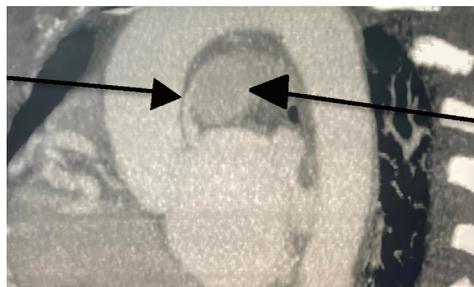


Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CASE REPORT

ALCAPA Case Review in Images: An Interesting Etiology of Adult Cardiac Arrest With Eight-Year Follow-Up Post Surgical Correction

Amal Khan, MS IV; Mehreen Ali, HS IV; Som Bailey, DO; Thomas Shields Livingston, MD; Srujana Chakilam, MD

Anomalous origin of the left coronary artery from the pulmonary artery (ALCAPA) is a rare congenital coronary artery anomaly affecting 1 per 300,000 newborns.¹ In patients with ALCAPA, the natural lowering of pulmonary artery (PA) pressures in the neonatal period causes a left-to-right shunt with blood from the left coronary artery reversing into the pulmonary artery and subsequent myocardial ischemia.^{2,3} It is very uncommon for ALCAPA to be diagnosed in adulthood, as over 90% of untreated newborns die within the first year of life. Survival without surgical correction is dependent on collateral circulation between the coronary arteries.

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PROGRAM SPOTLIGHT

Chronic Thromboembolic Pulmonary Hypertension (CTEPH) Program at University of Michigan Health

CLD talks with Drs. Vallerie V. McLaughlin, Victor M. Moles, Vikas Aggarwal, Jonathan W. Haft, and Prachi Agarwal.

Can you give us an overview of CTEPH and the program at the University of Michigan?

Dr. Val McLaughlin, Director, Pulmonary Hypertension Program: Chronic thromboembolic pulmonary hypertension (CTEPH) is rare. We think that it affects 3% or 4% of patients who have had acute pulmonary embolism (PE) and it is difficult to diagnose. Symptoms are insidious and include a lot of nonspecific symptoms such as dyspnea that are part of the workup of any patient with PH who is referred.



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IMAGING TECHNOLOGY

EchoPixel's 4-D Holographic Intraoperative Imaging for Cardiac Anatomy

CLD talks with Jacob Dutcher, MD, and Sergio Aguirre, Founder and CEO, EchoPixel.

What is intraoperative holographic therapy guidance?

Sergio Aguirre, CEO, EchoPixel: EchoPixel is a startup company focusing on virtual or augmented reality in medicine. We provide physicians a hologram floating in front of a flat screen, enabling not only their ability to view pre-op images like computed tomography (CT) and magnetic resonance imaging (MRI), but also live, real-time ultrasound in 4D. That means physicians are able to see a heart in front of the screen floating on top of the cath lab table. The hologram allows for the immediate identification of patient anatomy, and also the live location in the heart of equipment like catheters or other delivery systems.



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EchoPixel's 4-D Holographic Intraoperative Imaging for Cardiac Anatomy

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It can be used to navigate, which is why we call it 'holographic therapy guidance', in the sense that physicians use a hologram to guide a particular therapy, be it delivering or implanting a device, doing ablations, or even, in a recent case, removing a tumor. The technology is FDA cleared, and we have been selecting key sites and luminaries in order to bring more people to the podium who can talk about their experience with clinical implementation.

Jacob Dutcher, MD: I am the medical director at EchoPixel, and an interventional cardiologist involved in structural heart procedures, including transcatheter aortic valve replacement (TAVR), atrial septal defect (ASD) closure, and left atrial appendage occlusion (LAAO), among others. For all of our current procedures, we have relied heavily on two-dimensional (2D) imaging and are just starting to scratch the surface of the use of 3D and 4D imaging. EchoPixel makes it easier to understand the anatomy and structures of the heart with real-time spatial resolution. It uses our ultrasound images to create a digital twin of the heart in the form of a hologram and I am able to

interact with that image. I don't have to rely on an ultrasound sonographer or a transesophageal echocardiogram (TEE) physician to rotate or turn the probe. All I need them to do is acquire a cube of data containing the area of interest within the heart. From there, I can then interact with the resulting holographic image using a stylus. I am able to twist, turn, and rotate the image, or view it backwards or upside down. The hologram sits immediately in front of me in three dimensions, so I can also just turn my head and look at it from a different view. EchoPixel creates a digital twin of the patient's anatomy — the view of a surgeon, as I call it. The real-time spatial resolution allows you to look at structures in a different but natural way, just as a surgeon would. It is like I am actually in the body, looking inside of the patient's heart, and I can visualize whatever I am attempting to fix or implant, instead of having to rely on 2D imaging and needing to change angles to obtain different views. Holographic therapy guidance is next-level imaging, it is extremely new, and we are still working on its development, but EchoPixel has been a game-changer in my practice. We are looking just at the tip of the iceberg — there will

be a lot more in terms of use and abilities coming down the road.

How many of your procedures have utilized holographic therapy guidance?

Dr. Dutcher: Thus far, we have done approximately 75 procedures using holographic therapy guidance, or what we call HTG. The vast majority have been LAAO procedures, predominantly using Watchman (Boston Scientific), but we have also used Amulets (Abbott Vascular). With HTG, we are able to view our catheters as they come up into the heart. HTG has also been incredibly useful for transeptal puncture. In order to get from the right atrium to the left atrium, you have to puncture the septum. If you are not in just the right spot, you could pierce the aorta or the back wall of the heart. You could also be positioned too high, which would make closing off the appendage challenging, or positioned too low, so you can't reach where you need to be. With true 4D live imaging that allows me to visualize my catheter, I can see exactly where I need to penetrate and where I am puncturing the septum, all at a higher level of visualization than ever before. As we move into the left atrium, my catheter is visible, and I can make subtle adjustments to navigate directly into the appendage. Once in the appendage, we deploy the device, and then typically use 2D imaging to do a full circular pan to scan the whole device, which can be time-consuming and sometimes you don't quite see everything. However, having live imaging with HTG means that when I deploy the device, I can see it instantly in three dimensions. It brings the instantaneous gratification of knowing the device is exactly where it needs to be, or whether it is a little too deep or sticking out too far, or it is cramped and too small. You can make all these assessments literally within seconds, whereas before we would have to pan and obtain fluoroscopic images, taking minutes to find out whether the device is in the right spot.

As you integrated HTG into your procedures, what was the learning process like?

Dr. Dutcher: We did our first HTG case in May 2021. The first 10 to 15 cases focused on learning how to use the technology, and what it could and could not do well. Patient safety and patient care come first, so HTG was done in parallel with all our standard imaging, including fluoroscopy and transesophageal echo. For those first cases, we relied predominantly on our standard imaging, but I had the HTG running to see what it provided. After that short learning curve, I have now figured out which of the steps HTG is equivalent to in standard imaging, where HTG struggles, and where it is superior. Now, for at least 75% of my procedures, I am relying predominantly on HTG, and then for the remaining 25%, I am using fluoro or the other standard 2D echo to help with certain steps. Over time, we are finding more opportunities where



Figure 1. Dr. Dutcher and team perform a left atrial appendage occlusion procedure using 4-D holographic therapy guidance.

HTG is helpful. Since it is a brand-new technology, there is some learning involved in figuring out how to best utilize it. We are close to being able to do an entire procedure with only HTG, without any other imaging modality, and anticipate being able to do so in the near future.

What equipment is required?

Sergio: EchoPixel is a software that drives a special display on a flat, 27-inch screen that runs from a computer. The setup is similar to the cart of an ultrasound machine, with a computer mounted in a display facing the cath lab table. The display is essentially what the doctor is looking at. There are some cameras that are used to track and enable these interactions, and a cable that connects from the computer into the ultrasound machine in order to feed the live images into the display.

What are the procedures where you feel that HTG might be useful?

Dr. Dutcher: We started with LAAO as our first procedure, because the appendage is a complex, 3D structure and we felt having advanced imaging would be helpful. Another reason is that LAAO procedures are elective, generally considered lower risk, and are shorter procedures. When you have a brand-new technology, it is best to bring it into a safe, controlled environment. HTG will be helpful for even more complex structural heart procedures, such as repairing mitral and tricuspid valves. Once we develop better technologies for the tricuspid valve, HTG is going to be particularly useful for those procedures. It will also be helpful in visualizing holes in the heart, so imaging for an atrial septal defect or a ventricular septal defect, as well as for other complex congenital heart conditions.

Another set of patients where I believe HTG will be incredibly useful is in patients with poor kidney function or history of a severe allergic reaction to contrast dye. Many of our structural heart procedures require contrast dye to light up structures under fluoroscopy. Contrast dye can cause an allergic reaction in some patients and be harmful to the kidneys, especially in those with preexisting kidney disease. However, with the use of HTG, I believe many of our typical images which previously required fluoroscopy and contrast dye can be replaced by HTG. Patients with kidney disease make up a large subset of our patients and with HTG, we are now very comfortable performing the LAAO with little to no contrast. In fact, of our last 10 cases, we have done 7 with no contrast at all. This advancement in imaging could be a game changer and allow us to offer these types of complex cardiac procedures to patients previously thought not to be candidates due to their poor kidney function. More to come on that in the near future.

An additional area we did not originally consider was how HTG can be helpful in removing something out of the heart. In a recent case, we were able to remove a tumor. As time goes on, we are going to



Figure 2A-B. The CentraCare - St. Cloud Hospital team after removing a fibroelastoma from a patient's heart with the use of holographic therapy guidance (EchoPixel) and the AlphaVac (AngioDynamics) emergent mechanical aspiration device.

learn even more about how this technology can be applied to various heart procedures. There are also many noncardiac procedures where HTG could be used, such as in gastroenterology — looking at the stomach, esophagus, and colon, and other complex structures within the human body. Right now, however, our focus has been on the heart.

Can you share how HTG helped to remove a tumor from a heart?

Dr. Dutcher: We had a patient who was experiencing unexplained shortness of breath. He had

undergone insertion of a few different pacemakers and had tried different medications without improvement. There was an incidental notation on one of the ultrasound images of a tumor or mass on the right side of the heart, so a colleague did a standard transesophageal echocardiogram, finding a tumor in the right atrium that was located above the tricuspid valve and close to the coronary sinus. It wasn't a large mass, but we were concerned about it potentially obstructing the tricuspid valve or the opening of the coronary sinus. The patient was then referred to surgery, which is the standard of

care, for two reasons. First, some heart tumors are dangerous and thus should be biopsied. Second, if you believe the tumor is causing problems, the patient may feel better with it removed. Some tumors are obvious in causing problems; they may be large and completely obstructing a valve. Then there are other tumors, such as the one in our patient, where the obstruction was partial and it was difficult to know whether the tumor was causing the patient's symptoms. Our surgeons were reluctant to proceed, thinking, do we want to open this patient's chest and do a risky procedure that only might help him feel better? Surgery would allow us to obtain a biopsy, but we weren't sure if there would be a clinical benefit. So our surgeons were hesitant, but the patient was still having symptoms and we didn't know the cause. At our institution, we have weekly meetings to strategize about difficult, challenging cases. The meeting includes interventional cardiologists, heart surgeons, and imaging and heart failure specialists. There was concern that the tumor could be infectious and it could be a cancer from somewhere else in the body. One of my colleagues suggested removal with a catheter. We had recently used a brand-new technology, the AlphaVac (AngioDynamics) emergent mechanical aspiration device, to successfully remove a clot in transit in a patient with a pulmonary embolism. While that procedure was successful, we found it hard to understand the spatial relationship during the procedure, ie, where we were in the heart relative to where the clot was located. Perhaps we could potentially remove the tumor with the AlphaVac, but the question was, how are we going to know exactly where we are in the heart in order to grasp a tumor that was bouncing around inside of the heart? I suggested using HTG, which would offer excellent spatial resolution so we would be able to see the catheter in relation to the mass, and the team agreed it might be good approach. We had surgical backup on standby in case there was a problem. The procedure was done under general anesthesia to ensure that the patient remained still and was in a controlled environment. We were anticipating a challenging and difficult procedure, but it turned out to be easy and took only about 20 minutes. I used EchoPixel guidance to show my partner, Dr. Wade Schmidt, where the mass and catheter were located, and helped guide him so he could put the catheter on top of the mass. To create suction with the AlphaVac, you squeeze with your hand. He removed about two-thirds of the tumor on the first pass and then was able to grab the remaining portion on the second pass. Looking back, we probably could have done this procedure with conscious sedation and sent the patient home on the same day, but we felt cautious and decided to keep him overnight. The tumor turned out to be a papillary fibroelastoma, a benign tumor. A little over a month later, the patient returned for follow-up and said he felt only slightly better. Here we see why the surgeons were hesitant, because

we weren't sure how much the tumor was a cause of the patient's symptoms — but then there was the other component, which is that we didn't know what the tumor was. It could have been something more dangerous. However, fibroelastomas do grow. If we hadn't taken it out, it may have needed to be removed in six months or a year from now, because it could ultimately become obstructive, if it were to continue to grow. Using HTG for guidance, we were able to proactively remove it using a minimally invasive procedure instead of a surgical procedure.

Can you talk about the use of HTG for pre-procedural planning?

Dr. Dutcher: When I first started using HTG 5 years ago, it was as a 3D holographic pre-procedural planning tool for Watchman procedures, and it dramatically improved our procedures to the point that we presented the data at the 2020 American College of Cardiology (ACC) Scientific Sessions in Chicago.^{1,2} We regularly use 3D HTG for pre-procedural planning. I am using it predominantly with CT as my imaging base, but it can be used with ultrasound, MRI, and other imaging modalities. For the tumor case described above, we found it helpful to get a CT prior to removing the mass. I used it as an additive imaging modality to help plan for the tumor removal. The 3D CT hologram clearly identified the size of the tumor, its attachment point to the right atrial, and the ideal angle to visualize it with fluoroscopy during the actual procedure. The 3D CT holographic imaging allowed me to line up a view where the pacemaker wires crossed and the mass was coming off directly above. We could then reproduce that fluoroscopic angle in the cath lab based upon the prior CT.

Any final thoughts?

Sergio: Dr. Dutcher will be presenting more data regarding his case results. We are beginning to use HTG for transcatheter edge-to-edge repair in the mitral and tricuspid spaces. The tumor case was particularly exciting because it combines all the elements that we had envisioned for the technology due to the spatial awareness that our software delivers. It was a very exciting case and exciting to see it performed so easily. We had been exposed to tumor imaging from our pre-op side, from the planning software where surgeons had identified tumor positioning and locations. To have the software enable tumor removal in a less invasive way fulfills the vision of this technology. We do see a lot of applications in other parts of the anatomy, but cardiac anatomy is complex and moving with blood flow. This anatomy offers clinical problems where our technology can shine. We will continue to do cardiac work in structural heart treatment and electrophysiology procedures. We have been doing a lot already in the congenital heart defect space, primarily with the planning system. This software is a great example of how we believe minimally invasive therapies can be best optimized.

Dr. Dutcher: Our ability to remove the tumor shows how the EchoPixel technology allowed us to take a potentially complex procedure and turn it into something simpler and much lower risk. Even more common than tumors or masses in the heart are clots in the heart. In addition to having clot in the pulmonary arteries, some pulmonary embolism patients have active clot migrating through the heart. The clot may wrap around the tricuspid valve or sometimes it is stuck in the patent foramen ovale. Historically, options have included surgical removal. People have tried giving blood thinners, but sometimes a blood thinner will actually loosen the embolus and then it travels into the pulmonary artery and creates a larger pulmonary embolism. We have had patients die in that scenario. Being able to remove these clots without having to do surgery will be a game changer for these patients. It requires advanced imaging in order to identify the clots, because they are often bouncing around in the heart. With holographic therapy guidance, we can see that clot live in real time in relation to our catheter. It is just a matter of manipulating the catheter up to the clot and sucking it out. Some institutions have also used the AngioVac (AngioDynamics) to remove bacterial infection on heart valves in cases of endocarditis. Typically, these cases would be addressed with surgery, but some operators are using catheters. This may be something we think about trying as well in the near future, using HTG to guide us. ■

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Jacob Dutcher, MD

Director of Structural Heart and STEMI Programs, CentraCare Heart and Vascular Center, St. Cloud, Minnesota; Chief Medical Officer, EchoPixel, Santa Clara, California



Sergio Aguirre

Founder and CEO, EchoPixel, Santa Clara, California

