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ROOM CONSIDERATIONS WITH TAVR

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Abstract

While transcatheter aortic valve replacement is considered a viable alternative to traditional surgery for patients with critical aortic stenosis, it is still a cardiac surgical procedure with a steep learning curve. Space consideration is a key aspect of the procedure's success. A TAVR program requires the commitment from and investment of institutional resources, the outfitting of an appropriate procedure room, and meticulous training of a multidisciplinary TAVR team. Careful integration of the various imaging modalities, medical specialties, and equipment is necessary to ensure the safety and efficacy of the procedure and to treat complications that may arise.

Introduction

Transcatheter aortic valve replacement (TAVR) has gained traction as a successful therapeutic option in patients with critical aortic stenosis who cannot have surgery¹ and is much less invasive than open surgical aortic valve replacement. Even so, the procedure remains considerably more complex than other percutaneous cardiac procedures and should still be viewed as a form of cardiac surgery. This concept should become more apparent as physicians grow more comfortable with the direct aortic approach, which requires either a mini sternotomy or a small thoracotomy incision.² It is also important to recognize that the learning curve for performing TAVR is steep, particularly given the nature and comorbidities of the patients who are currently candidates for the procedure.^{3,4}

As TAVR evolves and the devices become smaller and easier to use, it is very likely that access site difficulties will diminish. For the near future, however, consideration should be given to determining which of the available rooms to use for the procedure or deciding how best to design a suite for this purpose. This idea should be driven by the fact that while TAVR is less invasive than surgical AVR, it is nonetheless a cardiac surgical procedure and, more akin to aneurysm repair or valve replacement than to coronary stent implantation. Accordingly, beginning a TAVR program requires the investment of considerable institutional resources, the outfitting of an appropriate procedure room, and meticulous training of a TAVR team. The approach that has been generally encouraged has been to form a multidisciplinary team that includes members from the cardiac catheterization laboratory, cardiovascular operating room, cardiovascular imaging, and cardiovascular anesthesia. Commitment of the parent institution to support such a program and to recognize that considerable resources are required is invariably needed to allow the procedure to be performed safely.

Although most attention has been directed at equipment to be placed in the suite, an extremely important early consideration is the suite's physical location and outfitting. The primary aim in selecting or designing such a suite should be to allow valve team

members to work together efficiently without interfering with one another and without compromising the safety of the procedure. Thus, the major challenge in preparing a suite for TAVR involves integrating the various imaging modalities, the medical specialties, and the equipment — all of which are required to perform the procedure safely and effectively and to treat complications that are likely to occur. As TAVR teams become more experienced, and as valve prostheses evolve, some of these modalities may no longer be used routinely. However, there is currently enough case-to-case variability inherent in the procedure that they will be useful on many if not most occasions.

TAVR Space Requirements

TAVR procedures can be performed in specially outfitted cardiac catheterization laboratories. The general recommendation is for space exceeding 800 square feet.^{5,6} In many parts of the world, TAVR procedures are performed in such catheterization laboratories; in the United States, “hybrid” operating rooms are frequently used. Joint recommendations from the cardiac and surgical societies are to be published in the near future. However, it is important to recognize that outfitting catheterization laboratories so that surgical procedures can be performed there, and outfitting operating rooms so that high-quality angiography and hemodynamic measurement can also be accommodated, is often a daunting task. Surgical removal of the prostheses is exceptionally difficult, and since the infections of percutaneous valvular prostheses are likely to be lethal, appropriate aseptic conditions are mandatory. These include appropriate ventilation and laminar air flow, appropriate venting for anesthetic gases, and restricted access to nonessential personnel who may not be familiar with the more rigorous standards required in operating rooms as opposed to catheterization suites. Other considerations include adequate overhead lighting with adjustable lamps for open surgical procedures, and adequate electrical supply and booms for running anesthesia and other equipment — including cardiopulmonary bypass or other forms of ventricular support, transesophageal echocardiography, and possibly transcranial Doppler).

While easy accessibility for the interventional cardiologist and cardiac surgeon is important, accessibility for the anesthesiology department is probably more critical; although some procedures are now performed with moderate sedation, many are still performed with general anesthesia. In both cases, the presence of an anesthesiologist is needed. Accessibility to the blood bank and to laboratory facilities for blood gas, hematology, and electrolyte results should be considered when selecting the location. The other aspect of location concerns the availability of equipment, including the instruments needed to perform open-chest procedures, adequate suction, red cell rapid autotransfusion, and percutaneous rescue procedures. Maintaining a full stock of angioplasty equipment to manage coronary arterial complications and a full stock of various covered stents and peripheral vascular balloons is not likely to be possible. However, the suite must have enough room available to store the basic array of guiding catheters, guide wires, stents, and equipment needed to treat vascular access and coronary complications. In addition, the room needs to be situated in a location that allows rapid transport of unusual equipment that may occasionally be needed to manage a complex and unstable clinical scenario.

Planning should also include provisions for adequate imaging chains and hemodynamic recording systems. Although the procedure can often be performed with standard coronary angiographic equipment, the features of the patient population who receive TAVR mandate that advanced imaging capabilities be present. First, because of the age of this patient population and the frequency of accompanying atherosclerotic disease, severe peripheral vascular disease is common. Consequently, advancing large catheters (18-24 Fr) through tortuous and calcified iliofemoral or subclavian vessels frequently requires modifications of the original treatment strategy. It also mandates large-format image intensifiers or flat-panel detectors to guide catheter placement and rapid diagnosis and treatment of vascular access-site complications, particularly dissection, perforation or rupture of the aorta, iliac vessels, or subclavian arteries. Additionally, the X-ray gantries need to be selected so these issues can be addressed. Consensus statements from the American College of Cardiology, Society for Thoracic Surgery, and Society for Cardiac Angiography and Interventions clearly indicate that freestanding portable C-arms are not acceptable for use in TAVR.^{5,6} Selection of high-quality radiographic equipment that can sweep from the upper thorax to the femoral artery without having to interrupt the procedure to rotate the C-arm is preferable. Second, renal compromise is also common in this patient population, so management of femoral access issues is made safer by digital subtraction angiography to reduce the amount of contrast that is required. Finally, compromise of coronary circulation by compression of calcified valve leaflets against the coronary ostia is a rare (<1%) but rapidly lethal complication of TAVR.³ Even in the absence of ostial occlusion, transient decreases in cardiac output are fairly common, and in the absence of an obvious explanation, the implanting operator may feel compelled to perform emergency coronary angiography. Therefore, it is important to have imaging capabilities including the ability to perform cranial and caudal angulation necessary for emergency coronary angiography and stenting.

Another important imaging consideration is the use of transesophageal echocardiography. Although this modality is not used universally, in many cases it is useful for assessing paravalvular leaks and left ventricular contractility after rapid pacing runs, to check for pericardial effusions during periods of hypotension, and to ensure that the anterior leaflet of the mitral valve is not compromised in the case of low implants of self-expanding valve prostheses. Considerable space is required for placement of the echocardiographic equipment, and it is important that placement of the recording console not interfere with anesthesia. In our practice, the transesophageal probe is extended over the patient's left shoulder and directed slightly caudally.

A final consideration in selecting angiographic equipment involves integrating other imaging modalities into the angiographic viewing monitors. The ability to use one monitor as a "slave" to the transesophageal echocardiogram facilitates the operator's ability to select implantation depth of the valve and to evaluate postprocedure echocardiographic findings. To facilitate valve implantation, it is helpful to have available X-ray systems that can integrate software currently being developed. A variety of additional features designed to integrate other images, such as CT angiography, and to co-register them with fluoroscopic images are becoming available. These programs are particularly useful and may obviate the need for repeated contrast injections when selecting the optimal angle for valve implantation and when negotiating tortuous iliac vessels. Finally, because valve implantation must be performed with a good deal of precision, software is now available to help operators calculate optimal implanting views and overlay masks corresponding to the available valves over the fluoroscopic image of the aortic root to indicate the optimal placement depth within the aortic annulus.

Conclusion

It is likely that the specifications for procedural suites will continue to evolve as the valve technology undergoes further development. As the procedure becomes easier to perform, as the catheter size required for valve implantation decreases, and as valve seating within the aortic orifice becomes easier, the number of support services that are needed will decrease and suite selection may become easier. On the other hand, extension of TAVR to lower-risk populations, which is planned in at least two current clinical trials, will result in greater expectations concerning procedural results and lower tolerance of complications. Additionally, trials incorporating percutaneous coronary interventions performed at the same sitting as TAVR will require high-quality angiographic equipment and will require that both procedures be performed in a streamlined fashion. As such, it is unlikely that the basic requirements outlined above will become less rigorous. Therefore, one should anticipate that outfitting suites for the procedure will be more rather than less encompassing.

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