

A Central Hub for Structural Heart Intervention Facilitates Collaboration, Innovation, and Patient Satisfaction at UH Harrington HVI

Partnering With Siemens Healthineers for Advanced Imaging, Lower Radiation, and Greater Efficiencies of Care

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University Hospitals' (UH) Harrington Heart & Vascular Institute (HVI) in Cleveland, Ohio, is changing paradigms for structural heart diagnostics and treatment with its advanced imaging and hybrid operating room (OR) suite, which opened in July 2019. Most facilities place computed tomography (CT) and magnetic resonance imaging (MRI) equipment in the basement, with doctors' offices and catheterization laboratories on different floors. Patients must navigate within a facility to find the appropriate place to see their doctor and then complete their diagnostic workup. The procedure often is performed in yet another location. UH Harrington HVI put its patients at the forefront when designing a single,

central hub for structural heart disease evaluation, diagnosis, and treatment.

Mehdi Sishehbor, DO, MPH, PhD, President of Harrington HVI, explains: "My predecessors, Dr. Marco Costa and Dr. Daniel Simon, had a vision that the future of interventional cardiology and the treatment of heart and vascular disease would be an image-guided interventional/surgical suite that could combine the strengths of interventional cardiology and cardiac surgery with advanced interventional devices and imaging (CT and MR) to perform procedures in a safe and efficient way. These imaging modalities could serve as a platform to do procedures with less radiation, more efficiency, and greater patient satisfaction."



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Control room for the hybrid OR and CT scanner room. The hybrid OR with the robotic intraoperative angiography ARTIS pheno system can be seen through the left window; the SOMATOM CT scanner can be seen through the right window.

Enabling Multidisciplinary Collaboration

The proximity of physician offices, imaging equipment, and the hybrid OR has created a culture of collaboration among clinical cardiologists, interventionalists, surgeons, and advanced imaging physicians. Ad hoc consultations among peers, common at Harrington HVI, has blossomed to frequent brainstorming. “When you are working in the same space, it allows for direct feedback. We can exploit each person’s expertise to develop novel approaches to existing problems,” explains Imran Rashid, MD, PhD, FRACP, Director of Cardiovascular MRI at UH Harrington HVI.

Steven James Filby, MD, Director of the Cardiac Catheterization Laboratory at UH Cleveland Medical Center, concurs: “Dr. Rashid’s office is literally across from the hybrid OR. We’ve germinated so many ideas for new projects based on conversations that we have had about patients and existing projects.”

Guilherme F. Attizzani, MD, Director, Valve and Structural Heart Disease Center at Harrington HVI, notes how the new physical space changes clinician interaction. “Now we are in geographic proximity with the imaging team. We didn’t have that in the past. This enables us to develop closer collaboration with

“Dual-energy CT improves the clinician’s diagnostic confidence.”

**Imran Rashid, MD, PhD, FRACP
Director, Cardiovascular MRI**

them. We are optimizing CT protocols to use less contrast media. We give the imaging specialists real-time feedback on imaging quality. We can also ask them for their input: What can you offer us in terms of pre- and post-procedural imaging?”

Innovation is a natural byproduct of the heightened collaboration at UH Harrington HVI, which has developed new protocols for left atrial appendage (LAA)

occlusion, transcatheter aortic valve replacement (TAVR), and transcatheter mitral valve replacement (TMVR). The SOMATOM Definition Flash CT scanner, MAGNETOM Aera 1.5T MRI system, and robotic intraoperative angiography ARTIS pheno system are employed to reduce patient exposure to radiation, stratify patients for structural heart interventions, and enhance patient outcomes.

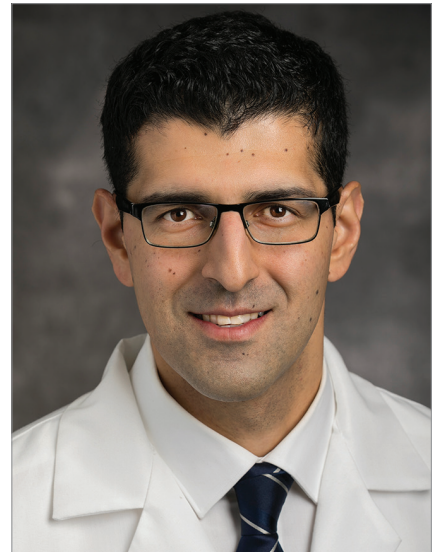
UH Harrington HVI also strives to reduce patient’s exposure to medical radiation through low-dose CT scans and MRI. It has established CT protocols using the SOMATOM Definition Flash CT scanner’s dual-energy capability to use a lower-energy beam for certain imaging views. It also has incorporated MRI into patient assessment and collaborated with Siemens Healthineers to devise non-contrast sequences for the MAGNETOM Aera 1.5T MRI system to accommodate individuals with kidney impairment.

Same-Day Evaluation, Procedure, and Discharge for LAA Occlusion

At UH Harrington HVI, the SOMATOM Definition Flash CT scanner is used to confirm a patient’s eligibility for an LAA occlusion device. LAA evaluation done by CT occurs in less than 10% of facilities in the United States. In addition to documenting the absence of a thrombus in the LAA, CT angiography (CTA) is more accurate than a transesophageal echocardiogram (TEE) in determining the appropriate device size. CTA also can produce three-dimensional rendering of images, which depicts the

LAA’s morphology and characterizes the thickness and morphology of the septum. The latter allows the interventionalist to plan the angle of septal puncture to best access the LAA during implantation.¹

UH Harrington HVI’s CTA imaging protocols with the SOMATOM Definition Flash CT scanner incorporate dual-phase and dual-source imaging for LAA occlusion candidates. With



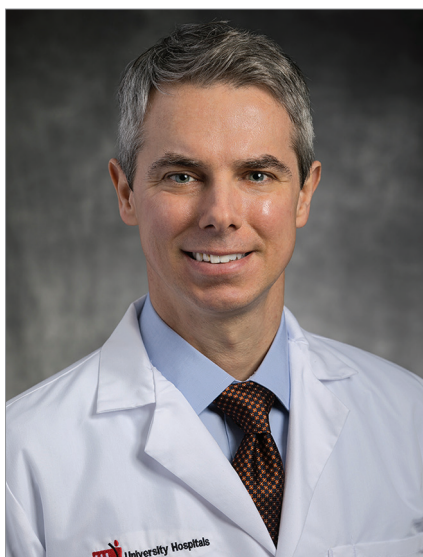
**Imran Rashid, MD, PhD, FRACP,
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**SOMATOM Definition Flash CT
128-slice scanner.**



MAGNETOM Aera 1.5T MRI system.



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dual-phase acquisition, a CTA image is taken when the contrast is injected and another image is taken within one minute of the first scan. By taking two images, it is more readily apparent if there is a clot in the LAA, as a thrombus may seem to be present if the LAA is incompletely filled with contrast on initial imaging. While other facilities routinely perform dual-phase imaging, unique to UH Harrington HVI is that the second image is taken with dual-energy CTA in which a lower-energy x-ray beam is used (40keV versus 120keV in standard CT scans). Dual-energy CTA with the SOMATOM Definition Flash CT scanner improves image quality and enhances LAA thrombus conspicuity on delayed-phase scans with lower contrast use.

Leveraging a feature of the robotic intraoperative angiography ARTIS pheno system called CT Fusion, the CTA images are overlaid on real-time fluoroscopy images during the LAA occlusion device implantation. The LAA image is traced out of the CTA image, leaving bony structures to be co-registered with fluoroscopic projections. CT Fusion with the ARTIS pheno system

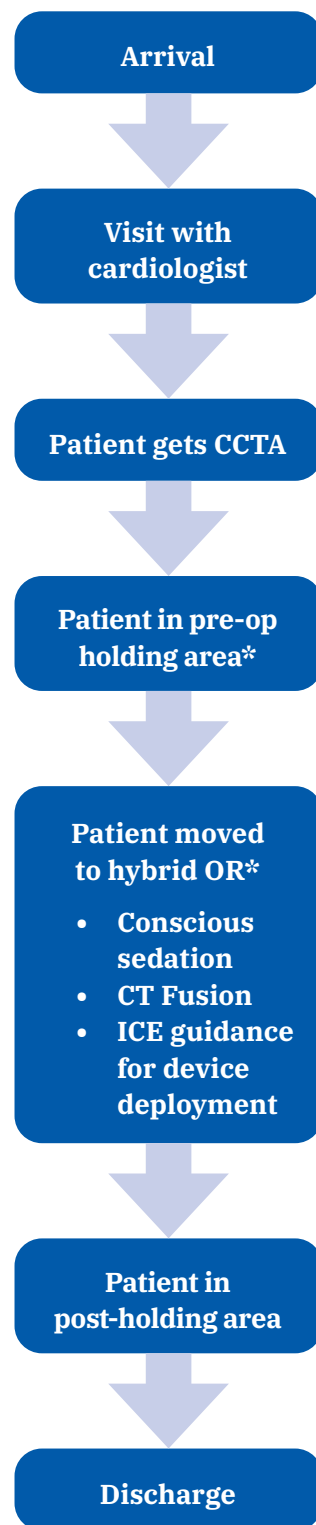
permits the LAA margins and key landmarks to be superimposed on the digital fluoroscopic image of the LAA during the procedure, shortening procedure time, and lowering radiation exposure and contrast use. UH Harrington HVI's protocol includes another innovation to LAA occlusion procedures: use of intracardiac echocardiography (ICE) to guide deployment of the LAA occlusion device. ICE negates the need for TEE and general anesthesia. The combination of a pre-procedure CTA with the SOMATOM Definition Flash CT scanner, CT Fusion with the ARTIS pheno system, and ICE makes same-day discharge possible.

Dr. Filby conveyed the benefits: "Having to make only one trip to the hospital is a tremendous convenience for our patients, particularly those who are coming from a distance. Taking pre-procedural CTA images is important for procedural planning. Registering, or fusing, those CTA images onto real-time fluoroscopy images has allowed us to achieve even higher success rates."

In its early experience with this protocol (n=71), UH Harrington HVI found that CTA had a 97.2% accuracy in device size selection. Devices sizes ranged from 21-33mm for Watchman (Boston Scientific) and 20-35mm for Watchman FLX (Boston Scientific). All patients received conscious sedation for the procedure; device deployment was successful in all patients. Roughly one-third of patients were discharged on the same day, and 63.4% were discharged the day after the procedure (some patients were kept overnight, as a post-procedure transthoracic echocardiography [TTE] could not be completed on the day of the procedure.)¹

Lori Hammer, BSN, RN-BC, Manager of the Valve and Structural Heart Disease Center, shared the origin of the one-day protocol. "Dr. Filby had this wonderful idea. He said, 'We have the CT scanner right next to the hybrid cath lab. Why don't we have the patient do the CT and then go immediately for the procedure?' It used to be that patients

LAA Occlusion at UH Harrington HVI



*The patient may be moved from the CT room directly to the hybrid OR or wait in the pre-operative holding area.



Sanjay Rajagopalan, MD, FACC, FAHA, Chief, Cardiovascular Medicine, University Hospitals, Harrington Heart & Vascular Institute, Cleveland, Ohio

“The suite allows unprecedented opportunities for innovation utilizing dual-source CT and cardiac MRI, in conjunction with advanced structural intervention. Fusion imaging for accurate positioning and reduction in procedure time and cath lab costs are being realized today. The use of low-dose contrast protocols with TAVR using as little as 25cc for a chest, abdomen, and pelvis has reduced contrast-induced nephropathy in our patients. Finally, advanced imaging that facilitates virtual-reality guidance for advanced vascular and electrophysiology procedures is a real possibility for remote catheter guidance. We are just scratching the surface with regards to the possibilities.”

Sanjay Rajagopalan, MD, FACC, FAHA

would come for a CT scan two weeks before the procedure.”

UH Harrington HVI has refined its LAA protocol further in order to create a single visit for LAA occlusion. On the same day, patients with AF can be seen by a cardiologist, get CT imaging, and then proceed to LAA occlusion device implantation. The proximity of physician offices, the advanced imaging center, and hybrid OR enables a one-day visit. This is important for patients who may be traveling to UH for consultation. During the COVID-19 pandemic, the one-day protocol has also been important in minimizing potential exposure for both patients and HCPs.

In order to effect same-day evaluation, procedure, and discharge, the team at UH Harrington HVI had to optimize scheduling among different departments and ensure sterility during the patient experience. For the latter, a multidisciplinary team consisting of interventionalists, imaging specialists, infectious disease physicians, and registered nurses (RNs) collaborated to devise protocols and pathways permitting a patient to be moved directly from the CT room to the pre-operative holding area or the hybrid OR.

The Concierge service, a dedicated scheduling team for structural heart patients, is crucial for UH Harrington HVI’s one-day LAA occlusion assessment and intervention. Concierge has access to calendars for physicians, imaging equipment, and the hybrid OR. It oversees pre- and post-procedure visits and imaging. As a result, Concierge effectively maps each patient’s day at Harrington HVI.

With experience, each LAA occlusion evaluation and procedure has become more seamless. “We’re up to 100% accuracy in terms of CTA predicting Watchman device size. Our patient satisfaction has increased and hospital stays have decreased. Now, more than 90% of patients have same-day discharge. In 2021, we’ve seen 170% growth in our LAA occlusion volumes, with a 100% success rate in device deployment,” Dr. Filby commented.

CT and MRI for Improved Accuracy: Transcatheter Aortic Valve Replacement (TAVR)

UH Harrington HVI has replaced pre-TAVR TEE with pre-procedural CTA of the chest, abdomen, and pelvis. The SOMATOM Definition Flash CT

scanner protocol includes a single-phase acquisition with dual-energy imaging to improve the quality of the imaging of the patient’s aorta as well as the iliac and femoral arteries. The CTA also generates data that allows HCPs to select the appropriate valve size for each patient.

Unique to UH Harrington HVI, patients undergo pre-TAVR cardiac MRI with the MAGNETOM Aera 1.5T MRI system. In cases where the degree of aortic stenosis is questionable, cardiac MRI can help determine whether the aortic stenosis is severe. “There are patients who are between the existing values for moderate and severe aortic stenosis. MRI adds corroborative information to help in the decision-making process,” explains Dr. Filby. Interventionalists at UH Harrington HVI can integrate MRI into their decision-making since the MAGNETOM Aera 1.5T MRI system is dedicated solely to cardiovascular imaging, removing the need to compete for equipment time with other departments within the hospital.

Dr. Attizzani, Director, Valve and Structural Heart Disease Center expounded: “We are combining all the imaging modalities available to us to



The robotic interoperative angiography ARTIS pheno system.

arrive at the diagnosis of aortic stenosis. We strive to connect the dots with three different imaging modalities — MRI, CT calcium score, and echo. By doing so, we might be able to optimize the workflow down the road. We do MRI pre-TAVR for most patients, which is unique to us. We look at gradient, velocities, contractile reserve, and scarring of

tissue. It helps us to decide whether the patient needs TAVR. Cardiac MRI also helps with prognostication of whether the patient will benefit from TAVR.” The MAGNETOM Aera 1.5T MRI system also provides important anatomical information on a patient’s vasculature and size of the aorta, which helps with procedural planning.

UH Harrington HVI is recognized as a Center of Excellence for minimalist TAVR. In the national Transcatheter Valve Therapy (TVT) registry, patients who had TAVR with conscious sedation had significantly lower mortality rates at 30 days and shorter hospital stays compared to those who had TAVR with general anesthesia.²

Greater Accuracy With ARTIS pheno C-Arm for Transcatheter Mitral Valve Replacement (TMVR)

UH Harrington HVI also performs minimally invasive procedures for mitral valve disease. Echocardiography is performed to ascertain whether a patient is a candidate for TMVR.³ In addition to TEE, patients have a pre-operative CT with the SOMATOM Definition Flash CT scanner at Harrington VHI. The pre-TMVR CT scan plays an important role in defining the mitral annulus,

sizing the bioprosthesis, identifying key anatomical structures, and modeling the potential impact on the left ventricular outflow tract (LVOT).

TMVR is performed under general anesthesia, as TEE guides placement of a MitraClip (Abbott). With the addition of an anesthesiologist and sonographer in the hybrid OR, the robotic interoperative angiography ARTIS pheno system makes it easier to accommodate more HCPs in the interventional room. “You can move the C-arm of the ARTIS pheno in multiple directions, which is really unique and helps because the anesthesiologist or TEE team often is positioned near the patient’s head,” explained Dr. Attizzani. “It’s also beneficial considering that we treat patients of different sizes and we can adjust the C-arm for each patient.”

ARTIS pheno’s C-arm can be adjusted robotically. “We utilize the ARTIS pheno for all our procedures, and all the interventional staff and physicians have been trained on it. You can reach certain positions using ARTIS pheno that are difficult with other systems,” adds Jessica Lee, BSN, RN, Invasive Cardiology Manager.

ARTIS pheno has preset functions that can make interventional procedures more intuitive. For instance, an



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entire procedure protocol can be pre-programmed into the system for recall on command with simple easy-to-use controls, called Case Flows. The ARTIS pheno system also enables a single position or multiple positions to be pre-stored and recalled according to the end user's preference. This functionality helps ensure accuracy and confidence in system usage, allowing physicians and staff to focus more on patient care rather than advanced technology.

Cyndie Lowrie, System Director Diagnostic & Procedural Services, says that Siemens Healthineers personnel have been instrumental in helping Harrington HVI capitalize on all the features of the ARTIS pheno system. "Siemens Healthineers representatives have strong clinical experience. We learn from them about new features and how we can apply those to our imaging and procedures."

Dr. Attizzani is excited about how the MAGNETOM Aera 1.5T MRI system might help Harrington HVI add to the scientific evidence on mitral regurgitation (MR): "We've started doing MRIs for patients with mitral regurgitation. We're doing a stress MRI both pre and post MitraClip. We're trying to refine the understanding of when patients experience MR. Patients may not show severe MR when they do a resting echo but they have severe MR after exercise. These are the patients we're trying to target. It helps with deciding when to treat patients. Should they be treated sooner?"

"The biggest goal is making sure that patients receive the highest quality of care and have an incredible experience."

Sara Rahmani, MS-HSM, Administrator of Cardiovascular Medicine, Harrington Heart & Vascular Institute



Controls for the robotic interoperative angiography ARTIS pheno system.

Patient Experience

The dedicated advanced imaging and hybrid OR suite has created extraordinary convenience for patients with structural heart disease. As evidenced in UH Harrington HVI's LAA occlusion protocol, patients can have pre-procedural imaging and undergo a minimally invasive procedure under conscious sedation in a single day. "The workflow is really efficient and it creates a seamless experience for the patient," Dr. Rashid observed.

The Harrington HVI team is also cognizant that many patients feel vulnerable when facing a procedure. "When patients arrive for a Watchman procedure, they are met by the team that will be completing their procedure so we provide continuity of care for patients. That's important. Our nurses make patients and their families comfortable and create a calming atmosphere. They're with the patients before the procedure and with them in post-operative holding," Jessica Lee, Invasive Cardiology Manager, explained.

It is similar for patients who have a valve procedure

at UH Harrington HVI. Lori Hammer, Manager of the Valve and Structural Heart Disease Center, commented: "My team manages the flow of patients receiving the various structural heart interventions we do at Harrington HVI. We're with the patients from referral through time of procedure, and then our nurse practitioners do follow-up. Patients have been thrilled with the level of care that they have received and have extended their compliments of the hybrid OR staff, too. Everyone at Harrington HVI is very patient-centric."

Multidisciplinary Clinical Team Experience

The work environment at UH Harrington HVI is dynamic and engaging. "There's a lot of collaborative care that occurs and that's generated excitement. One of the epicenters of that excitement is the advanced imaging and hybrid OR suite that allows for the proximity of so many different types of physicians to share ideas toward the betterment of patient care, research ideas, and innovation. It really has been a nidus," Dr. Filby shared.

"Physicians and staff are willing to embrace new ideas and to innovate. That kind of sets the tone. We have the right mix of personnel who are forward-looking and have access to this



From left to right: Guilherme F. Attizzani, MD; Steven James Filby, MD; Sara Rahmani, MS-HSM; Jessica Lee BSN, RN; Mehdi H. Shishehbor, DO, MPH, PhD; Imran Rashid, MBBS, PhD, FRACP; and Lori Hammer, BSN, RN-BC.

amazing infrastructure. Our vision is looking to how we can use this technology to improve patient care,” Dr. Rashid added. “I think our approach is permeating throughout UH.”

Sara Rahmani, MS-HSM, Administrator of Cardiovascular Medicine, agreed. “There’s an innovative, entrepreneurial mindset among the physicians, nurses, technologists, and administrators.”

Allied professional managers and administrators assist in developing protocols and logistics to optimize patient flow. “A lot of the things we’re doing at Harrington HVI are one of a kind. They haven’t been done before. There weren’t protocols in place so we have to think about how we can make something like one-day LAA occlusion work operationally,” Sara Rahmani commented. For the one-day LAA occlusion protocol, Harrington HVI brought together physicians, nurses, adminis-

trators, and front desk personnel to devise the optimal patient flow.

Even with Harrington HVI’s dedication to innovation and advancing medicine, patient care and outcomes remain central to the entire healthcare team. “We’re creating new standards of care for patients,” Sara Rahmani noted.

Dr. Shishehbor, President of Harrington HVI, shared his vision for the future: “We want to use nominal radiation in diagnostic imaging and percutaneous procedures. We want healthcare delivery to be much more efficient for patients. Patients should be able to come in, see the physician, get bloodwork done, get CT done, and then have a procedure. We’ve done this with LAA occlusion. We’re expanding this approach to other interventional vascular procedures. We’re already engaging with other departments for novel ways to treat a variety of diseases.”

“The future is integrated intervention. We’re doing that today at UH Harrington Heart & Vascular Institute,” Dr. Sanjay Rajagopalan concluded.

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