Guiding the future of transcatheter tricuspid interventions

How 4D ICE NUVISION™ could provide new hope to fragile patients running out of time and options

Next-generation intracardiac echocardiography is providing a new perspective on transcatheter tricuspid interventions. The prevalence of severe tricuspid regurgitation (TR) and poor prognosis have fueled breakthrough innovations in valve repair and replacement, with advances in intraprocedural imaging driving more progress.

Up until recently, patients with moderate to severe TR had limited treatment options, leading to heart failure, hospitalizations, and a diminished quality of life.[1] Multiple studies have called attention to high mortality rates associated with medical therapy and current surgical options[2] — highlighting the need for alternative solutions. While emerging transcatheter technologies have shown promising results in safety and efficacy, success is heavily dependent on the quality of procedural imaging.[3,4]

The Structural Heart team at Ascension Via Christi St. Francis in Kansas is part of that progress. The globally-recognized program, which is led by Bassem Chehab, MD, is participating in several pivotal studies to develop new therapeutic options for patients with failing tricuspid valves. Dr. Chehab was also an early adopter of the 4D ICE NUVISION™ ultrasound catheter by Biosense Webster, Inc. part of Johnson & Johnson MedTech,* which has opened the door to more minimally invasive procedures.

With real-time, volumetric imaging, a 90° x 90° field of view, and an independent rotating tip, the 4D ICE NUVISION catheter has become Ascension Via Christi's preferred tool while treating tricuspid regurgitation. The sophisticated technology, powered by GE HealthCare's Vivid™ ultrasound system, is designed to allow multiplanar and real-time 4D volume imaging of target structures with minimal manipulation. The Structural Heart program is also leveraging the catheter to guide mitral valve repairs and treat congenital heart disease.

We recently asked Dr. Chehab to share his insights on the latest advancements in tricuspid interventions and the value of 4D ICE in clinical practice.

Can you describe the evolution of your structural heart program at Ascension Via Christi?

Dr. Chehab: *From day one, we were heavily focused on quality, excellence, and good academics. We treated a wide range of structural heart patients, and our program grew tremendously. We went from performing 50 TAVR procedures a year to 350 or 400. We also increased TEER or tricuspid/mitral valve repairs from 30 procedures to more than 100 annually. In 2015, we*

initiated our research program and were involved in numerous IDE clinical trials which included multiple sponsors and technologies. Our team hit high marks. We were top enrollers in both national and global trials. Today our program is one of the top TEER programs in the U.S. primarily because of our multi-disciplinary approach in imaging and ensuring that we are always on the cutting edge with technology.

What has been your experience in using 2D ICE in the structural heart arena?

Dr. Chehab: *I've been using what I will call "standard" ICE since 2009. It was always an excellent technology and tool, but it was lacking from a technical or software standpoint. There was never a good marriage between software and hardware, and this was always the limiting factor with 2D ICE.*

As we started our program, the value of 2D ICE was largely confined to congenital heart disease conditions, like ASD (Atrial Septal Defect) and PFO (Patent Foramen Ovale). At that time, it wasn't sufficient from a structural perspective compared to what we have today. We tried to push the envelope many times within our structural heart interventions, but it didn't work well for us.

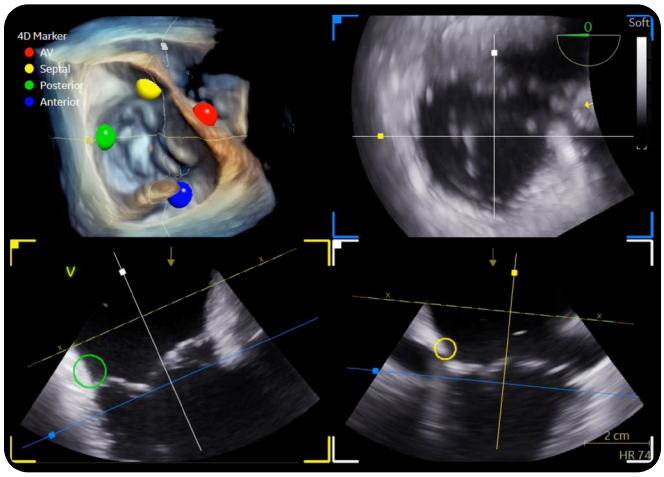
Also, TEE has progressed so much in the last decades that it's been hard for ICE to catch up. TEE allows for 4D technologies, 4D reconstructions, and all volumetric studies. And when combined with FlexiSlice MPR (Multi-planar Reconstruction) and the biplane options offered with GE HealthCare's system, 2D ICE was really behind.

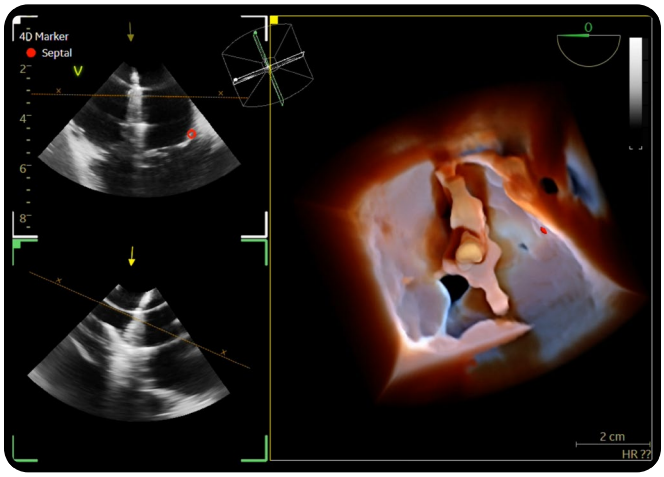
Tricuspid disease has been largely undertreated, but we're now seeing a lot of growth. What's contributed to this growth, and what does this mean for your patients?

Dr. Chehab: *The tricuspid space is ready to blow up as the advancement in imaging technologies has significantly increased treatment options. Previously, in our tricuspid interventions, we would struggle with clear imaging. Believe it or not, one of the main screen failures in tricuspid trials is imaging — not anatomical or clinical screen failures. You'd insert the TEE probe into the patient, and you just couldn't see anything. You couldn't see the tricuspid well enough to fix, repair, or replace it. We tried imaging with 2D ICE as well, and it didn't bring much to the table either.*

> *"It adds value. If you have sites with heavy volume and they're comfortable with their imaging cardiologist, then adding a 4D ICE catheter is like gold. It's only going to make them better and improve and excel even more. I love having options — and this is an amazing option."*

We now have imaging that enables clear visualization of structural anatomy. What does this mean for our patients? Many people may no longer need to medically manage their TR symptoms. High-quality imaging expands valve repair or replacement options which can drastically improve quality of life for patients.





You were among the first in the U.S. to use the 4D ICE NUVISION catheter. What were your initial impressions and why was it appealing for tricuspid interventions?

Dr. Chehab: *I was skeptical in the beginning. I started with congenital cases, PFO and ASD. The first cases worked well, and I believed there was more potential. Then as I was imaging the septum for congenital cases, I glanced at images of the tricuspid and it was like a crystal-clear picture. The quality, the details, the high definition of the tricuspid leaflet blew my mind. That was my first step.*

At that time, many people in the U.S. were also starting to see the need to do more tricuspid cases with 4D ICE. So we started using the 4D ICE NUVISION catheter in the tricuspid space and this is where it really blew my mind. It's unbelievable.

How has the 4D ICE NUVISION catheter's unique design been beneficial in procedures?

Dr. Chehab: *When the right atrium is large, the imaging catheter can get lost in space. For example, with 2D ICE it can take 8 to 10 moves to get to the position you want. This is a lot of movement. As I started to use 4D ICE NUVISION catheter for imaging the tricuspid, I noticed that it took me a third of the time and effort. That is a significant reduction in time for imaging during interventions.*

The beauty of the 4D ICE NUVISION catheter is that the tip allows for 360° rotation and the system includes a knob that allows you to scan the space around the crystal tip. This is a key feature, and I don't think it's available on any other system. It minimizes the sensation of being disoriented in the right atrium so you're consistently confident of where and what you are imaging.

> *"I performed two very challenging cases with edge-to-edge repair for the tricuspid valve. If I was just using TEE, I would have stopped. I added the 4D ICE NUVISION catheter and it took less than an hour to complete both cases, and we had excellent results. It was smooth, streamlined, and we felt confident and relaxed."*

The feature also makes a big difference if there's any shaking or movement after you've already found the ideal spot for imaging. All you have to do is adjust the 360° rotation knob and you're right back in place. No need to go through large movements or feel lost in space.

With other systems, you need to flex or rotate your hand in multiple directions to find the right location. Every time you flex the crystals on the tip, you lose your image and then need to re-orient yourself.

Has stability ever been an issue with the 4D ICE NUVISION catheter in patients with severe or torrential tricuspid regurgitation or when imaging tricuspid valves in patients with large atriums?

Dr. Chehab: *We've had no stability problems with the 4D ICE NUVISION catheter. Although we did have stability issues with 2D ICE. If you're too high with 2D ICE, you lose the image quality and if you're too low, it's not stable and you won't see anything. You are just too close to the valve.*

The NUVISION design is very smart and user-friendly. One of the key features is the ability to manipulate the position of the catheter and it stays in place. It doesn't change and it doesn't move. The device is very stable and it stays exactly where you want it. That's what makes it so much easier for us. There's a noticeable change from 2D to 4D ICE.

How has the 4D ICE NUVISION catheter impacted your overall workflow?

Dr. Chehab: *The catheter design is very user-friendly and allows a single operator to do both the imaging and the tricuspid valve repair or replacement. Before we needed a dedicated operator with 2D ICE and someone to do the actual intervention. Right now, I'm the only operator.*

In our program, there are scheduling issues with imaging, so the 4D ICE NUVISION catheter has helped us a lot. It's adaptable to patient volume but doesn't replace an imaging

sonographer or imaging cardiologist. It adds value. If you have sites with heavy volume and they're comfortable with their imaging cardiologist, then adding a 4D ICE catheter is like gold. It's only going to make them better and improve and excel even more. I love having options — and this is an amazing option.

In addition to easing scheduling issues, how has the high-resolution, real-time catheter made a difference in exam time?

Dr. Chehab: *It used to take hours to complete a case and now we can do it in less than an hour. And that's even with a difficult case. A few weeks ago, I performed two very challenging cases with edge-to-edge repair for the tricuspid valve. If I was just using TEE, I would have stopped. I added the 4D ICE NUVISION catheter and it took less than an hour to complete both cases, and we had excellent results. It was smooth, streamlined, and we felt confident and relaxed.*

> *"There is no way I will do any tricuspid without 4D ICE NUVISION."*

Many structural heart programs are using GA (general anesthesia) for most of their procedures. Do you think 4D ICE could reduce the use of GA in the future?

Dr. Chehab: *In my opinion, one of the reasons why we do general anesthesia with tricuspid is that no one is going to tolerate a TEE probe for 3 to 4 hours while awake. No matter what you do — monitored anesthesia care or light sedation — there's no clinical reason to put someone to sleep if you're repairing or replacing a tricuspid valve. It's an imaging issue and a TEE issue. The second you take away the need for TEE, you take away the need for anesthesia. There's a direct link.*

A few years ago when we were still learning with the 4D ICE NUVISION catheter, we always did TEE and 4D ICE. But as the comfort level and the learning curve changed, we started turning off the TEE probe and doing 4D ICE with the TEE probe as a backup. As you become more confident, you determine that you can do it all with 4D ICE and you don't need to put the patient to sleep. And that's the game changer.

> *"4D ICE NUVISION catheter is a major breakthrough. The accuracy and confidence we have in repairing or replacing a tricuspid valve is equal or on par with replacing an aortic valve with a TAVR or doing a mitral edge-to-edge repair. It has also given us better outcomes."*

You described your progression utilizing the 4D ICE NUVISION catheter. How are you incorporating it into tricuspid valve procedures today?

Dr. Chehab: *There is no way I will do any tricuspid without 4D ICE NUVISION. It's in our protocol right now. Any operator who does not use it in our program is going to get a review from me that says, 'Why are you putting the patient at risk and why are you doing something that is going to take four hours versus one hour?' It's a must.*

How would you describe the value of the 4D ICE NUVISION catheter and the potential impact on tricuspid interventions?

Dr. Chehab: *4D ICE NUVISION catheter is a major breakthrough. The accuracy and confidence we have in repairing or replacing a tricuspid valve is equal or on par with replacing an aortic valve with a TAVR or doing a mitral edge-to-edge repair. It has also given us better outcomes. There's no way to even start to describe where 4D ICE is going to go in the tricuspid space. Alone, the use of the 4D ICE NUVISION catheter has significantly improved the reduction of tricuspid regurgitation. I think this technology is really a game changer and the key to expanding care for more patients. So we don't have to tell patients, 'we can't treat you because we cannot see very well, or you will have to wait for different technologies.' With 4D ICE NUVISION catheter, it's here today, it's ready, and available. There is no reason for anyone to delay the care of any tricuspid patient because of bad or suboptimal imaging. You just have to start using it.*

Ascension Via Christi was also one of the early adopters of the world's first mini 4D TEE probe. Can you describe your experience?

Dr. Chehab: *My first reaction was, 'What in the heck is this? Is this real? It's not going to work and we already have a TEE.' But I was wrong. It makes sense that the mini probe may help to reduce complications for people who have esophageal strictures, but the value goes way beyond that. I didn't understand it until I started using it.*

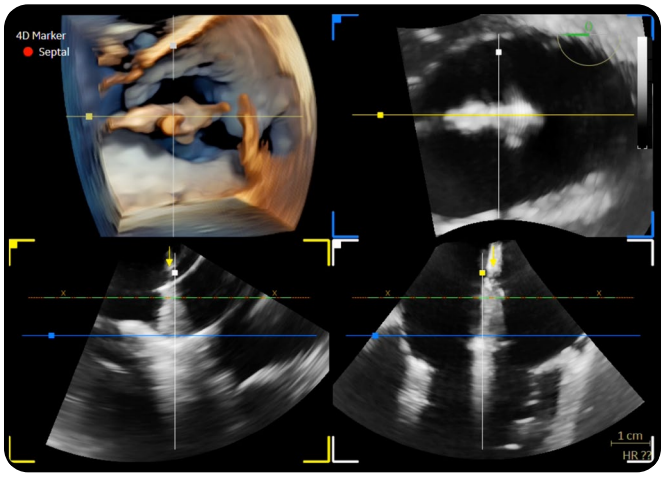
With a mini, the question is: can you compensate and have the same image quality as regular 4D ICE? I thought that there was no way, and I was very wrong. It's only slightly less quality than what we have with the adult 4D TEE from GE HealthCare, but really a negligible change.

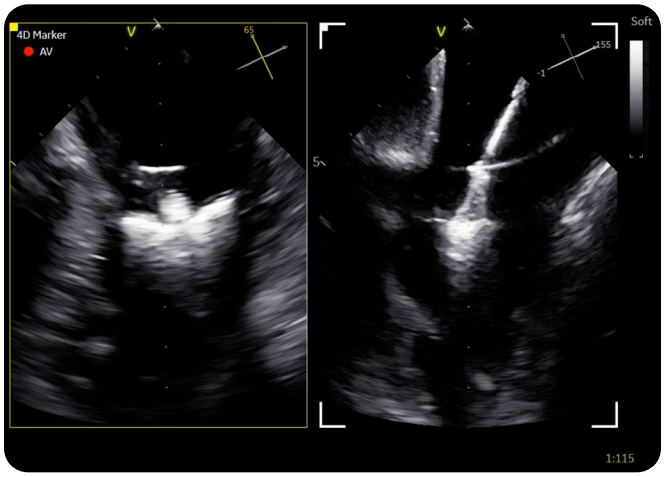
I am comfortable using the mini 4D TEE for a lot of things I do with 4D TEE. It again helped me shift from general anesthesia to conscious sedation. For example, when I'm doing an appendage closure, sometimes I have a challenging transeptal puncture and the patient is awake and I don't want to pass the TEE probe. I will pass the mini probe and the patient tolerates very easily and it takes me two minutes. I'm done with my transeptal puncture, take the probe out, and I finish the rest with the 4D ICE NUVISION catheter. It really allows us in certain challenging cases to mix and match the technology and has complemented our program.

> *"Alone, the use of the 4D ICE NUVISION catheter has significantly improved the reduction of tricuspid regurgitation. I think this technology is really a game changer and the key to expanding care for more patients."*

How can the 4D ICE NUVISION catheter and mini 4D TEE probe be expanded to more structural heart interventions?

Dr. Chehab: *4D ICE NUVISION is essential for tricuspid imaging or you're done. It's definitely a must. For our aortic program, we do a lot of TAVR cases and use conscious sedation. When we started doing TTE and TEE ages ago,*





general anesthesia was used, but now we've gone to conscious sedation.

With transthoracic cases, we're sometimes not sure how much PVL is on the aortic side. And you know these patients are fully heparinized, so the last thing you want to do is use a big TEE probe. While they're awake, I just pass the mini 4D TEE probe and it's atraumatic — it's an easy insertion. Then I can assess the aortic valve with hyper-accuracy to make sure that I'm comfortable, so this is the value of the mini 4D TEE probe.

Today's structural heart programs include aortic valves, TAVR, LAAC, the mitral valve, and now the tricuspid valve. The Vivid ultrasound portfolio includes 4D TTE, 4D TEE, mini 4D TEE and the 4D ICE NUVISION catheter. What are the benefits of these tools?

Dr. Chehab: *The value of the GE HealthCare imaging portfolio is its versatility. It takes away a lot of the thinking and frustration from these structural procedures. The patient is not getting the best outcome without a plethora of options. That includes a cutting-edge 4D TEE integrated with innovative software like you have with GE HealthCare, a mini 4D TEE probe, and 4D ICE NUVISION catheter.*

Whether it be related to the tricuspid, mitral, atrial appendage, aortic, congenital, etc., anything from a structural heart standpoint, I feel confident in my imaging. That's the beauty of having a portfolio in your hand.

> *"There is no reason for anyone to delay the care of any tricuspid patient because of bad or suboptimal imaging. You just have to start using it."*

What surprises you most about GE HealthCare cardiovascular ultrasound and the Vivid portfolio?

Dr. Chehab: *Nothing surprises me anymore because I've been surprised so many times. What surprises me is the dedication GE HealthCare has for structural. That's changed the game and that has put us at a different level. It's very rare for an imaging company to understand the interventional world because historically the culture has been 'we sell you the machine and we're done.' That's how it's been done with many other companies in the past and continues with some today. With GE HealthCare, the Vivid product, and cardiovascular imaging department, they're dedicated to case coverage and have excellent clinical support. I've had cases where GE HealthCare clinical specialists have shared ideas from other programs, so they're very experienced, dedicated, and passionate about what they do.*

I'm not buying a machine. I'm also buying all the clinical experience and the clinical specialists that come with the machine. And I think that's my biggest asset — more than just having 4D ICE or having Vivid software. I'm getting the whole package and getting the whole deal, and that's what I like. ■

Dr. Chehab, MD, FACP, FACC, FSACI is an Associate Professor of Medicine at University of Kansas and Director of the Structural Heart Program at Ascension Via Christi. He specializes in complex coronary and structural cardiology interventions, with a deep focus on clinical trials and new cardiovascular drug and device research. Dr. Chehab is also the author of multiple peer-reviewed journal articles and has received several awards for his research.

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*4D ICE NUVISION catheter is not available in all markets. The 4D ICE NUVISION Catheter is not CE-marked. 4D ICE NUVISION is distributed by Biosense Webster, Inc., part of Johnson & Johnson MedTech.

Dr. Chehab is a paid consultant for GE HealthCare and was compensated for participation in this article. The statements by Dr. Chehab described here are based on his own opinions and on results that were achieved in his unique setting. Since there is no "typical" hospital/clinical setting and many variables exist, i.e. hospital size, case mix, staff expertise, etc. there can be no guarantee that others will achieve the same results.

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