Building a Structural Heart Practice

How the right tools and support can benefit your patients and institution.

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Over the past 50 years, innovation in interventional cardiology has driven the field to move outside the confines of the vascular bed to treat diseases involving congenital and acquired disorders of the heart, thus creating a new field of interventional medicine referred to as structural heart disease (SHD). This new subspecialty encompasses a diverse group of innovative treatment options for disorders traditionally managed by cardiac surgery, ranging from the modification of abnormal native cardiac structures to the deployment of valves, clips, and plugs.

The practice of interventional cardiology will continue to evolve in the next several decades. Although coronary interventions will likely remain the dominant procedure for most adult cardiac interventionists, the field of SHD will witness great growth due to the evolution of catheter-based technologies and an increasingly aging population. The most profound change will be in the expansion of valvular and congenital heart disease procedures. Recognizing the future growth and complexity of this emerging field, many centers are establishing their own SHD program to fill the anticipated need created by this evolving speciality, as well as to prepare a new generation of physicians who desire comprehensive practical training in a novel array of percutaneous interventions.

Building a new SHD practice that will grow and sustain itself over time can be challenging. New skills and resources are required to treat these complex patients, and an approach that combines interventional skills, collaborative clinical management, surgical techniques, and new types of equipment is needed.[1,2] The purpose of this article is to outline the essential aspects of establishing a successful SHD program.

OPERATOR REQUIREMENTS

The success of SHD interventions relies heavily on the operator's knowledge of cardiovascular anatomy and physiology, the incorporation of novel image guidance technologies, the acquisition of new procedural skills, and compliance with current societal guidelines regarding indications, patient selection, and physician training. The SHD field spans many disciplines, including pediatric and adult interventional and noninvasive cardiology, cardiovascular surgery, radiology, electrophysiology, neurology, and anesthesiology. Regardless of specialty background, physicians interested in SHD should have a cognitive understanding of the disease entities being evaluated and treated, as well as the therapeutic options available, including the advantages and disadvantages of various surgical, nonsurgical (ie, medical), hybrid surgical, and catheter-based treatments. One should understand the current indications, complications, and expected outcome of invasive strategies.

Physicians performing SHD interventions must have a thorough understanding of the regional anatomy of the heart. Indeed, these procedures represent a major deviation from the conventional coronary and vascular procedures because they frequently involve navigation of catheters and devices in open three-dimensional (3D) space, interacting with moving targets. Therefore, the importance of acquiring the necessary 3D anatomic spatial understanding of the heart and gaining proficiency in the use of adjunctive imaging modalities is critical to success.

Expertise in the application of imaging modalities is a crucial part of the cognitive skillset base and is as important as proficiency in performing the procedure itself. This particularly applies to transthoracic (TTE), transesophageal (TEE), and intracardiac echocardiography (ICE) imaging, which are integral to this field. Since its introduction to guide device closure of atrial septal defect (ASD) and patent foramen ovale (PFO) in the early 2000s,[3] ICE has evolved into an established imaging modality that conveys a definite advantage when performing ASD, ventricular septal defect, PFO, and left atrial appendage (LAA) closure, as well as mitral valvuloplasty. As opposed to TEE, ICE offers equiva-

PERCUTANEOUS SHD DIAGNOSTIC AND INTERVENTIONAL PROCEDURES

- Performance and interpretation of diagnostic right and left heart catheterization, including:
    - More complex congenital cases (such as transposition of great vessels, Tetralogy of Fallot, Fontan circulation)
    - Selective angiography of anatomical structures (such as LAA, pulmonary veins, aorta)
- Intracardiac echocardiography
- Transseptal left heart catheterization
- Left ventricular apical puncture
- Closure of PFO and ASD
- Closure of ventricular septal defect
- Closure of venovenous collaterals, arteriovenous malformations, and patent ductus arteriosum
- Closure of paravalvular leaks
- Closure of baffle leaks and pseudoaneurysms
- Closure of LAA
- Angioplasty and stenting of aortic coarctation, as well as pulmonary arteries and veins
- Percutaneous balloon valvuloplasty
    - Aortic (antegrade and retrograde techniques)
    - Mitral (single- and double-balloon techniques)
    - Pulmonary and tricuspid
- Percutaneous valve repair/replacement
- Alcohol septal ablation for hypertrophic cardiomyopathy
- Retrieval techniques (snares, forceps, and catheters) for foreign body or device embolization

lent echocardiographic views for certain select procedures, such as ASD and PFO closure and guidance for transseptal puncture, without requiring general anesthesia and allows the interventionist to guide imaging without the need for an anesthesiologist or additional echocardiographic personnel.

Cardiac CT angiography and magnetic resonance angiography are essential tools for preprocedural assessment and guidance of therapeutic procedures. SHD specialists should have a mastery of off-line review of CT angiographic and magnetic resonance angiographic images, as well as the software necessary for postacquisition image processing to carry out essential decision making and verify measurements required for successful, complication-free interventions. Initially, the interventionist can partner with a colleague who is an expert in these advanced imaging modalities.

The spectrum of SHD interventions is growing and is outlined in the *Percutaneous SHD Diagnostic and Interventional Procedures* sidebar.[4] These procedures require knowledge and technical skills using equipment much different from basic adult coronary and peripheral vascular disease interventional procedures. Acquiring all of the required cognitive and technical skills is difficult and should ideally be achieved through a formal dedicated year of training in SHD.[5,6] However, if this pathway is not available for operators wishing to establish a SHD program, other resources are available to gain expertise in this field.

Several programs for physicians are routinely offered, ranging from courses taught by experts in the field, to practice sessions with simulator programs or animal models, to hands-on training programs for new therapies such as transcatheter aortic valve replacement (TAVR), LAA closure, and percutaneous mitral valve repair. Several valuable industry-sponsored training opportunities are offered to aspiring SHD operators, and so physicians should develop good relationships with industry and take advantage of these resources.

It is crucial for new operators to recognize that mentorship from experienced SHD interventionists is an essential component of the training. Partnering with other SHD physicians and pediatric interventional cardiologists, who have the basic building block skills needed for structural interventions, is a tremendous opportunity to learn these unique, niche, low-volume skills. Live case demonstrations allow for interaction with experienced operators and present an opportunity to observe new techniques and tricks for success and avoiding complications. Once the basic SHD techniques are mastered, transition to more advanced procedures becomes possible. For example, physicians who master balloon aortic valvuloplasty or transseptal puncture will be able to transition their way to more advanced procedures, such as TAVR, LAA closure, and percutaneous mitral valve interventions.

The SHD field is rapidly evolving, and guidelines on best practices have been created to guide SHD operators, ensure the highest quality, remove barriers to patient access for these new procedures, and ensure proper rollout of these technologies to new centers across the country. Recently, the Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American College of Cardiology Foundation, and the Society of Thoracic Surgeons have jointly established detailed recommendations regarding the requirements for operators and institutions performing TAVR and percutaneous mitral valve interventions.[7,8] These recommendations are summarized in Table 1. Operators should be familiar with and strive to meet these requirements. At this time, no formal intersociety recommendations are available for other structural procedures, but they are likely to emerge as the SHD field continues to grow and mature.

ESTABLISHING A MULTIDISCIPLINARY STRUCTURAL TEAM

The original clinical trials for TAVR integrated the concept of a multidisciplinary heart team (MDT) approach to patient care. This concept has gained traction and has entrenched itself in the national coverage decision for the Centers for Medicare & Medicaid Services regarding TAVR procedures.[9] Additionally, the American College of Cardiology and American Heart Association gave the MDT a class IA recommendation in their 2014 guidelines for the management of valvular heart diseases.[10] The MDT component of a SHD program combines specialists with the intellectual and technical knowledge base, appropriate ancillary support staff, and physical facilities. Thus, establishing a MDT is an essential part of any SHD program. The combined experience and expertise ensure appropriate patient selection, development of detailed and intricate patient-centered treatment plans, and improved coordination of care. Furthermore, it has been shown that a team approach improves outcome of patients requiring complex proce-

<table>
<tr><th colspan="4">TABLE 1. INSTITUTIONAL AND OPERATOR REQUIREMENTS FOR TAVR AND MITRAL VALVE INTERVENTION</th></tr>
<tr><th colspan="2"></th><th>Transcatheter Aortic Valve Replacement Requirements</th><th>Mitral Valve Intervention Requirements</th></tr>
<tr><td rowspan="15">New programs</td><td>Interventional program</td><td colspan="2">1,000 caths/400 PCIs per year</td></tr>
<tr><td rowspan="2">Interventionist</td><td>100 structural procedures lifetime or 30 left-sided SHDs per year (60% should be balloon aortic valvuloplasty)</td><td>50 SHD procedures per year (including ASD/PFO and transseptal punctures)</td></tr>
<tr><td colspan="2">Suitable training on devices to be used</td></tr>
<tr><td rowspan="2">Surgical program</td><td>50 total AVRs per year (≥ 10 AVRs should be high risk (STS score ≥ 6)</td><td>25 total mitral valve procedures per year (≥ 10 must be mitral valve repairs)</td></tr>
<tr><td>≥ 2 institutionally based cardiac surgeons (> 50% time at hospital with surgical program)</td><td>–</td></tr>
<tr><td rowspan="4">Surgeon</td><td>100 AVR in career (≥ 10 of which are high-risk (STS score ≥ 6)
or 25 AVR per year
or 50 AVR in 2 years and ≥ 20 AVR in last year prior to TAVR initiation</td><td>–</td></tr>
<tr><td colspan="2">Experience with, and management of, peripherally inserted cardiopulmonary bypass</td></tr>
<tr><td colspan="2">Experience with open retroperitoneal exposure of, and surgical intervention on, the iliac arteries</td></tr>
<tr><td colspan="2">Suitable training on devices to be used</td></tr>
<tr><td rowspan="2">Training</td><td colspan="2">Cardiologists must be board certified/eligible in interventional cardiology</td></tr>
<tr><td colspan="2">Surgeons must be board certified/eligible in thoracic surgery</td></tr>
<tr><td>Outcome</td><td colspan="2">All cases must be submitted to a single national database</td></tr>
<tr><td rowspan="3">Existing programs</td><td>Institutional</td><td>Existence > 18 months: 30 TAVRs (total experience); existence < 18 months: 2 per month</td><td>15 mitral procedures (total experience)</td></tr>
<tr><td rowspan="2">Training</td><td colspan="2">Cardiologists must be board certified/eligible in interventional cardiology</td></tr>
<tr><td colspan="2">Surgeons must be board certified/eligible in thoracic surgery</td></tr>
<tr><td colspan="4">Abbreviations: AVR, aortic valve replacement; PCI, percutaneous intervention; STS, Society of Thoracic Surgeons predicted risk of mortality.</td></tr>
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dures.[11] This has been emphasized for TAVR and ASD/PFO closure, in which a MDT is particularly helpful in adequately selecting patients for these percutaneous interventions, and has lead to positive outcomes for these procedures.[12-15]

An ideal SHD team should incorporate knowledge and competencies from the following field specialists: interventional cardiologists, cardiovascular surgeons, congenital heart disease specialists, cardiovascular imaging specialists (including echocardiography and CT), cardiac anesthesiologists, intensivists, nurses, a structural program coordinator, physical and occupational therapists, and social workers.[12] The key to a successful program, above possessing such expertise, is a spirit of collegiality and collaboration among members of the team. For some procedures, such as TAVR, both a cardiologist and surgeon are required to participate in all aspects of the procedure. It is therefore essential to cultivate a good working and collaborative relationship with cardiac surgeons involved in the structural procedure program. Having shared physician reimbursement for collaborative procedures has been shown to promote the team approach.[7] Finally, the MDT should meet on a regular basis (eg, weekly) to discuss potential candidates, previous cases, complications, and potential programmatic improvements.

Careful patient selection is paramount to program success. The evaluation of these patients should be done in a dedicated SHD clinic, where candidates can meet with members of the team and get a focused multidisciplinary assessment.[12] The SHD clinic should have an imaging suite with integrated TTE and TEE capacity to provide easy screening and accurate assessment of patients.

As the SHD field continues to expand, we are likely to see further entrenchment of the MDT concept for other structural procedures. Therefore, establishing a formal MDT early in the development of the SHD program is vital to its formation, success, and long-term durability.

PROCEDURE ROOM REQUIREMENTS

When building an SHD program, particular attention should be given to the procedure room where these interventions will be performed; it should be optimally designed, equipped, and staffed to ensure that the procedures will be done smoothly and safely. SHD interventions should not be routinely performed in a standard catheterization laboratory or operating room (OR), although such rooms can be adapted to satisfy the needs of SHD interventions. These procedures should ideally be performed in a specifically designed hybrid OR interventional suite equipped with a fixed cineradiographic imaging system and flat-panel fluoroscopy located in a sterile environment (Figure 1).[7] A hydrid OR is highly desirable for some procedures, such as those requiring a surgical access (eg, percutaneous valve replacement), possible conversion to an open surgical procedure (TAVR, ventricular septal defect closure, or paravalvular leak closure), or the need for emergency procedures (eg, extracorporeal membrane oxygenation insertion or emergent thoracotomy).[16] In the absence of such a room, an interventional cardiac catheterization laboratory can be modified to contain the proper equipment (see the *SHD Interventional Suite Minimal Requirements* sidebar) to meet minimum OR standards. In addition, the room should be equipped with appropriate lighting and imaging systems and be at least 800 ft^2 to accommodate all the personnel and equipment required, including anesthesiology, echocardiography, and cardiopulmonary bypass equipment, when needed.[7,8,17] The procedure table should function as well for open surgical exposure as for catheter-based interventions. A tour of the facilities at an institution with a well-established SHD program can be very useful during the planning stages of a new SHD center.

Given the role of imaging in SHD interventions, it is important to invest in state-of-the-art multimodality imag-

Figure 1. Example of a hybrid operating room for SHD interventions. Our state-of-the-art hybrid operating room structural interventional suite with all the required equipment is shown (A). Interventional cardiologists collaborating with a cardiac surgeon during a procedure (B).

ing technology. The flat-panel fluoroscopy imaging system should offer catheterization laboratory quality imaging and ideally be equipped with a biplane unit, particularly for interventions such as pulmonary valve replacement and closure of paravalvular leak. Of note, the use of a mobile C-arm imaging system in an OR is not adequate and should not be used in lieu of fixed, floor or ceiling mounted, flat-panel fluoroscopy technology. Furthermore, there should be a dedicated echocardiography machine with 3D imaging capacity readily available in the room. Given the limitation of two-dimensional imaging modalities in the adequacy of representing complex spatial relationships, advanced 3D imaging modalities are needed for successful SHD interventions. This can be achieved through 3D TEE/ICE or the use of 3D rotational angiography and C-arm CT reconstruction. Three-dimensional rotational angiography capability integrated into the fluoroscopy imaging system can be particularly useful for TAVR, pulmonary artery, and aortic coarctation interventions (Figure 2). Additionally, dedicated, large, flat-panel high-resolution screens are helpful to facilitate image display to all essential personnel.

Considering the spectrum of congenital and acquired structural cardiovascular diseases that are now amenable to percutaneous treatment, a wide array of fungible procedural equipment is required not only to carry out the procedure but also to expediently address serious, often life-threatening complications. Having the necessary equipment close at hand can make the difference between life and death when a complication is encountered. All necessary equipment should therefore be stored in close proximity and be readily available on demand. Necessary equipment for a SHD laboratory should include various access kits, endovascular sheaths and introducers, a wide range of guidewires for various purposes, cardiac diagnostic and interventional catheters, vascular closure devices, balloon dilatation catheters of various lengths and profiles, bare-metal and covered coronary and peripheral stents, occlusive vascular devices, snares, forceps and other retrieval devices, drainage catheters, and hemodynamic support devices.[7,8]

OTHER INSTITUTIONAL RESOURCES

To facilitate the pre- and postprocedural care of these patients, adequate outpatient clinical facilities and resources are necessary. The SHD clinic should be designed to offer seamless, high-quality, patient-centered care. During a single office visit, a patient should be able to undergo noninvasive testing, evaluation, and consultation with the MDT, including a SHD proceduralist and a cardiac surgeon. Furthermore, providing extra amenities such as parking, lunch, and guides to help navigate large institutions will ensure a positive patient experience and increase the likelihood that patients will continue getting their care at that institution.

SHD INTERVENTIONAL SUITE MINIMAL REQUIREMENTS

- Fixed cineradiographic unit with flat-panel fluoroscopy and high-resolution digital video image processing capacity that offers catheterization laboratory quality imaging
- In-room cabinet storage for equipment
- Invasive hemodynamic physiologic equipment
- Circulating heating, ventilation, and air conditioning laminar flow diffusers that meet OR air requirements
- Asymmetrical/symmetrical six-lamp 2- X 4-ft troffers (inverted, usually metal trough suspended from the ceiling as a fixture for fluorescent lighting) to provide adequate high-output lighting for surgical intervention
- Adequate number of power receptacles for surgical equipment
- Capability of running cardiopulmonary bypass apparatus in that room
- Gas outlets for the anesthesia machine
- Adequate room size to accommodate the standard equipment required in a cardiac catheterization laboratory
    - High-definition displays and monitors
    - Oxygen analyzer
    - Defibrillator/resuscitation cart
    - Oxygen supply
    - Suction
    - Compressed air
    - CO-oximeter
    - Activated clotting time analyzer

The postprocedural care of these complex patients differs from other cardiac procedures. These patients should generally be transferred to a cardiac intensive care unit after the procedure. It is important that the staff be prepared and well trained to address the unique needs of these patients after SHD procedures to ensure an optimal outcome. Training can be achieved through in-training sessions for the staff in the form of continuing education programs. The MDT concept should be extended to include nutritionists, occupational therapists, and psychiatrists to reduce deconditioning, prevent prolonged hospital stays, and enhance postprocedural recovery.

For a SHD program to continue to grow, it is vital that there be a continuous stream of patients referred to the program. Investing in a marketing program can be helpful in recruiting new patients and can be directed both to patients and referring physicians. Program announcements, newsletters, outreach programs, printed media, radio, and

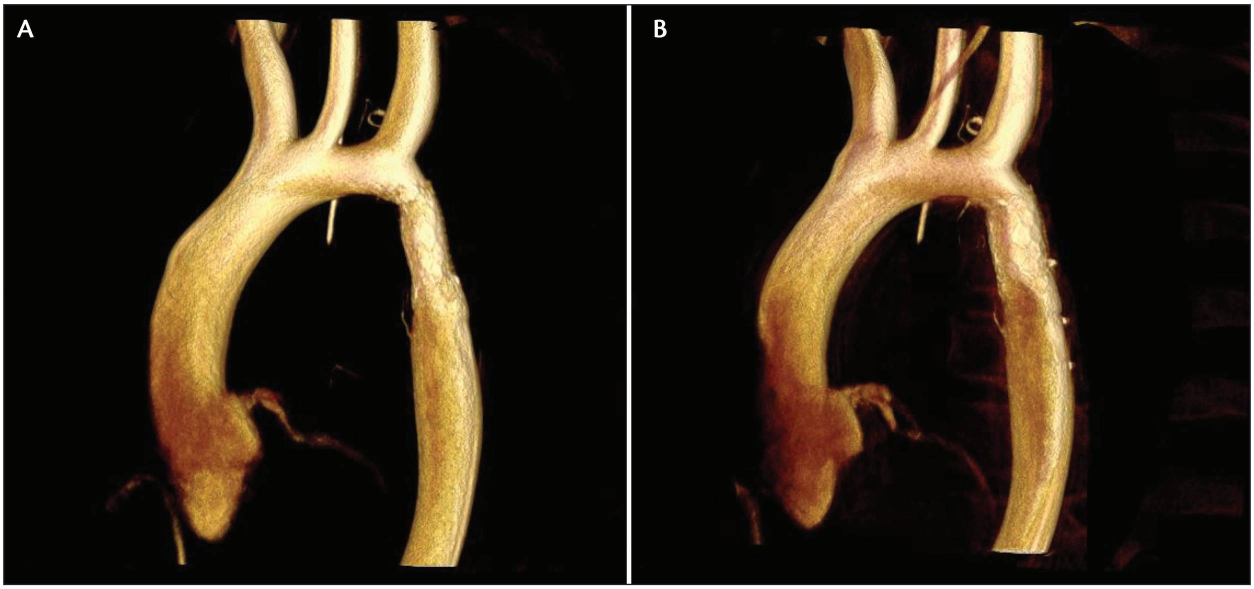

Figure 2. Three-dimensional rotational angiography reconstruction of an aorta. Three-dimensional rotational angiography was used in this case of aortic coarctation angioplasty. Pre- (A) and postintervention (B) reconstructions are shown.

TV advertisements can lead to a significant increase in the number of both self- and physician-directed referrals. Ultimately, establishing a center of specialized care in SHD will attract higher volumes of patients, which will provide downstream benefits to the entire institution.

Finally, a new SHD program should be regularly evaluated. Procedural results and complications should be carefully reviewed on an ongoing basis. Such review will ensure the growth and correction of problems that could impair the success and expansion of the program. Procedural results should be tracked and shared with all members of the team. Moreover, all SHD programs should take part in postmarketing surveillance and national registries so that results can be shared and experience built upon.

SUMMARY

Starting a structural program is challenging and requires major individual and institutional commitment, but with all the right tools and with institutional support, a strong and successful SHD program can be created to the mutual benefit of patients, physicians, the MDT, and the institution. ■

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