The First Hybrid Freestanding Lab in Florida: The Cardiovascular Institute of Trinity

Cath Lab Digest talks with Luis Annoni-Suau, MD, FACC, Electrophysiologist; Rami Akel, MD, FACC, FSCAI, Interventional Cardiologist; Julio Dias, RCIS, HSA-BAS, Director; Chris Findlay, RT(R) Lead Technologist/Safety Officer, Trinity, Florida.

Luis Annoni-Suau, MD, FACC, Electrophysiologist

Can you tell us about the Cardiovascular Institute of Trinity?

We have the first hybrid lab in the state of Florida. By that, I mean we are a facility with an outpatient cath lab as well as a certified ambulatory surgical center (ASC). The Cardiovascular Institute of Trinity has 7000 square feet with one interventional room. There are eight beds, as well as two radial suites holding four chairs each, where people can also recover after procedures. Most of our cardiac cath interventions are done through the radial approach. Our dual classification allows cardiologists and electrophysiologists to do cases in either of the two settings. Different days are allocated for each. The days where we do ASC procedures, we cannot do cath lab procedures, and vice versa. In the ASC, we are able to perform initial implants of pacemakers and defibrillators, as well as battery change-outs. Most insurance companies prefer angioplasties and peripheral vascular interventions be done in the ASC setting, and so they contract with us in the ASC rather than the cath lab. There is more supervision by the state for an ASC than with the general cath lab. The fact that we are able to have these two entities within one room has allowed us to get better contracts with private insurance companies in Florida. Also, the ASC setting has allowed us to contract with private insurance companies for electrophysiology studies and ablations.

What drove you to open this center?

We wanted to do something that would help the community and make procedures less expensive with better quality — where everybody can win. We had been researching this concept for the past three years. Initially, we started out thinking that we were only going to do an office-based, outpatient cardiac cath lab. When we realized that without adding the ASC element, we would not be allowed to do devices or electrophysiology (EP) procedures, nor stent angioplasty, we decided to instead invest more, understanding it would take longer, but with the feeling we would rather do it the right way.

What other procedures are you able to perform?

We have done several biventricular defibrillator initial implants, as well as upgrades and battery change-outs. As we have secured more private insurance contracts, we are currently in the process of installing the equipment to do EP studies and ablations. Our three electrophysiologists are planning to do most EP and ablation procedures except for atrial fibrillation, ventricular tachycardia in ischemic heart disease, and left-sided atrial tachycardia. For all EP procedures, we have secured anesthesia coverage with a well-regarded anesthesia group.

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Dr. Luis Annoni can be contacted at annoni@iccheartcare.com. Dr. Rami Akel can be contacted at ramiakel@gmail.com. Julio Dias, RCIS, HSA-BAS, can be contacted at j.dias@cardiovasculartrinity.com. Chris Findlay, RT(R), can be contacted at c.findlay@cardiovasculartrinity.com.

Figure 1. Left to right: Luther James RN, Tina McCoy RT(R), Julio Dias RCIS HSA-BAS, Sheree Leppinen BSN, Chris Findlay RT(R).

What procedures are being done on cath lab days?

We do diagnostic cardiac catheterizations as well as peripheral vascular interventions. Coronary artery stenting is only approved by private insurance and they require that those be done on the ASC days.

How many physicians are involved?

We are a group of ten physicians with seven cardiologists and three electrophysiologists that come from four different groups.

What were the hurdles that you had to overcome as the first hybrid facility in Florida?

Putting together an outpatient cath lab, if you do it right and already have the structure, will take 6 to 9 months. However, upgrading to an ASC facility is more complicated. It is required to be built within a specific and very rigid architectural and engineering set of regulations in order to be granted the proper licensure from the State of Florida. Our hybrid ASC is licensed by the Florida American Health Care Association (FL-AHCA) and it is credentialed by the Association from Ambulatory Health Care (AAHC). We initially thought it would take about a year and half to two years. It has taken probably around 27 months to open our doors. The requirements of the state as well as the federal government to get approval as an ASC are very complex and detail-oriented. To make a hybrid facility successful, you have to bring together a well-qualified and experienced group of physicians. However, we have been extremely pleased and pleasantly surprised by the fact that insurances want to contract with us. I think it is a combination of factors. Our physicians have been practicing anywhere from 15 to 25 years in the area. We have built our reputation based on the high standards of patient care, the volume of cases, and an impeccable success rate in performing cardiac procedures. I have been in private practice for 21 years and over the last 18 years, I have been doing most of my EP procedures and ablations as outpatient. Most patients will get their device and go home within the next 2 to 4 hours. EP ablations would be discharged within 6 hours. My EP partners also have similar experience. I believe that the main reason the private insurers have contracted with us has to do with the stellar performance of this group of physicians and the fact that we are not changing our practice patterns.

Did you have to get any additional credentialing?

Yes, we also received accreditation by the Commission on Office Laboratory Accreditation (COLA) as a Clinical Lab facility and a license from the Board of Pharmacy as a Modified Class II B Pharmacy.

What is your plan for surgical backup?

We have contracted with a large hospital about 2 miles away. In case of an emergency, the patients are promply transferred by EMS to this institution.

You don't need to have EMS on site?

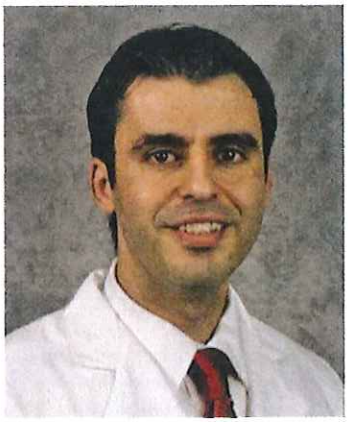
No. This is not a requirement. However, for interventions, we have balloon pumps and other assist devices in our facility.

How long have you been open?

We started doing cases in the summer of 2016. We began with Medicare patients, and around September, we started working directly with the private insurance companies. At this point, we have most of the major private insurances on board. As we keep doing more and more cases, the private insurances have asked to come and tour the lab. The private insurance world is looking at the huge savings for them and their roster of patients by not performing these procedures at the hospitals.

Can you tell us about your imaging system, Trinias (Shimadzu)?

We use the Trinias for all our procedures. In the beginning, when we compared what Shimadzu was offering to products from other imaging companies, we realized that Shimadzu was offering significantly more to us in terms of equipment, technology, service, and warranty. We were very impressed with their image quality, and now that we have done several cases, we are captivated by the high definition of these images. We chose a 60-inch screen monitor to display the different cardiovascular and EP input we get from the system. This monitor can display one to six different and simultaneous viewing monitors. For example, when we implant a new device, we choose half of the screen to display the live fluoroscopic image and then the other half is split in two, one to show review cine image, and the other to show EP and hemodynamic signals. As an electrophysiologist, I will say that the image details we get from this equipment are incredible. When I implant a left ventricular lead, I can see, in full detail, the angioplasty wire running through the lead all the way out and into the peripheral vein that I want to go into. Because of this excellent image definition, we have been able to cut time from the procedure. I have heard a similar reaction from my partners on the cardiac cath side, as well as those doing peripheral interventional procedures. When I compare the Trinias system images to the images displayed by competitive systems used at hospitals, I feel like I am comparing a 4K ultra high-definition TV to a tube color TV.



Rami Akel, MD, FACC, FSCAI, Interventional Cardiologist

As a peripheral and cardiac interventionalist, can you share your experience with Shimadzu's Trinias system?

We have been highly impressed with the image quality in the Trinias system. The image definition has been outstanding with excellent definition of calcification within the vessel and crisp visualization of the patient's anatomy. This is above and beyond anything that I have used from other vendors. I have used three other companies' imaging systems, and the Trinias surpasses anything that we have ever seen before.

What are the system features you use most?

I regularly use the Road Map feature in peripheral intervention; this comes with easily adjustable brightness of the vessel and body landmarks. The bolus chase function offers excellent image quality of the run even if movement of the limb occurs. Further detailed images can be obtained using digital subtraction angiography with an excellent image resolution. The system's transverse movement, meaning the ability to move the flat panel detector around the patient to accommodate cardiac angiography, carotid angiography, and peripheral angiography in the same space if need be, has been very helpful as well. The flat panel detector is automated and easy to move around.

Can you tell us about SCORE RSM [Real Subtraction Mode], a unique Shimadzu technique for digital subtraction angiography, and its use in leg runoffs?

Many of our patients will end up moving their legs, particularly as the contrast makes its way down to the feet. You are trying to image that area, and the second the contrast hits it, most patients can't help but jerk and move their leg. The SCORE RSM feature allows you to still have a workable bolus and chase runoff.

Figure 2. The Cardiovascular Institute of Trinity, Trinity, Florida.

Now we have the ability to safely perform our cardiovascular diagnostic and therapeutic procedures in an outpatient setting, where the patients will be observed for several hours post procedure and can go home the same day. With our state-of-the-art facility, we will be leading the next wave of cardiology.

Obviously, if you have patients where it is a major concern that you are not visualizing well, you can come back and do a digital subtraction runoff, but the SCORE RSM is a very useful tool, giving you an overall idea of the anatomy before you know what area you need to zero in on.

Dr. Annoni mentioned that most procedures are done radially on the cath lab side.

I am a dedicated radial operator; more than 95% of my cases are done radially. It is my default access for coronary diagnostic and interventional procedures, particularly in an outpatient environment. I have been doing radial access for the past 7 or 8 years. Coming out of training, I was doing femoral access and got fed up with all the groin complications. I committed to change all my cases to radial and it has been the best transformation in my practice of cardiology.

The majority of the time you can traverse the arm without any problems and just look at the shoulder, but if you have any issue, with the transverse movement of the Trinias system, it is fairly easy to move the flat panel detector to a place to visualize the arm without having to move the patient or interrupt the flow of the case.

Do you think there is more fluoro time and therefore more dose based on accessing the patient from a different location — radial approach vs femoral approach?

Not at all. Some operators are heavy on the pedal and some are not, and I think that if you are a heavy-footed operator with your femoral access, it is going to be the same way with radial. In my experience, the radial cases have less fluoroscopy time, with the lack of catheter exchanges (more than 90% of my cases are single-catheter cases as opposed to 3 catheters and 2 exchanges in femoral cases), along with the fact that I don't look at the catheter going up. As long as I can see the wire up in the subclavian, I typically don't look down in the arm. This means that most of the time, my radial cases are shorter and with less radiation than a straightforward diagnostic femoral case with three catheters.

Do you think that the visualization you get with the Trinias system helps to reduce radiation dose?

Absolutely. Unfortunately, our patients have become heavier over time than what we have seen before, which is the nature of the population that has this disease. Crisp images help reduce the number of pictures you need to take and enable you to make better treatment decisions.

How do you find the use of the tableside controls?

The tableside controls are fairly easy to use. The features are simple and the controls to move the table are fairly intuitive. Typically the technologists are the ones setting up for the RSM, but it seems to be an easy process as well.

Any final thoughts?

Our lab functions almost like a full hybrid OR, where we are able to perform a variety of endovascular, cardiac, and vascular interventions, in addition to pacemakers and implantable cardioverter defibrillators (ICDs). On the endovascular side, we are able to perform the gamut of procedures all the way from coronary intervention to carotid angiography and even below-knee complex critical limb ischemia intervention.

This is an evolution of how we do cardiovascular work. As the technology continues to advance, we are getting better and better about treating these patients with minimal morbidity. As such, the hospital facility has become a bit of an overkill. Now we have the ability to safely perform our cardiovascular diagnostic and therapeutic procedures in an outpatient setting, where the patients will be observed for several hours post procedure and can go home the same day. With our state-of-the-art facility, we will be leading the next wave of cardiology.

Are you participating in any registries?

We are participating in the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR. We definitely want to make sure that we hold ourselves to a very high quality standard. Our main emphasis is on excellent patient outcomes in addition to a better patient experience in a smaller facility, with staff that is eager to make sure the patient has a good experience throughout their stay. We are avoiding and eliminating many of the extra costs that are unavoidable in a hospital facility.

Julio Dias, RCIS, HSA-BAS, Director

Tell us about your experience with the Cardiovascular Institute of Trinity.

We have two facilities in one — a cath lab and running in conjunction with that, a surgery center. Different procedures are allowed on different days. Right now,

Figure 3. The front lobby area.

Figure 4. One of the two radial recovery lounges.

Figure 5. The recovery area holds eight beds.

Figure 6. A view of the lab from the control room.

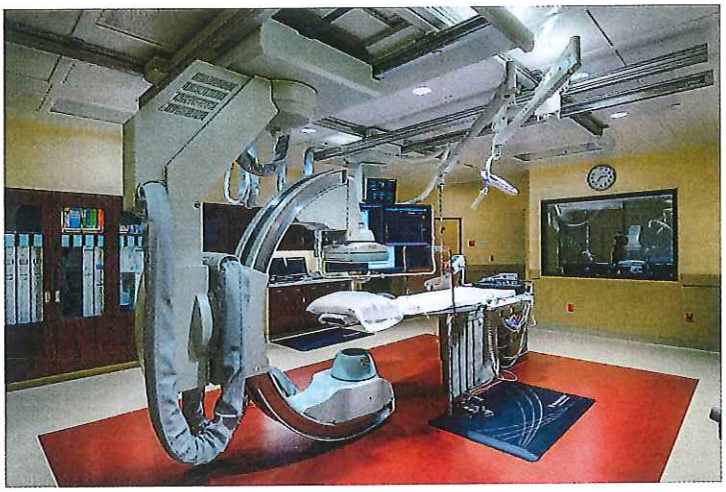


Figure 7. The hybrid lab with the Trinias system (Shimadzu).

Monday and Thursday we run the cath lab, and Tuesday, Wednesday, and Friday, we run the surgery center. Our biggest challenge right now is putting the managed care contracts together and finding out exactly what patients we are able to do on certain days related to our reimbursement and the contract that we have signed.

You have one hybrid lab and are using the Trinias system. How do you find it in terms of ease of use and image quality?

The image quality is phenomenal. It is the best I've ever seen and I've been in the business for about 15 years. The image quality really does speak for itself. It eliminates a lot of x-ray required in terms of time to complete the procedures. When we get a good quality image, we don't have to take three or four pictures; for us, one picture is good enough. That has been helping us tremendously. The way the system is set up, we can do just about every case: we can switch it over and do a radial case, a peripheral case — we do utilize digital subtraction angiography and we have to have the capabilities of doing just about every procedure that is out there. We now are actively working on incorporating the existing Trinias system and the Mennen hemodynamics system that we use with Boston Scientific EP system, because we are also going to do EP studies. The compatibility involves a lot of integration and a lot of effort on all sides, with Boston Scientific, with Mennen, and with Shimadzu, to make sure that the systems integrate with each other. Also, many systems won't allow you to change certain things on the tableside itself, but the Trinias system allows us to do most of what we really need at the tableside. Some systems require you to go back into the control room in order to change it from one setting to another. The Trinias system allows us to have full functionality right at our fingertips at the tableside.

Can you describe more about the physical nature of the room?

All the cables are hidden, because we are a surgery center. No cables are allowed to be touching the floor. We have a regular control recording room that we utilize. It is set up in a manner fairly common to most cath labs. We also have a Medrad injector system (Bayer) connected to the table. We have a fairly large room, since it is a hybrid room.

How has the system reliability been?

Reliability has been very good. We did have a couple little hiccups here and there in the beginning, but all the issues have now been taken care of. We are definitely able to do the procedures with no issues.

Do you have any suggestions for those who may be interested in starting up a similar hybrid center?

Hire people that have experience and can function as a unit. Our team has close to 100 years of experience working in cath labs. By being able to put a good team together, you eliminate a lot of issues. It's not just that we are doing so many different procedures in the outpatient setting. There is much more related to policies and procedures, because we are an accredited cath lab and also an accredited surgery center. We deal a lot with the state and the county, from fire departments to biomedical waste pickup, to air/gas with the medical gas system. Every square inch of this building has to be on par on an everyday basis. When the state comes in, our doors are open. Anytime anyone wants to inspect the facility and make sure we are doing what we are supposed to be doing, we have to be ready. We are very adamant about sterile techniques, sterile corridor, and proper attire. No one can come in from outside without changing into our scrubs. We have preventative maintenance contracts with just about everyone we deal with. Our air conditioning system needs to be in place. We do a generator test every single week when we come in the morning. So, as you can see, our day-to-day workload is much more than just doing procedures. Hiring the correct people definitely helps.

Chris Findlay, RT(R), Lead Technologist and Safety Officer

What has been your experience in using the Trinias system?

The physicians we work with are very self-sufficient and utilize the controls independently. The technologists do more with the peripheral functions. As far as running the table, we set up the start and end times, and run the table. The nice part about the Trinias system is that you need only one single shot with digital subtraction when performing runoffs. With most systems, if you do a runoff with any movement from the patient, you have to retake the images due to blurring. The SCORE RSM mode prevents any blurring of the pictures as we run down the leg in a peripheral case. The C-arm has rotation in an almost 360-degree area. This gives the flexibility to move wherever you need it in order to complement a large variety of procedures. The table itself can rotate on an axis, which gives you an opportunity to bring in a bed if you need to do a procedure within the bed itself. But what really caught my eye initially was the excellent imaging. Shimadzu's technology has great detail. With the size of the monitor, you really need the detail. Other imaging systems I've worked with usually have monitors that are half the size. With the Trinias' 60-inch monitor and great imaging, we can see every detail with any pacemaker lead we insert. We can see every little detail of the screw, without even magnifying the image. The system works well and it can pretty much can do it all.

How are you using the slave monitor?

The slave monitor is located on the console in the procedure room. There are times during the procedure when visibility is affected. The slave monitor gives us the opportunity to view the images during these difficult positions. It's nice and small, and can fit in an area where the physician can see it. Traditional x-ray system controls can be difficult to arrange and usually require that the controls have to be moved to the other side of the table. This can increase procedure time unnecessarily. The slave monitor serves the circulating nurse as well. He or she can see what is going on without actually even being on the same side as the physician and the technologist.

We have two other monitors in our control room. One of the monitors allows us to process and develop our images on the fly, while the physician is still doing the procedure. This way, the physician can still fluoro and what we're doing on the side doesn't affect what he sees in the procedure room. ■

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