What is the impact of the Watchman approval on structural practice? What are the roles of the electrophysiology and interventional cardiology physician?

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The left atrial appendage (LAA) remains a most ubiquitous structure that presents us with unique challenges and complexities in clinical care. For decades, clinician scientists have pursued the elimination of the LAA as an important piece in solving the puzzle of systemic thromboembolism (STE) in patients with atrial fibrillation (AF). LAA became synonymous with systemic thromboembolism in patients with AF. Although the early surgical experience was encouraging, subsequent analysis of nonrigorous data raised the issues of incomplete closure and continued risk of STE, resulting in reduced enthusiasm for LAA closure in the surgical world. However, this concept gained new interest and focus with the invention of percutaneous closure devices.

This year, after data from 2,000 patients and a decade-long hiatus, the Watchman device (Boston Scientific Corporation) was approved by the US Food and Drug Administration, opening up the LAA space for further exploration. With 2 to 3 million AF patients in the United States alone and several million more around the globe that are warfarin eligible, LAA occlusion comes to the forefront in a much bigger way. LAA closure will be a significantly larger endeavor than percutaneous valves or atrial septal closure devices. Obviously, it presents several challenges to the structural space; the following list highlights some of those challenges that are obvious, as well as others for which we will need to find solutions as we start implanting these devices:

- Who is the right candidate?
- Does the structural community have the necessary skill set to roll out this device on a larger scale?
- With an indication as open and broad as it sounds, can the global health systems afford it?
- What should we do with patients who are warfarin ineligible, either due to bleeding or recurrent STE (failed oral anticoagulation strategy)?
- What is the role of other occlusion devices, and how do they compare with Watchman?
- What are the data on the impact of LAA occlusion on LA reservoir and neuroendocrine function?
- What are the differences between endocardial and epicardial exclusion systems?
- What is the role of LAA in arrhythmia initiation and maintenance? Will epicardial ligation systems work better than the endocardial systems? Does it mean different LAA exclusion devices for different indications?
- As resources continue to shrink and the burden of research is continuously shifting to the Medicare population, how can we establish the safety and efficacy of the next generation of devices?

Historically, the structural space has been dominated by interventional cardiologists; however, LAA

exclusion devices brought electrophysiologists into the fray. Electrophysiologists' comfort with and skill set of navigating in the LA and LAA and dry pericardial access make them an extremely valuable asset to the expansion of the field. Despite early grumblings about who owns the LAA space, both the interventional cardiology and electrophysiology specialties have clearly established that they are relevant to the space in their own right. The debate should not be about who should close the LAA. Instead, the focus should be on how to enhance the overall skill set of the operators to make the delivery of this important therapy safer and more efficacious.

I firmly believe that the team-based approach that made percutaneous valve programs successful applies to the LAA space as well. We should approach this as a program rather than a procedure. The technical skills and knowledge of the structure from each of the specialties will obviously pave the way for more robust program development. We should come up with a comprehensive LAA program at each institution that can manage the full breadth of operations, from appropriate identification of eligible patients and patient education to LAA exclusion, as well as to short- and long-term follow-up. It is time to initiate a nationwide registry to evaluate the real-world experience with these devices and to bring about the necessary modifications in how we use these devices in the future. The adaptation is still severely limited by the lack of coverage from both private and public sector third-party payers. The third-party payers should realize that judicious use of this technology will lead to enormous cost savings and improved patient morbidity and mortality.

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The epidemic of AF is evident to practicing cardiologists. Although the reality that up to half of all high-risk AF patients are not anticoagulated may be less intuitive, cardiologists regularly encounter patients in whom chronic anticoagulation is undesirable, if not impossible, due to a history of bleeding, falling, or lifestyle. US Food and Drug approval of the Watchman device has been widely welcomed as an option for the large number of patients with AF who are not good candidates for chronic oral anticoagulant therapy. The arrival of the Watchman device introduces a host of questions regarding who is best suited to implant the device and how the workload will be shared.

LAA closure with the Watchman device is a demanding new procedure that includes large-sheath femoral access and groin management, transseptal access to the left atrium, echocardiographic- and fluoroscopic-guided navigation within the left atrium, unsheathing of a self-expanding nitinol device, and complication management, including rare pericardiocentesis. Many structural heart specialists, such as those who perform the MitraClip (Abbott Vascular) procedure, are comfortable with transseptal puncture and three-dimensional, echo-guided navigation and immediately recognize LAA closure as a procedure that should belong in their repertoire. Similarly, many electrophysiologists have tremendous transseptal experience, navigate within the left atrium, are expert in the management of AF, and immediately recognize LAA closure as a procedure that should belong in their repertoire. Even though many interventional cardiologists do not have transseptal experience, echo-guided transseptal puncture is a learned skill that is well within the ability of interventional cardiologists who dedicate the requisite time and energy to learning this technique.

Although interventional cardiologists may have initially considered structural heart evaluation and treatment a subspecialty of their discipline, cardiac surgeons have become expert in all aspects of transcatheter aortic valve replacement and mitral valve repair with the MitraClip device, contributing a complementary understanding of cardiac anatomy and patient care to these procedures. Structural heart expertise is a function of interest, energy, and commitment, rather than historic training pathways of cardiac surgery, coronary intervention, or electrophysiology.

Similar to other structural heart interventions, Watchman LAA closure demands a commitment to understanding the anatomy, imaging, device, and procedure. Many interventional cardiologists and electrophysiologists, including those with experience in the left atrium, may wisely recognize that they do not have sufficient time and focus to become expert in a demanding new procedure. However, interventional cardiologists, electrophysiologists, and select cardiac surgeons all care for patients with AF and, if interested, may learn to close the LAA with the Watchman device. Patients will be best served when institutions identify

a limited team of physicians who become expert in this procedure. Collaboration between interventional cardiologists and electrophysiologists may provide complementary procedural expertise and clinical options.

The Intermountain Heart Institute has participated in each of the Watchman trials (PROTECT AF, PREVAIL, and CAP registries). Interventional cardiologists and electrophysiologists have often scrubbed together during Watchman implantations, as well as Lariat (SentreHeart, Inc.) LAA closures. Patient care, including screening, periprocedure management, and follow-up, is managed by the structural heart team, which includes advanced practitioners, medical assistants, and research coordinators who understand our care plans and who communicate frequently with implanting physicians. Minithoracotomy with radiofrequency arrhythmia management and LAA exclusion is also considered as we strive to provide each unique patient with an appropriate solution for his or her AF-associated symptoms and stroke risk.

There is a tremendous unmet need for nonpharmacologic management of stroke risk in patients with AF. LAA closure with the Watchman device is a demanding new structural heart procedure that requires training, commitment, and focus. Interventional cardiologists, electrophysiologists, and select cardiac surgeons may become expert in LAA closure given interest, training, and commitment. The ideal comprehensive AF program will include a multidisciplinary, collaborative team to provide each unique patient with an appropriate solution to manage his or her AF. ■