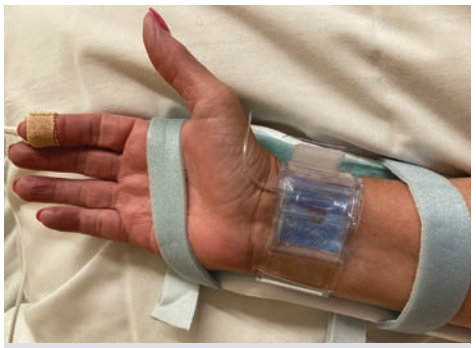
Cath Lab Digest

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



TRANSRADIAL HEMOSTASIS

Comparison of Two Methods for Transradial Hemostasis After Cardiac Catheterization and Impact on Post-Procedure Efficiency

Jane Meitler, MSN, RN, ACNS-BC, CV-BC; Theresa Briggs, MSN, RN, RCIS; Amanda Sedacki MSN, RN, CV-BC; Jeanne Hlebichuk PhD, RN, NE-BC

Transradial access (TRA) for invasive cardiac catheterization procedures has increased over the last decade.[1] According to the National Cardiovascular Data Registry, the practice of TRA for percutaneous coronary intervention procedures increased from 16.1% in 2012 to 53.7% in 2021.[2] Despite this rapid increase in TRA utilization, the United States still lags behind other countries.[3] Research has shown that use of radial access offers earlier mobilization, less risk of kidney injury, decreased mortality, and shortened length of stay as compared to the transfemoral approach.[4]

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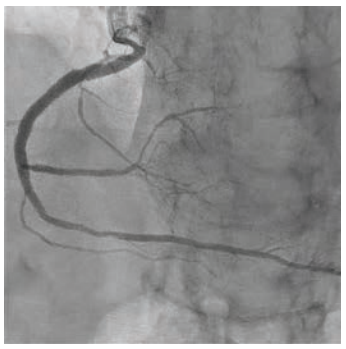
In This Issue

CALCIUM CORNER

An "IVL-First" Strategy Using 120 Pulses With the Next-Gen C²⁺ Shockwave Catheter

CLD talks with Brian K. Jefferson, MD.

What has been your experience with intravascular lithotripsy (IVL) and the Shockwave C²⁺ catheter?



We have used Shockwave IVL since its commercial launch in the United States, so we have a long experience with the use of IVL for calcium modification. The new C²⁺ IVL catheter offers fifty percent more pulses, for a total of 120, and these extra pulses often come in handy. Having 40 extra pulses allows us to treat lesions that in the past might have been too diffuse or too long for single-catheter IVL use, and we also can use the extra pulses in the C²⁺ to treat lesions in more than one vessel. In multiple cases, we have now been able to use a single IVL catheter in two vessels or in lesions where we might have previously used atherectomy due to pulse limitations.

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NEW TECHNOLOGY

Talking to TCT 2023's Shark Tank (Innovation) Competition Winner: HeartPoint Global's IntelliStent is an Adjustable, Multilumen Stent System for Pulmonary Hypertension in Congenital Heart Disease

CLD talks with Elena Amin, MBChB, pediatric interventional cardiologist at the University of California, San Francisco, and a member of HeartPoint Global's Advisory Board, and HeartPoint Global Chairman and CEO Seth Bogner.

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Talking to TCT 2023's Shark Tank (Innovation) Competition Winner: HeartPoint Global's IntelliStent is an Adjustable, Multilumen Stent System for Pulmonary Hypertension in Congenital Heart Disease

The Transcatheter Cardiovascular Therapeutics (TCT) meeting took place October 23-26, 2023, in San Francisco, California. This year's TCT Shark Tank Innovation Competition featured six companies presenting their technologies, chosen from over 50 submissions. TCT partnered with the Jon DeHaan Foundation to provide a $200,000 award to the 2023 competition winner, which was HeartPoint Global's IntelliStent technology, presented by Dr. Elena Amin.

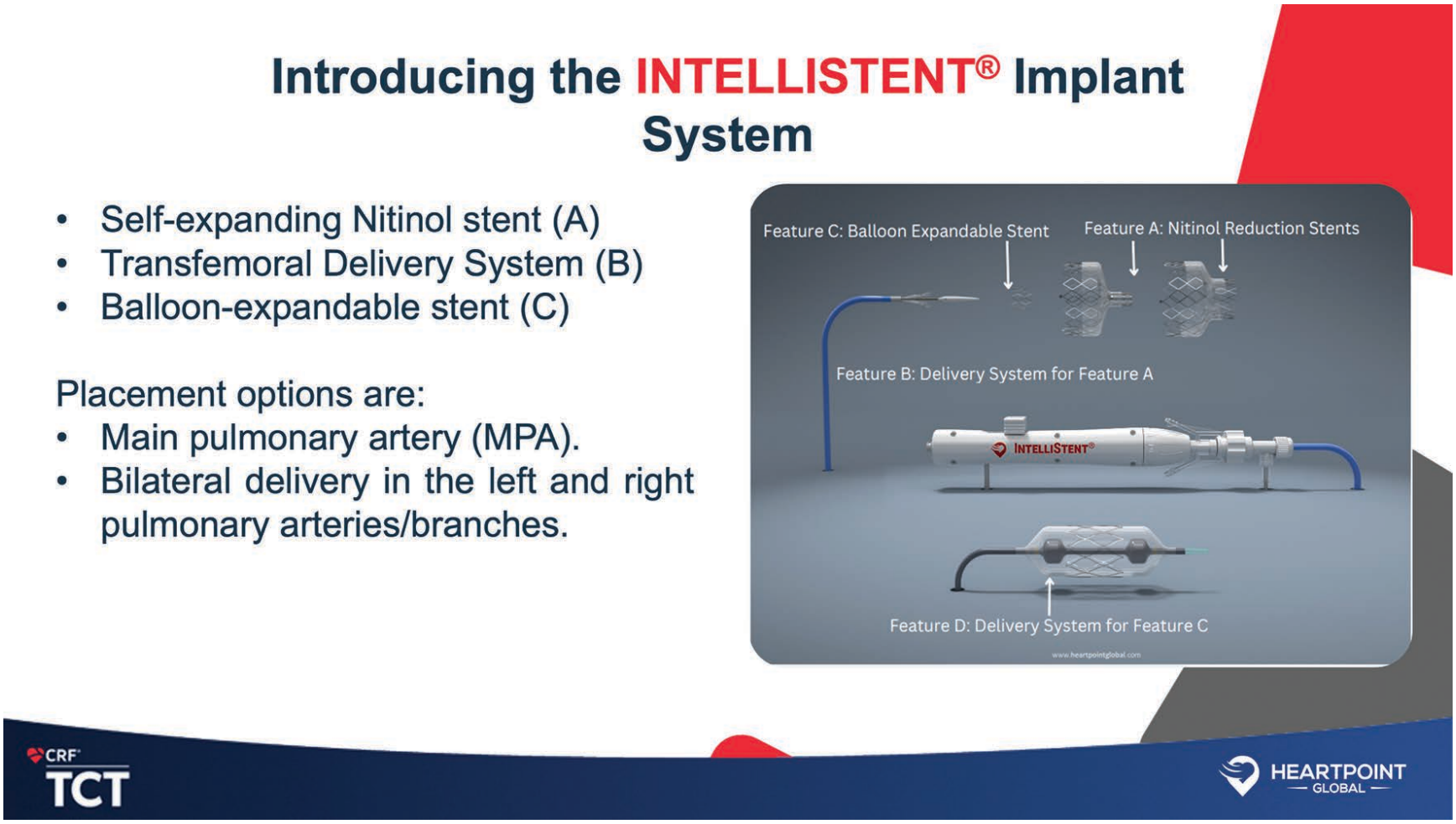
"IntelliStent is a transcatheter method of reducing blood flow in the intravascular space. For us in the congenital cath lab, the most desired innovation is a transcatheter pulmonary artery band that we can place and adjust ourselves, without the risks associated with sending patients for surgery."

— *Elena Amin, MBChB*

CLD talks with Elena Amin, MBChB, pediatric interventional cardiologist at the University of California, San Francisco, and a member of HeartPoint Global's advisory board, and HeartPoint Global Chairman and CEO Seth Bogner.

Can you describe the IntelliStent and provide some background around the clinical need?

Elena Amin, MBChB: IntelliStent is a transcatheter method of reducing blood flow in the intravascular space. For us in the congenital cath lab, the most desired innovation is a transcatheter pulmonary artery band that we can place and adjust ourselves, without the risks associated with sending patients for surgery. Pulmonary artery band surgery is already available for certain indications, but in most of the world, congenital cardiac surgery is limited, so complete repair or pulmonary artery band placement may not be available for a left-to-right shunt, which results from the most common congenital defects. A transcatheter pulmonary artery band could be the only way to save children from developing Eisenmenger syndrome. Essentially, you are protecting their lungs from the excess flow and pressure through unrepaired congenital cardiac defects until they can have surgery or in some cases, the pulmonary artery band may be destination therapy. This would be lifesaving for children and also for many adults who have a congenital heart malformation.



The question of when we could put in a pulmonary artery band all depends on timing. For patients who are at risk of Eisenmenger syndrome, if you can treat them before they progress to the point where the shunt becomes all right to left and their vessels are irreversibly damaged, you can put in a pulmonary artery band at any age, whether children or adults.

Seth Bogner, Chairman and CEO, HeartPoint Global: Ultimately, this procedure requires a paradigm shift. If you think about the existing therapies for things like dilated cardiomyopathy in pediatrics, the existing therapies are some medications that aren't extremely effective. When medications don't work, you might move to a left ventricular assist device (LVAD) and a transplant, which is not available in most of the world. It is actually not a great situation in the U.S., either, considering the limited number of organ transplants in the pediatric age range. Therefore, it makes sense to put a band into the pulmonary arteries, increase the pressure in the right ventricle, and change the morphology of the interventricular septum. The IntelliStent can provide a temporary bridge, improving the functioning of the left ventricle. Infants will often get better with the band or it can work as a bridge to transplant. Placement is a straightforward, low-risk procedure compared to putting in a mechanical heart. The IntelliStent is a simple nesting of stents that could be used anywhere in the vascular system. There are quite a few applications where we need to reduce pressure or flow in a vessel. The next question is, can this experience be translated for adults? There is certainly interest in that as well. Another important aspect to point out is that an LVAD in the United States costs a million dollars a year for one patient. The IntelliStent, by an order of magnitude, is much less expensive, and rather than cost being per year, the cost is around an intervention.

"We are thrilled to name HeartPoint Global as this year's TCT Shark Tank Innovation Competition winner. Their IntelliStent device has the potential to transform the course of treatment for pediatric patients suffering with congenital heart disease (CHD). CHD affects over 20% of newborns globally, including 2.4 million in the United States alone. Millions more are undiagnosed globally."

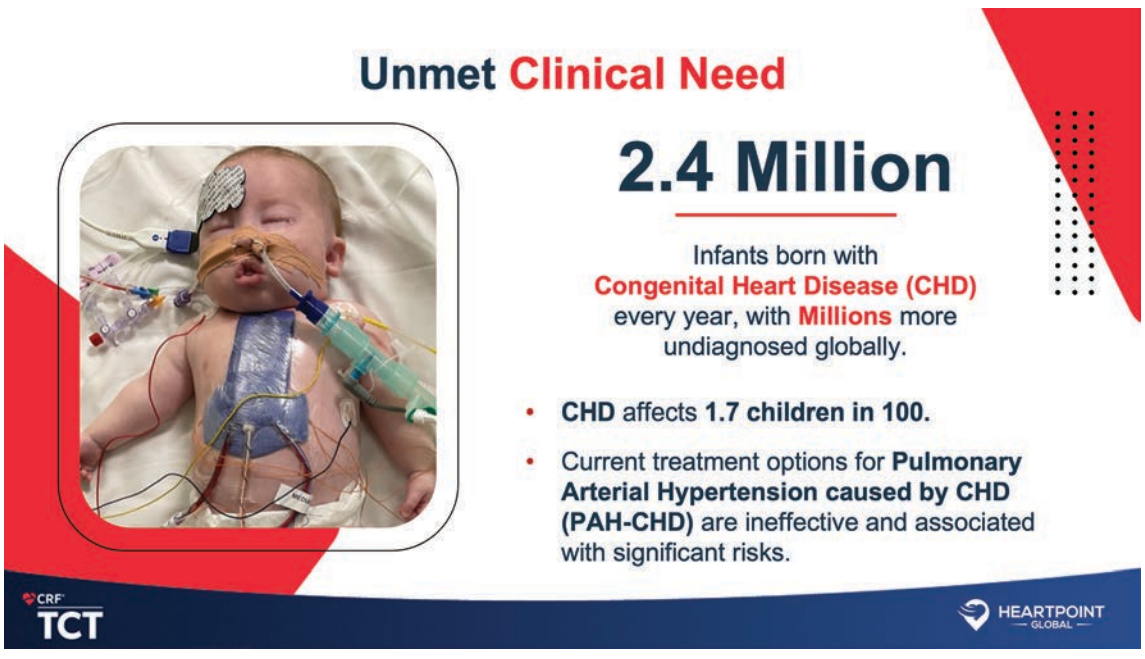
— Juan F. Granada, MD, President and Chief Executive Officer of CRF, the sponsor of TCT

HeartPoint Global is working with a number of people across the world.

Seth: Yes. In the developing world, when people have left ventricular dilated cardiomyopathy, they are just sent home, which is incredibly sad. This is not just in low-income countries, but in middle-income countries as well. The statistics are overwhelming: 75% of people and 90% of children worldwide do not have access to quality cardiac care. We are working with various organizations, including the Eurasia Heart Foundation. Their founder and President, Dr. Paul Vogt, is on our HeartPoint Global Board. We hope to have a significant impact. Yet, it is also a large problem in the United States because there are so many undiagnosed cases, and right now, our main focus is on working with the U.S. FDA.

What other advantages does IntelliStent offer compared to pulmonary artery band surgery?

Dr. Amin: Surgery requires general anesthesia, ie, deep sedation. For patients with any degree of pulmonary hypertension or complex congenital heart disease, that in itself is dangerous, because these patients can code on induction of anesthesia. One huge benefit is that you can do a transcatheter procedure with only moderate sedation. Second, during a pulmonary band surgery when you are changing flow and pressure in a vascular space, if the patient is under deep sedation, it is difficult to assess the impact of that change. If the patient is under moderate sedation, you can more accurately mimic the conditions to when the patient is awake, meaning you can tell if the lower pressure restriction is going to be useful for the patient. A transcatheter approach can also be done quickly at a lot less cost — and a big thing is that it can be done at a lot less risk. There is a very minimal risk of bleeding or infection, and recovery can be on a regular unit rather than an intensive care unit.



Seth: The beauty of the IntelliStent system is that you can adjust the flow and pressure anytime, even at the initial intervention, and a day later, a month later, or a year later, as the conditions change in the patient. The patient needs a functional right ventricle, so if we see too much pressure in the right ventricle, we could come back later and do the adjustment again. The IntelliStent is adjustable, either up or down. As the patient grows, we can expand the system with a balloon catheter. It allows us to account for changing conditions in the patient at any time.

What does follow-up look like for these patients?

Dr. Amin: Surgically, when bands are placed, it is often not the right type of restriction, meaning there is either too much restriction or a very loose band, or if the patient has bilateral bands with one on each pulmonary artery, there could be discrepant flow, which is less than ideal. With the IntelliStent, you can do imaging studies when the patient is awake, or just see how they are

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— Elena Amin, MBChB

Elena Amin, MBChB
Pediatric Interventional Cardiologist, University of California, San Francisco, California; Member, HeartPoint Global Advisory Board

Seth Bogner
Chairman and CEO, HeartPoint Global

feeling and if their walk test is better. If there is not an accurate restriction of flow, you can then take the patient back to the cath lab and make the band more restrictive. There is an acute follow-up post device placement, and then less frequent long-term follow-up. Some-times patients have the IntelliStent as a bridge to surgery. Sometimes patients get better, and then we bring them back to reverse the band altogether. In terms of follow-up, once a self-expanding stent is delivered into the pulmonary arteries and in place, it doesn’t need to be checked frequently, which is positive in terms of resource allocation. Patients can generally be followed clinically without returning to the cath lab.

Can you tell us about the preclinical study results and your plans for an upcoming clinical trial in the United States?

Seth: We had four rounds of preclinical studies, all done in Israel and all very successful. There were no sign of thrombosis or clotting. The results were fantastic. What we learned is that the effect that we are looking for happens at a much lower rate of pressure reduction than previously thought. This is much safer for the patient as well. In surgical banding, they tie a band around the pulmonary artery, and then loosen it to where they think is correct. What the IntelliStent does is counterintuitive to that, instead slowly increasing the flow reduction, which is much safer for the patient. Then we wait to see what level we think it is at, and can go back and correct it if we are wrong, without surgery. An interventionalist could have a rather simple intervention where they put in another stent to increase the reduction. For our clinical trials, at present, we are planning and in negotiations with several sites to first evaluate safety. Before we investigate its use in small children, we will evaluate the use of the IntelliStent in adolescents and small adults. It has been very well received in the interventional cardiology community.

Dr. Amin, you noted that it is better to evaluate patients when they are under moderate sedation versus general sedation for surgery. Can you describe how you evaluate the flow restriction from IntelliStent during the procedure?

Dr. Amin: During the procedure, it is easy for us to directly measure pressure. We can place a catheter or wire through the stent itself, and measure distal and proximal pressures. You can also measure pressure in the right ventricle below the entire stent system. You can get a fairly accurate estimate of what the pressure is going to be when the patient is awake. We know it will be a few millimeters of mercury higher when the patient is awake. More importantly, we can measure the cardiac index and pulmonary-systemic flow ratio, or Qp/Qs. We can see what the banding does to the physiology of the heart.

What have you experienced regarding ease of use of the IntelliStent?

Dr. Amin: A self-expanding stent system without the flow restrictor is something that interventional cardiologists are used to handling. The delivery, handle, control delivery system, and release mechanism are all things that people are familiar with already. Regarding the covered portion of the stent, again, we are familiar with using this in pulmonary arteries and other structures. All of the concepts are familiar, making it very easy to give to any interventionalist and say they can successfully do this procedure. What is new is the concept of reducing flow in the intravascular space.

Can you talk about your Shark Tank presentation and experience at TCT?

Dr. Amin: It was quite a whirlwind. I absolutely believe in the technology and promise of the IntelliStent. I was very honored to present, share the stories of patients who could benefit from this type of transcatheter innovation, and explain how the device works. I was very proud to represent a technology that has the potential to help a lot of people worldwide.

Seth: We are so grateful to the Cardiovascular Research Foundation and Jon DeHaan Foundation for recognizing the work that we are doing and sharing our interest in bringing this simple, elegant, cutting-edge technology to a pediatric population where there is clearly an unmet need, as well as several additional indications. We are very optimistic about the future and grateful for the interest that many people and organizations have shown. Now, in the pediatric cardiology community, having heard about this device, there is a lot of excitement and questions about when it will be ready for patients. ■

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— Seth Bogner, HeartPoint Global Chairman and CEO