, patient care remains challenged by the lack of commercially available products. Specifically, this lies in the inability to treat patients without formal enrollment in our physician-sponsored investigational device exemption trial. These are challenges that could easily be overcome with the availability of off-the-shelf F/BEVAR devices such as the t-Branch graft (Cook Medical) and Excluder thoracoabdominal branch endoprosthesis (TAMBE; Gore & Associates). Ideally, such devices should be available to centers that have both the technical expertise in their use and the institutional resources to support the care of these sick and complex patients.

Significant disparities exist in the management of thoracoabdominal disease. Research has shown that women and patients of color are less likely to receive endovascular treatment for aortic disease, are less likely to be transferred to tertiary centers for ruptured aneurysms, and have higher mortality when treated.[2-4] Additional research and evolution in device design are needed to address this significant gap in patient care.

Although the causes remain poorly understood, there is little doubt that the lack of commercially approved devices for the treatment of TAAA is particularly detrimental to marginalized populations and those with socioeconomic disadvantages, as well as patients with limited means to travel for their procedures, without the health literacy to know about this option for care, or with emergent pathology. These challenges often result in lack of access to F/BEVAR devices, which have been shown to be safer and more effective than open techniques for most patients. As a result, women and patients of color are more frequently left untreated or treated with less well-studied, often inferior treatment modalities, such as parallel grafting, laser fenestration, and a wide variety of physician modifications of existing devices. These often unavoidable circumstances result in health care disparities for underserved populations. We have a long way to go in fully addressing these disparities, but expedited availability of commercially available (and now widely studied) endovascular devices for TAAA is an important start and a tremendous unmet need in the treatment of thoracoabdominal disease.

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Thoracoabdominal repair for both aortic aneurysms and dissections has made significant advances in recent years. The development of new imaging techniques and improved device designs has made endovascular repair the preferred treatment modality in most aortic centers worldwide. Unfortunately, regulatory constraints preclude their wide adoption, particularly in the United States and Asian countries. That lack of availability of the proper devices promotes the use of unorthodox and risky techniques that frequently result in complications and dismal outcomes. Unfortunately, many of those adverse events go unreported as no auditing of the outcomes exists. In addition to the lack of availability, the cost of these devices is quite significant, and current reimbursement does not cover all expenses related to the cost of the devices. Availability and cost are indeed the two biggest hurdles that need to be overcome before the most advanced therapies for thoracoabdominal repair can benefit most patients.

Despite the improved designs, current devices still rely on stents made from stainless steel and nitinol, whereas the coverage material is either polytetrafluoroethylene or Dacron. Such materials, though inert, are not absorbable and tend to be rigid. The normal aorta is elastic, and the burden on heart contractility would significantly improve with less rigid materials that are also biocompatible. Regarding the bridging stents, a hybrid design with balloon and self-expanding features is critically needed to better accommodate most anatomic variations of the target vessels. As most of these repairs are now being performed using exclusively transfemoral access, improved designs for such access are needed, including a wider availability of specific steerable sheaths. Finally, improved imaging that relies less on radiation should be developed, expanded, and implemented. FORS is a significant addition to imaging guidance, but the device design needs substantial improvement in terms of trackability, compatibility, and ease of use. ■