CONGENITAL CARDIOLOGY TODAY
Timely News & Information for Congenital/Structural Cardiologists & Cardiothoracic Surgeons Worldwide
North American Edition
Vol. 24 - Issue 12
December 2020

Table of Contents

Extreme Distortion of the Aorta: A Relative Contraindication for Transcathether Valve Implantation

Nasser J. Moiduddin, MD, FACC, FSCAI; Thomas Forbes, MD, FACC, FSCAI; William Suarez, MD, FACC ; Yousuf Muhammed-Nasser

Introduction

We present a rare complex adult congenital case of extreme distortion of the aortic valve with balloon coronary compression testing in a pulmonary homograft. We believe that this is a relative contraindication for transcatheter valve implantation despite normal coronary flow and no aortic insufficiency. A few studies have described aortic distortion with aortic insufficiency in patients having transannular patch. This patient developed severe aortic valve distortion without aortic insufficiency during homograft dilation due, in part, to the presence of a residual aortic pseudoaneurysm.

Clinical Case

The patient was a 26-year-old male with a history of Truncus Arteriosus Type I. He was status post complete repair with a ventricular septal defect patch, 12 mm pulmonary homograft in the pulmonary position, and ascending aortic arch patch repair. As expected, he underwent multiple revisions and surgeries. First, his 12 mm RV-PA pulmonary homograft was upsized to a 20 mm aortic homograft. Several years later, he developed Sick Sinus Syndrome, requiring an epicardial pacemaker that was later changed to a transvenous system. Ten years later, his truncal valve was replaced with a 27 mm freestyle prosthesis, and his RV-to-PA aortic homograft was exchanged for a 23 mm Contegra conduit. He developed increased right ventricular outflow tract gradients warranting consideration of a pulmonary valve implantation. In preparation for a potential transcatheter valve, he was noted to have a significant truncal root pseudoaneurysm, and subsequently was found to have subacute infective endocarditis with streptococcus mutans. He underwent pseudoaneurysm repair. The Contegra conduit was replaced with a 24 mm pulmonary homograft with a hemashield extension and he had removal of his pacing leads and generator. Over the years, he seemed to do well without the need for pacing. After endocarditis was ruled out, he was referred for another pulmonary valve implantation with increasing right ventricular outflow tract gradients. He developed increased right ventricular outflow tract gradients and he was referred for another pulmonary valve implantation. Given his multiple surgeries, the transcatheter approach was preferred.

Clinically he was asymptomatic, but sedentary. He was afebrile and his cardiac exam revealed an RV lift with palpable thrill. He had a harsh 4/6 systolic ejection murmur at the left sternal border. His diastole was quiet. There was mild cardiomegaly without infiltrates on a recent chest x-ray.

DECEMBER 2020

North American Edition Vol. 18 - Issue 12

TABLE OF CONTENTS

Echocardiography revealed moderate to severe pulmonary artery conduit stenosis proximally at a peak 55 mm Hg gradient. His calculated RV systolic pressure was 70 to 75 mm Hg. His ascending aorta was severely dilated with a suspected aneurysm on the antero-lateral side of the neoaortic (truncal valve). Biventricular systolic function was normal.

Palliative balloon angioplasty as a bridge to valve implantation showed no waist on the balloon, but significant recoil. Hemodynamic evaluation confirmed a PSEG of 55 mm Hg gradient and 2/3 systemic right ventricular pressures. There was no intracardiac shunt. His RV end diastolic pressure was about 10 mmhg and his left ventricular end diastolic pressure was about 12 mmhg. Angiography showed significant narrowing to 10 to 11 mm that extended almost 3 cm from subvalvar area to the main pulmonary artery, **Figure 1**. In preparation for transcatheter valve implantation, pre-stenting coronary compression RVOT balloon testing with a 22 x 4 cm Atlas Gold balloon and a minimal residual waist at 20 mm showed significant severe distortion of the aorta and valve annulus, **Figure 2. Video 1** shows an MPA injection, compression testing at multiple angles, and coronary flow evaluation, along with intracardiac echocardiography, exemplifying our hesitancy to proceed. The decision to pre-stent and subsequent placement of transcatheter valve was abandoned in favor of repeat surgical conduit and aortic pseudoaneurysm revision.

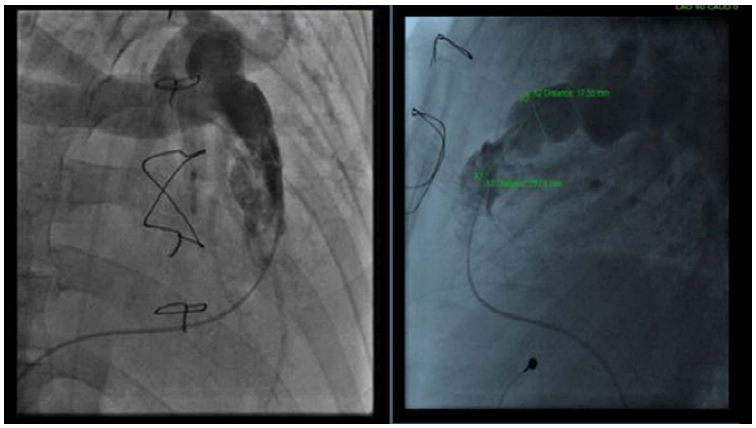


FIGURE 1 *AP: Shallow RAO view, Lat: Straight. There is a calcified 24 mm pulmonary homograft that is stenotic down to 11 mm. The area of narrowing extends approximately 3 cm from the subvalvar area to the main pulmonary artery. There are confluent pulmonary artery branches.*

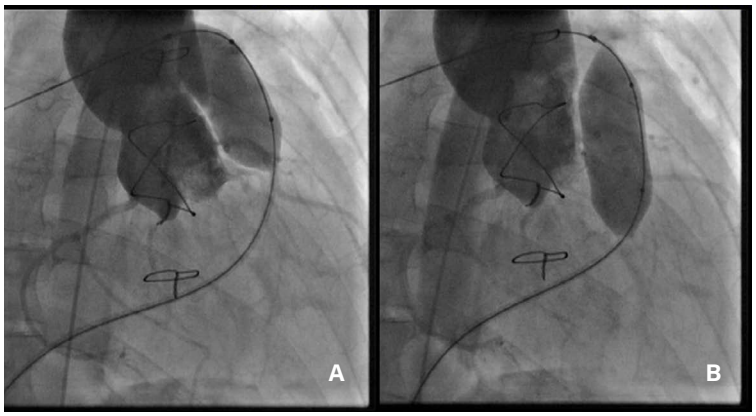
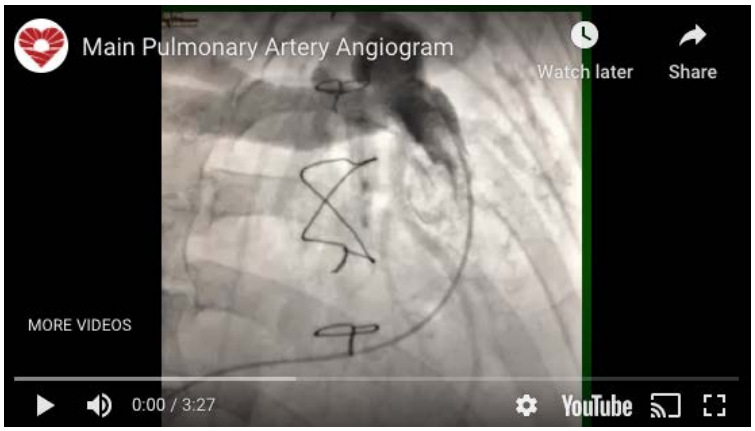


FIGURE 2 *Anterior Posterior, Shallow RAO: Aortagram with simultaneous RVOT balloon coronary compression testing with an Atlas Gold 22 x 4 cm slightly distally (**A**), and slightly proximal (**B**). The aortic cusp is completely distorted with the balloon proximal. Coronaries are not compromised also shown in **Video 1.** Pacing was not needed.*



VIDEO 1 *Initially there is a main pulmonary artery angiogram, followed by RVOT measurements, then an aortagram with simultaneous balloon compression testing in shallow RAO, straight lateral, and down the barrel views. Coronary flow is not compromised and there is no aortic insufficiency. Intracardiac echocardiography shows complete cusp deformation.* **Video: congenitalcardiologytoday.com/ed-resources/**

Discussion

This case is an example of extreme distortion of the aorta without severe aortic insufficiency and normal coronary flow. The question for us was whether this finding was a relative contraindication for either RVOT stenting or transcatheter valve implantation.

Torres et al,[1] in a retrospective case series, described characteristics of aortic distortion and outcomes during coronary compression testing with simultaneous RVOT ballooning. Six out of 18 patients were noted to have some sort of distortion and/or aortic insufficiency. Severe aortic root compression was defined as collapse of the entire aortic cusp and mild aortic root compression as being partial cusp distortion in any angiographic projection. Mild aortic distortion was not considered significant or a contraindication for pulmonary valve implant. Moreover, aortic insufficiency without aortic root compression was also not considered a significant contraindication. In postoperative echocardiograms, the mild distortion of the aortic cusp seemed to resolve after implantation. The authors argued it is possibly very common and may be, in part, related to altered unusual physiologic state during compression testing such as decreased LV preload, pacing with reduced cardiac output, or potentially balloon profile with long shoulders. In their case series, there were two patients, though, that were considered severe with aortic insufficiency that did not get the valve. They also identified patients with a LeCompte, Ross, or direct anterior posterior relationship of the aorta to be more at risk for such distortion.

A HIGH STANDARD FOR DURABILITY **PROVEN BY A DECADE OF DATA**

Melody TPV was the first transcatheter valve implanted in a human anywhere in the world and is the longest-studied transcatheter valve with the largest body of clinical evidence.

That unparalleled body of clinical evidence has recently expanded, with positive 10-year durability, safety, and efficacy data from the U.S. Investigational Device Exemption (IDE) Trial.

Melody™
Transcatheter Pulmonary Valve (TPV) Therapy

Melody™ Transcatheter Pulmonary Valve | Ensemble™ II Transcatheter Valve Delivery System

Important Labeling Information for the United States

Indications: The Melody TPV is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has ≥ moderate regurgitation, and/or a mean RVOT gradient ≥ 35 mm Hg. **Contraindications:** None known. **Warnings/Precautions/Side Effects:** DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations. DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins. DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances. Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV. To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV. The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV. If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice. Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site. Potential device-related adverse events that may occur following device implantation include the following: stent fracture,* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT, it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on manuals.medtronic.com. **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

UC202104730 EN 07/2020

Medtronic
Further, Together

Peer et al[2] described an 11-year-old with a Ross-Konno who underwent a transcatheter valve and with severe compression of the neo aortic root laterally to the homograft associated with progressive worsening aortic insufficiency, an erosion leading to an aorta pulmonary fistula, and cardiac arrest requiring ECMO before an emergent repair. Lindsay et al[3] described aortic root compression cases in about 16 patients, 14 of whom were tetralogy of Fallot with transannular patch operations. Some of those patients did have coronary compression. Two patients underwent successful transcatheter valve implant distally, despite aortic root compression. One patient, however, required explant of an Edwards-Sapien valve for a surgical valve implant after severe aortic root compression. The authors mentioned it was difficult to know how to accurately predict it, the clinical significance, and how to best avoid it. Pockett et al[4] described the use of three-dimensional rotational angiography as another way of visualizing both aortic root compression and coronary compression.

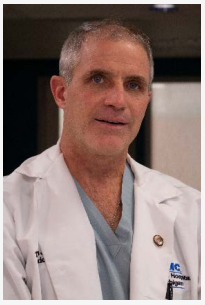
In our case, the aorta and pulmonary artery relationship was seen as slightly more favorable. The aorta and pulmonary conduit are side-by-side without a LeCompte. On the other hand, the aorta was dilated with a history of a pseudoaneurysm, potentially in retrospect, a red flag for aortic root compression. The absence of significant aortic insufficiency and coronary compression may be argued by some as not qualifying this patient to have severe aortic root compression. One argument is that if there is aortic root compression without insufficiency, would you remove the valve? However, it was very difficult to turn a blind eye to intracardiac echo and angiographic images. We also could not rule out an erosion/fistula in the future. We believe this was the correct decision to avoid a complication, despite sending him for an open chest procedure.

References

1. Torres AJ, McElhinney DB, Anderson BR, et al. Aortic Root Distortion and Aortic Insufficiency During Balloon Angioplasty of the Right Ventricular Outflow Tract Prior to Transcatheter Pulmonary Valve Replacement. J Interv Cardiol. 2016;29(2):197-207. doi:10.1111/joic.12270.
2. Peer SM, Sinha P. Percutaneous pulmonary valve implantation after Ross-Konno aortoventriculoplasty: a cautionary word. J Thorac Cardiovasc Surg. 2014;147(6):e74-e75. doi:10.1016/j.jtcvs.2014.02.032.
3. Lindsay I, Aboulhosn J, Salem M, Levi D. Aortic root compression during transcatheter pulmonary valve replacement. Catheter Cardiovasc Interv. 2016;88(5):814-821. doi:10.1002/ccd.26547.
4. Pockett CR, Moore JW, El-Said HG. Three dimensional rotational angiography for assessment of coronary arteries during melody valve implantation: introducing a technique that may improve outcomes. Neth Heart J. 2017;25(2):82-90. doi:10.1007/s12471-016-0931-6.

NASSER J. MOIDUDDIN, MD, FACC, FSCAI

Pediatric & Adult Congenital Interventionalist
Children's Hospital of Michigan (Adjunct)
Bon Secours Mercy Health
Detroit, MI, USA
419.205.6249
nmoidudd@dmc.org



THOMAS J. FORBES, MD, FACC, FSCAI

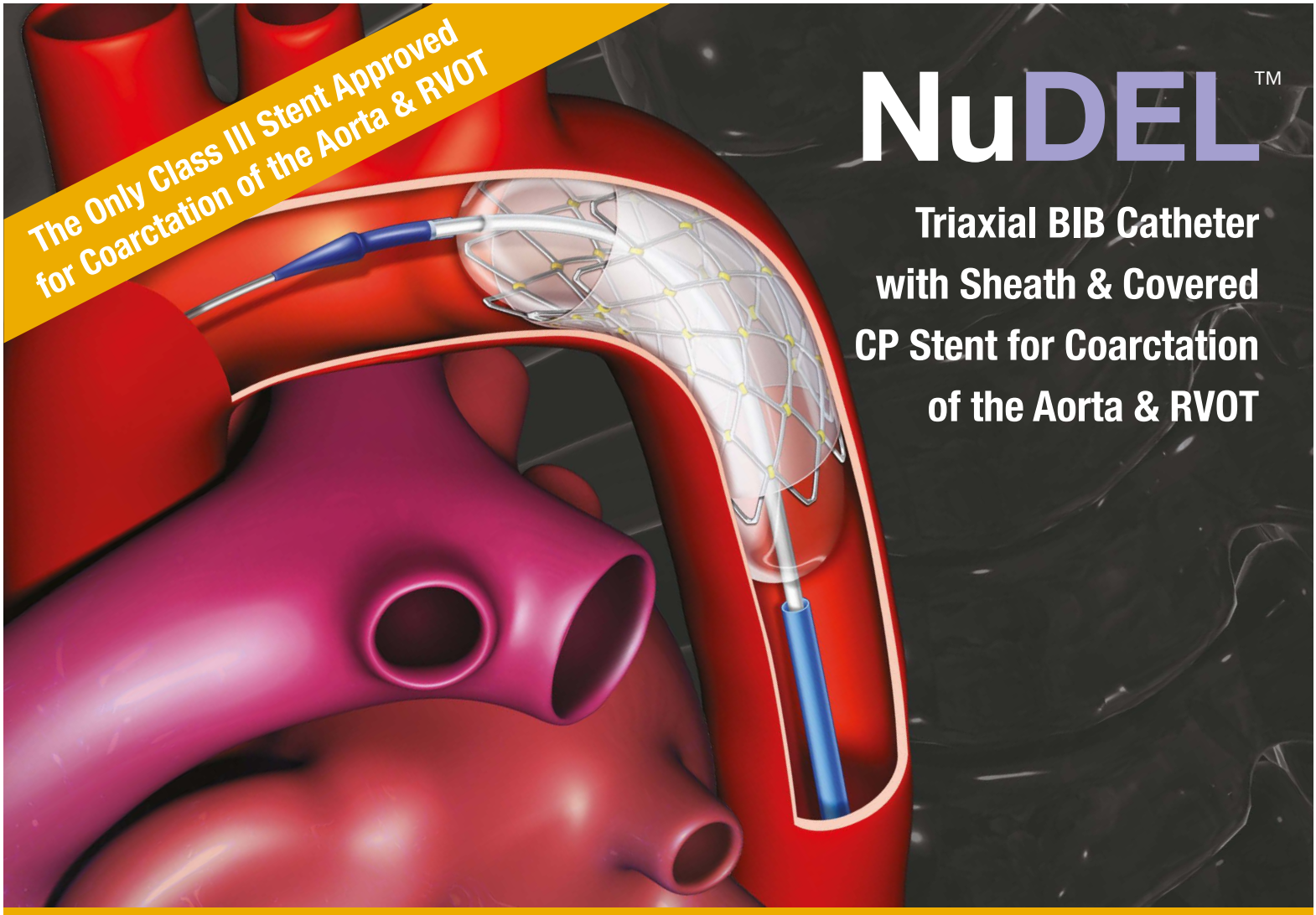
Catheterization Laboratory Director
Children's Hospital of Michigan
Wayne State University
Detroit, MI, USA

WILLIAM SUAREZ, MD, FACC

Chief of Pediatric Cardiology
Pediatric and Adult Congenital Interventionalist
University of Toledo Medical Center
Toledo, OH, USA

YOUSUF MUHAMMED-NASSER

Video & Graphics
Ottawa Hills, OH, USA



NuDEL™

Triaxial BIB Catheter with Sheath & Covered CP Stent for Coarctation of the Aorta & RVOT

The All-In-One Stent System

The NuDEL™ Stent Delivery System is designed for the efficient and effective treatment of Coarctation of the Aorta and RVOT Conduit Disruption.

The NuDEL™ includes a triaxial balloon in balloon designed catheter with a pre-mounted Covered CP Stent™, which is then covered by a sheath as an all-in-one system. Combining the proven technologies of the NuMED BIB® balloon catheter and the Covered CP Stent™, the NuDEL™ System employs both a compact delivery method and the "zig" pattern stent design.

The NuDEL™ System is available worldwide. Contact us or your local distributor to place an order.

NuMED
For Children
World Leader in Pediatric Cardiology

This device is subject to individual country regulations regarding the importation and sale of this product.

NuMED | 2880 Main Street | Hopkinton, NY 12965 USA
Tel: 315.328.4491 | Fax: 315.328.4941 | www.numedforchildren.com

CE 1639

University Hospitals Rainbow Babies & Children's

Nationwide Children's Hospital
When your child needs a hospital, everything matters.℠

The Congenital Heart Collaborative
University Hospitals Rainbow Babies & Children's
Nationwide Children's Hospital

Medical Director, Adult Congenital Heart Disease
University Hospitals Rainbow Babies & Children's Hospital

On behalf of Dr. Marlene Miller, Pediatrician-in-Chief for University Hospitals and Chair of the Department of Pediatrics at University Hospitals Rainbow Babies & Children's Hospital (UH/RBC), CareerPhysician, LLC, a leader in academic pediatric leadership recruitment, has initiated a **national search to identify a leader to serve in the role as Medical Director, Adult Congenital Heart Disease.**

The Director will have the responsibility to advance the regional and national reputation of the ACHD program and embrace a vision that encompasses the mission values of *UH/RBC: To Heal, To Teach, To Discover.*

Opportunity Highlights

- Currently, the Division of Pediatric Cardiology and the UH/RBC Heart Center has 21 faculty members (13 cardiologists which includes three board certified ACHD providers, three anesthesiologists, four cardiac intensivists, and one congenital heart surgeon), nurses and nurse practitioners, and fellowship trainees dedicated to serve the patients of Northeast Ohio.
- Services provided include comprehensive surgical program for children and adults with congenital heart disease, state-of-the-art interventional and EP therapeutics, an adult congenital heart team, dedicated cardiac imaging, cardiac anesthesia, and cardiac intensive care.
- The Heart Center has a dedicated cardiac step-down unit, a new hybrid catheterization and surgical suite within a long-established children's hospital along with a network of community and regionally based outpatient services.
- The **UH/RBC Heart Center is an internationally recognized program partner with the Nationwide Children's Hospital Heart Center in Columbus, OH collectively forming The Congenital Heart Collaborative (TCHC).** This partnership joins resources in providing the most comprehensive highest quality care on both campuses. TCHC is a dedicated service line with a common executive administration and functions as one program on two campuses with the commitment to expand access to high-quality comprehensive cardiac care regardless of patient age to the communities we serve while equally embracing a scholarly and educational mission. TCHC provides excellent cardiothoracic surgical, cardiac interventional, electrophysiologic, and non-invasive services. An example of the success of our partnership is our fetal cardiac interventional service comprised of members from both campuses and based at UH/RBC.
- Recognized as the top ranked children's hospital in northern Ohio, UH/RBC is a 244-bed, Level 1 Pediatric Trauma Center and principal referral center for Ohio and the region.
- Academic affiliation with Case Western Reserve University School of Medicine.

For more details about this opportunity, or if you would like to recommend an individual(s) who exemplifies the qualities we are seeking in a candidate, please contact Marcel Barbey at **marcel@careerphysican.com**, or at 817.707.9034. All interactions will remain confidential and no inquiries will be made without the consent of the applicant. ***UH/RBC is an AA/EOE/ADA employer committed to excellence through diversity.***

Collaboration, Innovation at the Heart of Phoenix Children's Heart Center

John P. Breinholt, III, MD

Interventional cardiology began largely as a diagnostic modality. Initially, our purview was to determine why children were born blue. Today, medical advances like cardiac ultrasound, color-flow Doppler and magnetic resonance imaging have made diagnostic cardiac catheterization less necessary in pediatrics. Instead, interventional cardiology has become an important treatment modality in its own right.

Evolution Of Interventional Cardiology

Today, our primary role as interventionalists is to use catheterization techniques to correct a wide range of congenital heart defects such as: Atrial Septal Defect, Patent Ductus Arteriosus, Coarctation of the Aorta, Semilunar Valve Disease and numerous others.

Many of these defects were once managed in surgery, but using a catheterization procedure, wherever possible, may drastically improve care. Surgery requires making a large incision in the chest, along with the associated risks of bleeding, infection and the inflammatory response to cardiopulmonary bypass. With catheterization, the procedure is minimally invasive and usually ends with a small bandage. Likewise, while surgery may require a lengthy hospital stay, cardiac cath offers a much quicker recovery and minimal time in the hospital.

A Team Approach

With every patient case, physicians with expertise in Fetal, Pediatric and Adult Congenital Heart Disease, along with specialists from the cardiac surgery and cardiovascular intensive care unit teams, come together to create a care plan. This is important because no two patients – and no two care plans – are ever the same. Our Heart Center Team, with expertise in every facet of cardiac care, can treat all types of conditions, from routine issues to life-threatening disease.

Beyond the aspects of planning care, this team model gives patient families a long-term perspective on their child's health and a glimpse at life beyond the immediate shock of a CHD diagnosis. It also means that heart patients grow up with their clinicians.

Clinical collaboration is just one part of our team approach. An empowered team, open communication, and a commitment to accountability and transparency top our list of priorities. Every single one of us – from schedulers and administrators to nurse practitioners and doctors – is an important part of the care team.

This approach, simple as it may seem, has made a huge difference for many patients and families over the years. Although most pediatric heart centers have access to the exact same technology and tools, a collaborative, non-siloed approach truly sets the best programs apart.

Hybrid Heart Care

A key aspect of our team approach is the opportunity for interventionalists and surgeons to partner on care. This comes to life in a variety of ways.

In some cases, interventionalists and surgeons work side-by-side in procedures, utilizing skills and equipment from their respective fields. Our surgeons regularly implant transcatheter valves that the interventional cardiologist help deploy/dilate. We can then later dilate that valved stent as the child grows. During other surgeries where the patient has an existing stent, the surgeon will create a direct approach to dilating that stent in the operating room. In other cases, a Ventricular Septal Defect, a condition that each could address with some challenge, is approached collaboratively, where a transcatheter device is deployed directly across the right ventricular free wall during surgery. These types of hybrid procedures are common in our institution, creating a team atmosphere in either the catheterization lab or the operative suite.

At other times, we employ a tag-team approach to deliver the best outcome for the patient. Atrial Septal Defects are commonly closed in the catheterization lab, although some require operative closure. We try to anticipate the latter, while still providing the opportunity to attempt transcatheter closure in appropriate situations. We schedule the patients for consultation with both groups and have a surgeon ready to take the patient to surgery the same day, if device closure is unsuccessful.

We have taken this approach to another defect: the perimembranous Ventricular Septal Defect. By and large, catheterization does not work well with these defects due to the proximity to the aortic valve and conduction tissue. However, for some defects, catheterization is a viable option, and has been increasingly performed around the world. We attempt to close the defect in the catheterization lab with the understanding that this approach may not be successful. In such cases, the infant will go to surgery under the same anesthesia.

Ultimately, we fix the problem, but attempt to do so with a less-invasive approach. Indeed, the opportunity to collaborate with our surgical team and explore different avenues makes a tremendous difference in patient care and outcomes.

Evolving Treatments For Smaller Children

Catheterization has become the preferred treatment for many heart defects, which include Patent Ductus Arteriosus. Indeed, interventionalists began routine closure of PDAs in children in the 1990s, but our field has taken a giant step forward in recent years: we now use catheterization on premature infants as small as one pound.

While everyone is born with a PDA, the vessel usually closes within the first few hours or days of life and becomes ligament tissue. Even in older children for whom it does not close, it seldom will become life-threatening. Repair for such a child, which involves inserting an embolization coil or other device through catheters and into the PDA, often offers long-term benefits more than acute ones.

However, the PDA in premature infants is a different story entirely. The blood vessel does not close in up to 50% of preemies, which may compromise perfusion of abdominal organs, or further injure lungs damaged from prematurity. For these babies, a PDA can be dangerous at best, and life-threatening at worst.

High-risk PDAs in preemies are typically handled with surgery. Surgeons make an incision on the left side of the chest and close the ductus by tying it with suture or ligating it with a small metal clip. The surgeon must also collapse the lung to reach the site. In such cases – and with such tiny babies – the cure can come with some risk.

Over the past few years – and with the advent of new devices and modification of catheterization techniques – we have started closing PDAs in the very smallest babies.

PDA Treatment Protocol in Preemies

The traditional approach to closing the PDA in children involves the femoral artery, and sometimes the vein, but this is dangerous for premature babies whose arteries are tiny and sensitive. To move forward without risking vascular compromise, we had to rethink the procedure altogether.

Instead of the femoral artery, we access the femoral vein with a 4f sheath. The PDA is crossed with a small caliber wire and a catheter is advanced over it to the ductal ampulla. An angiogram is performed at this location to delineate the PDA. The device is then delivered, often via the same catheter. Sometimes there is no wire or sheath exchange, and the catheter only crosses the valves once. To replace the final aortic angiogram, we use transthoracic echocardiography to visualize the aortic arch and pulmonary arteries to assure no obstruction is present.

To ensure the best outcomes, we use ultrasound guidance throughout the procedure. Considering premature infants' extreme sensitivity to temperature, we also use heat lamps, table warmers, and warm all flush solutions. To minimize any delays that may add risk, we intubate the baby in the NICU, if necessary, before proceeding.

Using an interventional, non-surgical procedure to close the PDA, babies come out of the procedure with just a band-aid on their leg. The procedure is far less risky and invasive, and outcomes are excellent.

Collaborating with Neonatologists

No matter how great the interventional option for preemies with PDA, Cardiology is not the service directing care for these babies. Instead, treatment is at the discretion of their neonatologist, often at an adult hospital where the baby was born. This presents several challenges.

First, catheterization must be performed in our cath lab. This means transporting the baby to Phoenix Children's Hospital and back again – with the risks this entails. On the other hand, if the neonatologist opts for surgery, a surgeon can perform the operation at the hospital where the baby was born. This is certainly an easier path.

Moreover, there is no accepted standard of care for PDAs in premature infants. Neonatologists have employed many different methods to treat them, from observation, to medications, to surgery. Despite shortcomings and side effects of medical management and heightened risks of morbidity and mortality with surgery, there are few studies demonstrating the efficacy or safety of transcatheter closure.

Indeed, while it is the primary choice for treating PDA in babies over eight pounds, it is only now being done for preemies – and in large numbers only at a few children's hospitals nationwide. As such, interventionalists will need to educate referring neonatologists on the benefits of this approach – and particularly its improved safety profile.

Building Partnerships to Bridge Patient Care

In my practice, I have made it a point to develop collaborative relationships with neonatologists. While I freely advise them on the benefits of catheterization in preemies with a PDA, I take special care not to usurp clinical decision-making. We develop the clinical protocol together.

I also started "big." I first suggest this approach with larger preterm babies – not micro-preemies. This becomes a bridge for building trust while demonstrating the efficacy of transcatheter closure in small infants. I have learned that once this trust is brokered, neonatologists are apt to refer even the smallest infants.

It is a point of pride for me that interventional strategies often take center stage for correcting congenital defects. With continued advancements in the field, we are truly creating new hope and healing for patients, from the tiniest premature babies to adults who have long suffered from CHD.

JOHN P. BREINHOLT, III, MD

Division Chief of Pediatric Cardiology
Director of the Cardiac Cath Lab
Phoenix Children's Heart Center
jbreinholt@phoenixchildrens.com

Offering Hope to Families of Infants with Congenital Differences

BEST CHILDREN'S HOSPITALS U.S.News & WORLD REPORT RANKED IN 5 SPECIALTIES 2020-21

Nicklaus Children's Hospital's Fetal Care Center is dedicated to families expecting an infant who will need medical attention immediately after birth. The program offers comprehensive, coordinated care from prenatal diagnosis to delivery, postnatal care and the transition to infant care.

Nurse navigators are available to optimize care access and serve as points of contact for the expectant family, community physicians, pediatricians, perinatologists and neonatologists, as well as coordinate the subspecialty consultations.

Nicklaus Children's offers an array of diagnostic services, including fetal ultrasound, fetal MRI and fetal echocardiography, with the goal to support families in obtaining a definitive diagnosis and plan of care during a single visit. Nicklaus Children's Hospital's subspecialty programs are routinely ranked by *US. News & World Report* in its annual listing of "*Best Children's Hospitals*" in the nation.

We have implemented additional safety precautions, such as arrival screenings and physical distancing measures. For parents who wish to make arrangements for their child to see his or her specialty physician virtually, telehealth options may also be available. For more information visit **nicklauschildrens.org/covid19safety**

The Fetal Care Center's special delivery unit is a birth center for healthy mothers of high-risk infants who will require immediate access to our team of pediatric intensive and critical care specialists after birth.

- **2** High-technology operating rooms
- **5** Antepartum rooms
- **5** Labor and delivery rooms

Nicklaus Children's Hospital

Fetal Care Center

To reach a Fetal Care Center nurse navigator, available 24 hours a day, call 1-844-553-3825 | Nicklauschildrens.org/FetalCare

Nicklaus Children's Hospital. For Health. For Life.

How Pediatric Cardiology Has Evolved Over the Last 50 Years: An Excerpt

P. Syamasundar Rao, MD

Introduction

When the author began his career in the mid-1960s, the field of Pediatric Cardiology was in early development. He has had the opportunity to witness the field's step-wise evolution and has documented it in a book titled "How Pediatric Cardiology Has Evolved Over the Last 50 Years".[1] The purpose of the book was to bring together advances in Pediatric Cardiology on the management of congenital heart defects (CHDs), with particular attention to the author's contributions. At first, the author's journey was introduced when he bestowed considerable attention on the development of new knowledge and the training and teaching of physicians around the world while providing care for patients with heart disease over a 50-year period. This appraisal focused particular attention on his scientific contributions to the literature. These include the spontaneous closure of physiologically advantageous Ventricular Septal Defects (VSDs); various issues related to a relatively rare congenital heart defect – namely, tricuspid atresia; and transcatheter, interventional pediatric cardiac procedures.

Physiologically Advantageous VSDs

When a VSD is a component of a complex heart defect, an open defect is critical in maintaining suitable intra-cardiac shunt; such a defect has been named physiologically advantageous VSD. While spontaneous closure of isolated VSDs was well documented in the 1960s and 1970s, closure of physiologically advantageous VSDs has not been a focus of prior studies. The initial observation of closure of such VSDs in patients with tricuspid atresia and double outlet right ventricle had prompted focusing on this issue. In addition to tricuspid atresia and double outlet right ventricle, such VSD closures have been documented in Tetralogy of Fallot, pulmonary atresia with VSD and Transposition of the Great Arteries with intact atrial septum. This concept may even be extended to closure of bulboventricular foramen in patients with double inlet left ventricle with ventriculo-arterial discordance. Extensive investigation of this issue in children with tricuspid atresia lead to the documentation of functional, partial and complete VSD closures. These observations have suggested that spontaneous closure of these VSDs occurs as often as in isolated VSDs and that the mechanisms of closure are similar to those seen in isolated VSDs. The closure may occur in utero, early in infancy, childhood and continues through adulthood. There is an immense natural tendency for spontaneous closure of these VSDs. In patients with tricuspid atresia and normally related great arteries, such closures will result in pulmonary oligemia requiring surgical palliation earlier than is otherwise necessary; while in patients with tricuspid atresia and transposed great arteries, such closures produce left ventricular outflow tract obstruction, requiring bypass of the VSD and the right ventricle by a pulmonary artery-to-ascending aorta anastomosis (Damus-Kaye-Stansel) or by a left ventricle-to-descending aorta conduit **(Figure 1).**

Tricuspid Atresia

The author's interest in spontaneous closure of physiologically advantageous VSDs was initially focused on tricuspid atresia cases. While examining these issues, the author's attention was drawn to other features of tricuspid atresia. The resulting studies led to the publication of several papers and book chapters including two books. Terminology; unified classification; description of rare types of tricuspid atresia; enumeration of demographic, electrocardiographic, and echocardiographic features; description of new findings of left to right atrial shunt in tricuspid atresia; cardiac catheterization; principles of palliation; role of percutaneous interventions; and insights into surgical approaches were reviewed.

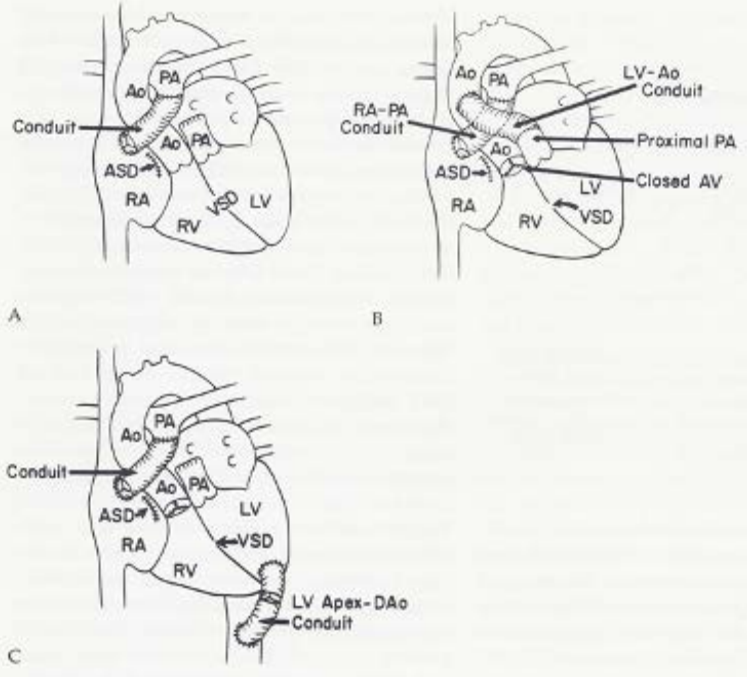


FIGURE 1 ***A)*** *Line drawing illustrating atrio-pulmonary type of Fontan for patients with tricuspid atresia with transposition of the great arteries. The left ventricular (LV) blood flows via the ventricular septal defect (VSD) and right ventricle (RV) into the aorta (Ao).* ***B)*** *If the VSD is small and restrictive, causing "subaortic" obstruction, this obstruction may be bypassed by connecting the proximal stump of the divided pulmonary artery (PA) to the Ao directly or via a non-valved conduit.* ***C)*** *An alternate approach is to connect the LV apex to the descending aorta (DAo). Atrial Septal Defect (ASD); Right Atrium (RA). Reproduced from Rao, PS, Br Heart J 1977; 39:276-88 and Rao PS, Ann Thorac Surg 1983; 35:121-31.*

Catheterization and Angiography

The early work regarding catheterization and angiography included demonstration of correlation of pulmonary venous wedge with pulmonary arterial pressures, advocacy for femoral route for cardiac catheterization in infants and children, defining the relationship of pressure and energy in cardiovascular chambers, showing usefulness of pulmonary vein wedge angiography in visualization of obstructed pulmonary artery, observation of non-opacification of patent ductus arteriosus in patients with large proximal shunts, and the utility of balloon occlusion aortography.

Transcatheter Interventions

Following adoption of Gruntzig's technique for pediatric patients by Kan and her associates, the author began to apply these techniques to pediatric patients. A systematic and methodical approach to the performance of these procedures and follow-up data collection resulted in publication of multiple papers, invited reviews and booklets/books.

Balloon Angioplasty and Valvuloplasty

Immediate, intermediate-term, and long-term follow-up (**Figure 2**) results; causes of re-stenosis; feasibility of relieving re-stenosis by repeat balloon dilatation; and influence of balloon size on the results of balloon dilatation following balloon dilatation of pulmonary stenosis, coarctation of the aorta, both native and post-surgical, aortic stenosis, and other stenotic lesions were reviewed. Development of significant valvar insufficiency (**Figure 3**) at follow-up after valvar balloon dilatations and extension of the procedure to patients with cyanotic congenital heart defects were also reviewed.

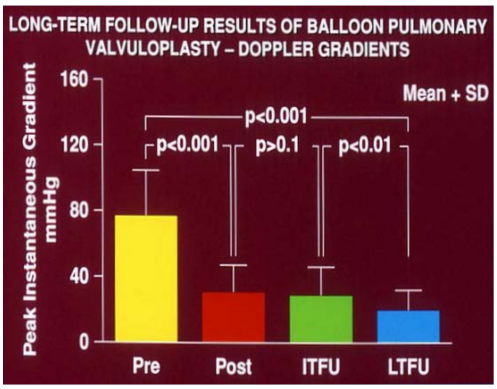


FIGURE 2 *Bar graph demonstrating maximum peak instantaneous Doppler gradients prior to (Pre) and one day following (Post) balloon pulmonary valvuloplasty, and at intermediate-term (ITFU) and long-term (LTFU) follow-up. Note the significant reduction ($p < 0.001$) after valvuloplasty, which remains unchanged ($p > 0.1$) at ITFU. However, at LTFU there was a further fall ($p < 0.001$) in the Doppler gradients. The mean + standard deviation (SD) are shown. Modified from Rao PS, et al., Heart 1998; 80:591-5.*

Transcatheter Occlusions

Immediate, intermediate-term and long-term follow-up results of percutaneous closure of atrial septal defects, patent ductus arteriosus, VSDs and other defects such as ruptured sinus of Valsalva aneurysm, aortopulmonary window and unwanted blood vessels (embolization of) were also presented.

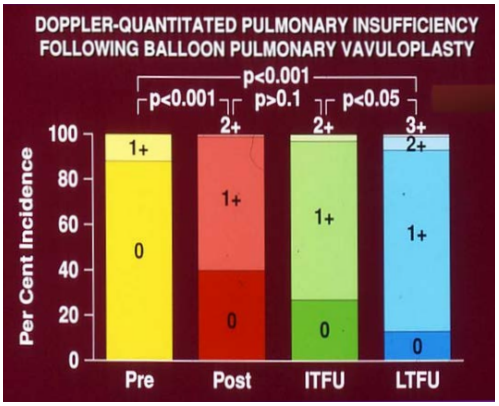


FIGURE 3 *Bar graph showing Doppler graded pulmonary insufficiency (PI) prior to (Pre) and one day after (Post) balloon pulmonary valvuloplasty and at intermediate-term (ITFU) and long-term (LTFU) follow up. 0, No PI; 1+, 2+, 3+, PI grade as per table above. A gradual but significant increase ($p < 0.05$ to $p < 0.001$) in the incidence of PI is seen. Modified from Rao PS, et al., Heart 1998; 80:591-5.*

Stents for Vascular Obstructive Lesions

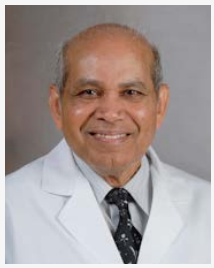
The technique and results of implantation of stents to open vascular obstructive lesions such as branch pulmonary arteries, right ventricular outflow conduits, aortic coarctation, and occluded aortopulmonary shunts were also reviewed. Use of stents to maintain the patency of the ductus arteriosus in patients with pulmonary atresia and Hypoplastic Left Heart Syndrome (HLHS) and to keep the patent foramen ovale open in HLHS or mitral atresia cases was also discussed.

Miscellaneous

In addition to the above-listed items, the author has made several other contributions to the treatment of Congenital Heart Disease, relative to: de Lange Syndrome; characterization of infective endocarditis; early identification and diagnosis of neonatal heart disease; usefulness of continuous positive airway pressure in the differentiation of cardiac from pulmonary cyanosis in the neonate; polysplenia syndrome; dextrocardia; electrocardiographic studies such as racial variations in electrocardiograms and vectorcardiograms between black and white children and their genesis and electrocardiographic differentiation of posterobasal left ventricular hypertrophy from right ventricular hypertrophy; multiple echo-Doppler studies such as echocardiographic estimation of left-to-right shunt in VSDs, contrast echocardiography, echocardiographic evaluation of left ventricular function, left ventricular muscle mass by m-mode echocardiography in children, influence of race and sex on echocardiographic measurements in children, Doppler echocardiography in non-invasive diagnosis of heart disease in infants and children, value of echo-Doppler studies in the evaluation of percutaneous interventional procedures, Doppler in the prediction of pressure gradients across aortic coarctation and valvar pulmonary stenosis, and echocardiographic assessment of congenital coronary artery anomalies; vasodilator therapy for cardiac failure in pediatric practice; anticoagulant therapy in children with prosthetic valves; prosthetic valves in children and adolescents; consensus statements on timing and type of intervention for common congenital heart diseases, neonatal catheter interventions, CHDs in adults, and management of cyanotic congenital heart disease.

References

1. Rao PS. Pediatric Cardiology: How It Has Evolved Over The Last 50 Years. Cambridge Scholars Publishing. New Castle upon Tyne, United Kingdom. 2020.



P. SYAMASUNDAR RAO, MD

Professor of Pediatrics and Medicine
Emeritus Chief of Pediatric Cardiology
University of Texas-Houston
McGovern Medical School
Children's Memorial Hermann Hospital
Houston, TX, USA
713.500.5738
P.Syamasundar.Rao@uth.tmc.edu

The Congenital Heart Collaborative | University Hospitals Rainbow Babies & Children's Nationwide Children's Hospital

Pediatric Cardiologist: Non-Invasive Imaging

The Congenital Heart Collaborative (TCHC), an affiliation between University Hospitals Rainbow Babies & Children's Hospital (Cleveland OH) and Nationwide Children's Hospital (NCH, Columbus OH) heart programs, seeks candidates in non-invasive imaging for a faculty position in our expanding group at UH Rainbow Babies & Children's Hospital. Candidates with fetal echocardiography experience will be preferred. The successful candidate will join a group of physicians that model teamwork, collaboration and dedication to their patients and partners. Our growing fetal program performs over 1,000 fetal echocardiograms a year and it has launched a highly successful fetal intervention team in conjunction with our maternal fetal medicine colleagues from our adjoined Women's Hospital. Our fetal program has performed 9 fetal cardiac interventions to date. The candidate will have additional opportunities to participate in quality improvement initiatives, clinical research, and education of medical students, residents, and fellows.

The successful candidate will be well-supported at a world-class children's hospital that has over 60 years of experience in the care of pediatric and ACHD patients; an outstanding educational and research enterprise at Case Western Reserve University School of Medicine, and an internationally recognized program partner with the NCH Heart Center. TCHC is a dedicated service line with a common executive administration and functions as one program on two campuses with the commitment to expand access to high-quality comprehensive cardiac care regardless of patient age to the communities we serve while equally embracing a scholarly and educational mission. TCHC provides excellent cardiothoracic surgical, interventional, electrophysiologic, and non-invasive services.

Please send letter and curriculum vitae to:
Janine Arruda, MD
Director of Non-Invasive Imaging at Rainbow Babies & Children's Hospital
janine.arruda@uhhospitals.org

In employment, as in education, Case Western Reserve University is committed to equal opportunity and diversity. Women, veterans, members of underrepresented minority groups and individuals with disabilities are encouraged to apply.

Among the nation's leading academic medical centers, University Hospitals Case Medical Center is the primary affiliate of Case Western Reserve University School of Medicine, a nationally recognized leader in medical research and education.

University Hospitals Case Medical Center | Rainbow Babies & Children's Hospital | Nationwide Children's — When your child needs a hospital, everything matters.

St. Joseph's Children's Hospital Welcomes New Chief of Pediatric Cardiac Surgery

PRNewswire/ -- St. Joseph's Children's Hospital, home to Tampa Bay's only comprehensive congenital heart disease program, proudly welcomes Karl Reyes, MD, as its new Chief of Pediatric Cardiac Surgery.

Dr. Reyes will work closely with hospital physicians, leadership and staff to ensure that the pediatric cardiac team continues to achieve the highest standards of safety and quality. The team's surgical outcomes already exceed national benchmarks as reported by the Society of Thoracic Surgeons.

"We believe that low mortality and short length of stay are cornerstones of the program quality," said St. Joseph's Children's Hospital President Sarah Naumowich. "Dr. Reyes' extensive experience as a cardiac surgeon and the compassion he has for his patients make him an excellent addition to our multidisciplinary team. He will help lead us to even greater accomplishments and growth."

Dr. Reyes was eager to join the St. Joseph's Children's Hospital pediatric and congenital heart program.

"I am impressed with how the team of cardiologists, surgeons, intensivists and anesthesiologists work in such close collaboration to make all significant patient care decisions. This is a time-tested model that has been shown to deliver the best outcomes and gives patients and their families a very special experience," Reyes said.

Dr. Reyes adds that he's also excited about St. Joseph's Children's Hospital's partnership with UPMC Children's Hospital of Pittsburgh, which has one of the country's best congenital heart programs according to U.S. News and World Report rankings.

"Together, we can take this program to an even greater level and provide the best care possible for patients with congenital heart disease in the Tampa Bay region and beyond."

Dr. Reyes comes to Tampa from the Children's Hospital of San Antonio, Texas where he served as an associate professor of Pediatric Cardiac Surgery at the Baylor College of Medicine. Prior to that, he worked at the UF Health Congenital Heart Center and served as an associate professor of surgery at the University of Florida College of Medicine.

St. Joseph's Children's Hospital in Tampa welcomes its new Chief of Pediatric Cardiac Surgery, Karl Reyes, MD. St. Joseph's Children's Hospital is home to Tampa Bay's only comprehensive Congenital Heart Disease program and its congenital heart surgery program is one of the largest in Florida.

Dr. Reyes also worked in his home country the Philippines prior to returning to the United States. He served as the head of Congenital Heart Surgery at St. Luke's Medical Center and was instrumental in the organization of the St. Luke's Center for Congenital Heart Disease, making it one of the country's premier programs. Dr. Reyes and his team were first in the Philippines to successfully perform cardiac surgery for Hypoplastic Left Heart Syndrome, and to perform hybrid cardiac procedures such as intraoperative stenting and periventricular device closure for muscular ventricular septal defects. He was also responsible for deployment of the Philippines' first Extracorporeal Membrane Oxygenation (ECMO) program.

Dr. Reyes graduated with honors from the University of the East College of Medicine in Quezon City, Philippines. His post-doctoral training included clinical fellowships at the Cleveland Clinic in thoracic and cardiovascular surgery and at Boston Children's Hospital - Harvard Medical School in congenital cardiovascular surgery. In his last year, Dr. Reyes was Chief Fellow at the Cleveland Clinic and Boston Children's Hospital.

In addition to his work, Dr. Reyes co-founded The Operation Heart Foundation which is a charitable organization that provides free care for infants and children with Congenital Heart Disease in the Philippines. He also volunteers with Gift of Life International.

Dr. Reyes has extensive experience in treating patients with complex congenital heart defects in neonates, infants, children, and adults. His expertise includes neonatal heart surgery, repairing heart valves, single ventricle physiology, tetralogy of Fallot with pulmonary atresia, and adult congenital heart disease.

St. Joseph's Children's Hospital is excited about the experience, passion and enthusiasm Dr. Reyes brings to its pediatric cardiac program.

SIU SCHOOL of MEDICINE

Pediatric Cardiologist

The Department of Pediatrics at Southern Illinois University School of Medicine is recruiting an M.D. for a fourth pediatric cardiologist at the Assistant or Associate Professor level. Faculty will join a rapidly expanding cardiology program at our Children's Hospital, an 80-bed CHA affiliated pediatric referral center for Central and Southern Illinois with a referral base of almost 2 million. The current program includes state-of-the-art noninvasive imaging in TTE, TEE, fetal echocardiogram, and advanced MRI imaging. We have developed a highly successful collaborative clinical and research program with a nationally recognized pediatric cardiology center. Opportunities exist to participate in resident and medical student education and receive an advanced degree in medical education. Candidates must be board eligible in Pediatrics and Pediatric Cardiology. Illinois licensure is required prior to official start date. Travel in central Illinois to outreach clinics is required.

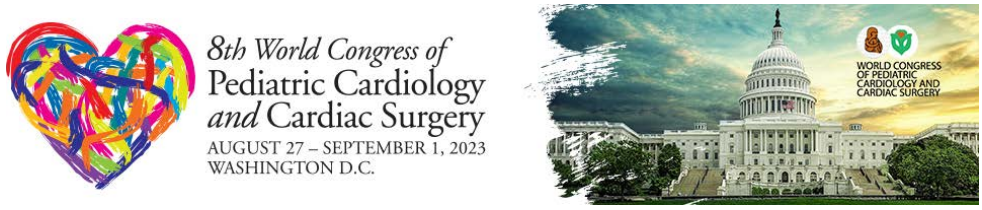
Applications are accepted online at: https://siumed.hiretouch.com/.

For additional information, please contact:
Ramzi Nicolas, MD
P. 217.545.9706
E. **rnicolas@siumed.edu**

SIU is an EO/AA employer.

8th World Congress of Pediatric Cardiology and Cardiac Surgery

A Letter from the Organizing Committee



Greetings from the Organizing Committee of the World Congress of Pediatric Cardiology and Cardiac Surgery!

The SARS-CoV19 Pandemic has resulted in overwhelming changes in virtually all aspects of our lives, including education and scientific meetings. As Co-Chairs of the *8th World Congress*, we want to emphasize that, first and foremost, your safety and well-being are our primary consideration. Therefore, after much discussion and weighing all the options, given the current global uncertainty we have decided to postpone the *8th World Congress of Pediatric Cardiology and Cardiac Surgery* until 2023. As before, the meeting will take place in Washington DC, USA; the new dates are August 27 - September 1, 2023.

We want to thank our executive team, organizing committee, scientific program committee, Societal Partners, Institutional Partners, Appin Consulting, and many more who have developed the amazing congress and scientific program originally scheduled for September, 2021. We will continue to capitalize on all of this hard work, as well as incorporating new science and technology, as we plan for an even better meeting in 2023.

To this end, over the coming years, we will be presenting a series of virtual webinars and other complementary events highlighting portions of the current 2021 scientific program.

For details on these courses, join our mailing list at **WCPCCS2023.org**.

Stay tuned for details, and see you in DC in 2023!

Sincerely yours,
Jeff and Gil

Jeffrey Jacobs, MD
Co-Chair, WCPCCS 2023

Gil Wernovsky, MD
Co-Chair, WCPCCS 2023

SAINT LOUIS UNIVERSITY EST. 1818

Division of Pediatric Cardiology
Saint Louis University
School of Medicine
SSM Health Cardinal Glennon
Children's Hospital

Non-Invasive Cardiologist

We are seeking an additional non-invasive cardiologist to assist our current faculty with the growing number of echocardiographic procedures performed at our institution. Experience in performing and interpreting both transthoracic and transesophageal echocardiograms is required. Participation in outpatient clinic and inpatient care is also required. An interest in clinical research is encouraged. Academic rank will be commensurate with qualifications and experience.

The cardiology division is housed within the Dorothy and Larry Dallas Heart Center at SSM Health Cardinal Glennon Children's Hospital. The Heart Center opened in 2009 and underwent significant expansion in 2016. An active congenital heart surgery program exists, and the hospital houses state-of-the-art operating rooms, neonatal intensive care unit, pediatric intensive care unit, electrophysiology lab, and a hybrid cardiac catheterization lab/operating suite. SSM Cardinal Glennon Children's Hospital is a free-standing children's hospital and is staffed by faculty members of Saint Louis University School of Medicine.

Interested candidates must submit a cover letter, application, and current CV to:
https://www.slu.edu/working-at-slu.php

Other correspondence regarding these positions can be sent to:
Kenneth O. Schowengerdt, MD
Wieck-Sullivan Professor and Director of Pediatric Cardiology
Saint Louis University School of Medicine
1465 South Grand Blvd, St. Louis, MO 63104
T. 314.577.5633
F. 314.268.4035
Kenneth.Schowengerdt@health.slu.edu

Saint Louis University is a Catholic, Jesuit institution dedicated to student learning, research, health care, and service. Saint Louis University is an Affirmative Action, Equal Opportunity Employer, and encourages nominations of and applications from women and minorities.

2021

JANUARY

11

PAC3 Inpatient Education Series
Webinar
https://zoom.us/webinar/register/WN_MbHxjyHqQqitplxmau8mew

FEBRUARY

11-14

CPP 2021 – The 6th International Congress on Cardiac Problems in Pregnancy
Porto, Portugal
https://cppcongress.com/register-now/

MARCH

10-13

Morphology and Echocardiography in Neonates and Children
Hands-on Interactive Morphology and Echo Course
Birmingham, AL, USA
https://www.congenitalecho.co.uk/

19-20

2020 World Heart and Cardiothoracic Surgery Conference (WHCS)
Bangkok, Thailand
https://heart.episirus.org/

SPECTRUM HEALTH Helen DeVos children's hospital

BEST CHILDREN'S HOSPITALS U.S.News & WORLD REPORT CARDIOLOGY & HEART SURGERY 2020-21

Adult Congenital Heart Disease (ACHD) Physician

The fully accredited, **nationally ranked Congenital Heart Center (CHC)** at **Helen DeVos Children's Hospital (HDVCH)** seeks a passionate Board Certified Adult Congenital Heart Disease (ACHD) physician to join its experienced staff. The ACHD program at HDVCH is an integrated part of the CHC and collaborates with adult cardiology. The ideal candidate will demonstrate a collaborative spirit and track record of working successfully across multiple fields of practice.

Helen DeVos Children's Hospital (HDVCH) is a free standing 234 bed state-of-the-art dedicated children's hospital. **HDVCH is ranked by U.S. News & World Report in eight pediatric sub-specialties including cardiology and cardiac surgery.**

Program Highlights:

- Recognized as one of the **Top 50 Children's Hospitals for Pediatric Cardiology & Heart Surgery** by the **U.S. News and World Report, 2020-2021**
- Established clinic case load of 1700 patient visits per year which is expected to double over the next two years
- The team is fully credentialed, and the program aligns with current ACC/AHA guidelines
- Surgical Program includes congenital cardiac surgery, cardiac intervention, congenital EP, CMR and CCT. Between 2016 and 2019 the team has performed 1240 surgeries, 1540 cardiac catheterizations and electrophysiological procedures.
- Lead interventionalist and lead surgeon have over 45 years of combined experience treating ACHD patients, additionally there are two full time clinical ACHD physicians, and 7 cardiologists who have ACHD board qualifications/board equivalence
- Pediatric Cardiology and the ACHD clinics are separate but co-located. Staff are experienced congenital heart professionals in TTE, EP testing and exercise physiology care
- Additional clinics include Maternal Fetal Medicine/Pregnancy Clinic and Transition Clinic
- Although administratively based in the Children's Hospital, the CHC is co-located within the Frederick Meijer Heart and Vascular Institute (FMHVI) at Spectrum Health. We partner with the FMHVI in managing advanced heart failure in ACHD patients and have an established program for VAD support and heart and lung transplantation

Position Highlights:

- Collaborative program enhancement and outreach
- Integral part of inpatient and outpatient services and provide support for the post-operative care of surgical patients
- Work with CHC leadership to plan for improved access for ACHD patients
- Dedicated CMR time
- Involvement in research and opportunity to develop research interests

Questions can be directed to Dr. Joseph Vettukattil at Joseph.vettukattil@helendevoschildrens.org

To apply, please visit: https://careers.peopleclick.com/careerscp/client_spectrumhealth/external/gateway/viewFromLink.html?jobPostId=148031&localeCode=en-us

Edwards PASCAL Transcatheter Valve Repair System Receives European Approval for Tricuspid Repair

PRNewswire - Edwards Lifesciences Corporation (NYSE: EW), the global leader in patient-focused innovations for structural heart disease and critical care monitoring, announced that it received CE Mark for the Edwards PASCAL transcatheter valve repair system for the treatment of European patients with Tricuspid Regurgitation (TR).

"Although the prevalence of tricuspid valve disease and the associated mortality are high, there are limited effective treatment options for these very symptomatic patients, who often cannot have surgery due to the prohibitive risk," said Prof. Jörg Hausleiter, MD, Medizinische Klinik der Ludwig-Maximilians-Universität München in Munich, Germany. "Transcatheter tricuspid therapy can be challenging due to the fragile leaflets and the large defects during valve closure. In our experience, the PASCAL system's independent grasping ability as well as the flexible and less traumatic clasp design are important features for our patients."

The PASCAL system is indicated in Europe for the percutaneous reconstruction of the tricuspid valve through leaflet repair by tissue approximation. The clasps and paddles gently grasp the leaflets to facilitate coaptation, while the spacer is designed to fill the regurgitant orifice area and prevent backflow. The clasps can be operated independently to facilitate optimized leaflet capture and the implant can be elongated to a narrow profile, allowing for safe maneuvering in dense chordal anatomy.

"Patients with tricuspid valve disease are in great need of solutions," said Bernard J. Zovighian, Edwards' corporate Vice President, transcatheter mitral and tricuspid therapies. "Edwards is the first company to introduce multiple transfemoral tricuspid repair therapies in Europe, providing physicians with both leaflet repair and annular reduction therapies to help meet their patients' needs."

In early clinical experience, the PASCAL repair system demonstrated high procedural success and significant clinical improvements in patients with challenging tricuspid anatomy and severe TR. Sustained TR reduction was observed at 30 days, with 85 percent of patients seeing a reduction to TR ≤2+ on a five-grade scale.

Edwards continues to build a body of clinical evidence for transfemoral tricuspid therapies, including with the CLASP II TR pivotal study investigating the PASCAL system in patients with symptomatic functional or degenerative TR, the TRISCEND study investigating the EVOQUE system for tricuspid valve replacement, as well as real-world experience. The launch of the PASCAL system for the treatment of TR patients in Europe is focused on procedural success and differentiated patient outcomes, with a high-touch clinical support model.

The PASCAL repair system is not approved in the United States.

Prof. Jörg Hausleiter is a consultant for Edwards and a member of its Advisory Board, receiving compensation for services including proctoring, educational presentations, expert advice and R&D insights, as well as associated travel.

The Heart Institute at the UPMC CHILDREN'S HOSPITAL OF PITTSBURGH Is *EXPANDING*! FIVE POSITIONS AT UPMC CHILDREN'S HOSPITAL

With a strategic plan for growth and expansion, the Division of Cardiology within the Heart Institute of the UPMC Children's Hospital of Pittsburgh / University of Pittsburgh School of Medicine is recruiting additional faculty positions.

DIRECTOR OF PEDIATRIC NON-INVASIVE IMAGING (ECHOCARDIOGRAPHY LABORATORY)

For this leadership level position, we are seeking an outstanding board-certified pediatric cardiologist with strong expertise in non-invasive imaging including all forms of echocardiography and/or cardiac MRI & cardiac CT. Applicants should be at the Associate Professor level (or above). In addition, evidence of solid leadership skills to take the Director role and help build up the Non-Invasive Imaging Program, working closely with division chief and hospital leadership. Candidates must have completed a 4th year pediatric imaging advanced fellowship and demonstrated an academic commitment in the field of imaging, with dedication to teaching, research and quality improvement. Candidates must be Board Certified in Pediatric Cardiology.

DIRECTOR OF CARDIOLOGY CLINICAL SERVICES

The Heart Institute is seeking an exceptional individual to lead the Clinical Services within the Division of Cardiology, actively participating with the Division Chief and Heart Institute Leadership in the supervision and development of clinical services, strategic planning, program coordination and expansion. The applicant should have demonstrated evidence of strong leadership skills and recognized expertise as academic physician. A commitment to excellence, integrity, collegiality and professionalism is a must. Applicants should be at the Associate Professor level (or above), and Board Certified in Pediatric Cardiology.

EXPERT PEDIATRIC ELECTROPHYSIOLOGIST

The applicant should be experienced in the management of pediatric EP and adult congenital heart disease electrophysiology with excellent clinical, teaching and research skills. Clinical skills should include radiofrequency/cryoablation, transvenous pacemaker/AICD insertion, ventricular tachycardia ablation and complex congenital heart disease EP cases. The well-established pediatric electrophysiology program is currently staffed by two experienced EP physicians and two dedicated EP RN. The EP team also works in close conjunction with the Heart-Vascular Institute of UPMC-Presbyterian adult hospital. According to academic rank and seniority candidate may be eligible to leadership position.

IMAGING FACULTY WITH EXPERTISE IN ECHOCARDIOGRAPHY, INCLUDING FETAL

We are recruiting for a full-time Board Eligible/Certified non-invasive imaging faculty with expertise on TTE, TEE and FETAL echocardiography. Completion of a 4th year imaging fellowship plus skill and independence in transesophageal echocardiography is a requirement.

Imaging faculty will join an outstanding team: Including eleven echocardiographers, 16 pediatric sonographers in a highly productive echo lab – with over 20,000 echocardiograms, including over 1600 fetal echo's and 550 TEE's.

Echocardiography program covers Children's Hospital, Magee Women's hospital and multiple outreach sites and a robust tele-echo program. The program includes collaboration with the adult cardiology program for ACHD cMR, as well as with Radiology enhancing the cardiac MRI program, and MFM colleagues to expand the Fetal Cardiac Program. Candidates must be board-eligible/certified in pediatric cardiology.

ADULT CONGENITAL HEART DISEASE FACULTY

The Division of Cardiology at UPMC Children's Hospital of Pittsburgh / University of Pittsburgh School of Medicine is recruiting for additional faculty to join the Adult Congenital Heart Disease (ACHD) program. The well-established ACHD program is currently supported by 2 ACHD physicians (including one ACDH Director), 2 advanced practice providers, a dedicated RN, research coordinator and social worker. The applicant should have expertise in the management of adult congenital heart disease with prominent clinical, teaching and research skills. He or she will be working closely with division chief, ACHD Director and hospital leadership to support program expansion. Candidates must be Board-Eligible/Certified in Pediatric Cardiology or Adult Cardiovascular Diseases and in Adult Congenital Heart Disease.

The Heart Institute provides comprehensive pediatric and adult congenital cardiovascular services to the tri-state region and consists of 27 pediatric cardiologists, 5 pediatric cardiothoracic surgeons, 8 pediatric cardiac intensivists and 10 cardiology fellows along with 19 physician extenders and a staff of over 100. We are honored to be ranked **#2 nationally** and **#1 in Pennsylvania** for pediatric cardiology and heart surgery by U.S. News and World Report. Our Cardiac surgical program is one of the top in the country, with a 3-star rating from Society of Thoracic Surgery (STS).

UPMC Children's Hospital of Pittsburgh has been named one of the top U.S. News & World Report's Best Children's Hospitals. Consistently voted one of America's most livable cities, Pittsburgh is a great place for young adults and families alike.

The positions come with a competitive salary and faculty appointment commensurate with experience and qualifications at the University of Pittsburgh School of Medicine. The University of Pittsburgh is an Equal Opportunity/Affirmative Action Employer. Interested individuals should forward letter of intent, curriculum vitae and three (3) letters of references. Informal inquiries are also encouraged.

For more information, please contact:

Jacqueline Kreutzer, MD, FSCAI, FACC
Chief, Division of Pediatric Cardiology
UPMC Children's Hospital of Pittsburgh, 4401 Penn Avenue, Pittsburgh, PA 15224
Jacqueline.Kreutzer@chp.edu or 412.692.6903

Yves d'Udekem, MD, PhD, joins Children's National as Cardiac Surgery Chief

"Children's National has the cases and expertise I was looking for," he says. "Even better, when you visit, it's clear that the entire Heart Institute team is energetic about working together. They're constantly seeking better ways to do this work and improve how we care for children and their families."

Dr. d'Udekem comes to Children's National from The Royal Children's Hospital in Melbourne, Australia, an institution that has led the advancement of Congenital Heart Disease care and research, performing more than 500 surgical procedures with cardiopulmonary bypass each year.

He has a broad spectrum of pediatric cardiac surgery expertise, with special emphasis in single ventricle congenital heart defects, when one lower chamber of the heart does not develop. One area of his research portfolio includes clinical research into long-term quality of life for people who had Fontan procedures — a critical surgical approach to adapt blood flow for people born with single ventricle heart disease. He has additional expertise in valve repair, artificial hearts and other cardiac assist devices.

"Sometimes it seems like I've been born and put on this earth for that single purpose — I have to bring life to patients with single ventricle hearts or assist devices," he says. He describes his path to pediatric cardiac surgery as serendipity, "It's more like pediatric cardiac surgery chose me."

"It is an honor to welcome Yves d'Udekem to the Children's National Heart Institute," says David Wessel, MD, Executive Vice President and Chief Medical Officer of Hospital and Specialty Services at Children's National. "He is a surgeon, physician and leader of the highest caliber. I can say without hesitation that Yves' leadership of our cardiac surgery team will change the lives of hundreds, if not thousands, of children and adults with congenital heart disease."

In preparation for Dr. d'Udekem's arrival, the Children's National Heart Institute and hospital leadership created a framework plan for success that will build on the legacy of excellence established by Richard Jonas, MD. Dr. Jonas, a world leader in congenital heart surgery who has made significant clinical and academic advances in the field, will continue his award-winning laboratory-based research at Children's National on neurodevelopmental outcomes for children with congenital heart disease.

Yves d'Udekem, MD, PhD, a pediatric cardiac surgeon recognized for expertise in the most challenging procedures for newborns and children with complex congenital heart disease, has joined Children's National Hospital as chief of Cardiac Surgery and co-director of the Children's National Heart Institute.

Dr. d'Udekem is Belgian-born with Canadian and Australian citizenship. He received his early training in Belgium and Toronto. As an attending cardiac surgeon in Belgium, he operated on both adults and children with congenital heart disease. Dr. d'Udekem then worked with internationally-recognized heart surgeon Marc de Leval, MD, FRCS, and others in London to train in congenital heart surgery at the Great Ormond Street Hospital for Children. From there, he was recruited to The Royal Children's Hospital in Melbourne, Australia, where he has been ever since.

Dr. d'Udekem has more than 350 research publications and has obtained more than $7 million in grant funding in the past five years for work to create the first research network of Australian children and adults who have undergone the Fontan procedure. He started seeing patients at Children's National in mid-September.

Watch as Children's National Welcomes Yves d'Udekem:
https://www.youtube.com/watch?v=d4gn9zGXbBQ

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation & Research
Office of New Drugs

Pediatric Cardiologist

Are you making an outsized difference to the public health and well-being of Americans? Would you like to? The physicians, scientists and other dedicated professionals at the U.S. Food & Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs located in Silver Spring, MD, contribute to the public health of millions of Americans every day. We pride ourselves on our dedicated and skilled staff and are looking for committed individuals to help us achieve our mission. OND's mission is to ensure that safe and effective drugs and biologics are available to Americans. We provide guidance to drug companies on a wide variety of clinical, scientific and regulatory matters and make decisions on whether new drugs or new uses of already marketed drugs should be approved.

The Division of Cardiology and Nephrology within the Office of New Drugs is seeking highly qualified physicians to serve as clinical reviewers for drugs used for pediatric cardiovascular conditions. We are seeking individuals who are board certified or board eligible in pediatric cardiology. We are particularly interested in individuals with expertise and/or interest in pulmonary arterial hypertension, pediatric heart failure/cardiomyopathy, or pediatric arrhythmias. Graduating fellows and junior faculty are encouraged to apply.

Primary responsibilities of the clinical reviewer include the following:

- Determines whether clinical trials of new drugs and therapeutic biologics in humans are soundly conceived and supported to justify human testing
- Reviews clinical protocols and provides input regarding study design
- Together with other team members, interacts with investigators and drug companies to guide development of drugs and therapeutic biologics
- Determines whether marketing applications should be approved based on an evaluation of the evidence of safety and effectiveness
- Consults, when needed and where appropriate, with other medical specialists and scientists within and outside FDA
- Assists in the development and conduct of training programs, educational activities, workshops and conferences
- Keeps abreast of the progress in medical and related sciences by reviewing the scientific literature and participating in staff seminars where cases and topics of interest are discussed

As a clinical reviewer, you will have the opportunity to:

- Advance the public health through new drug development;
- Experience teaching and training opportunities;
- Interact with pharmaceutical companies, world-renown disease experts, patients and advocacy groups; and
- Work with a wide range of scientific disciplines in a team-oriented atmosphere.

This position allows for one half-day per week of patient care, if interested.

SALARY & BENEFITS

- Salary is commensurate with experience and expertise
- Excellent federal government benefits package (health insurance, life insurance, retirement, etc.).
- Relocation expenses and student loan repayment may be paid to eligible candidates.
- Flexible and/or partial telework schedules available (after completion of initial training period).

QUALIFICATIONS

Applicants must have a Doctor of Medicine or Doctor of Osteopathy degree from an accredited medical school. Graduates of foreign medical schools must be certified by the Education Commission for Foreign Medical Graduates. Candidates must be U.S. citizens. Permanent U.S. residents may apply for staff fellowship appointments. Excellent oral and written communication skills and an ability to work effectively in a team are necessary to be successful in this role. A competitive candidate will have experience working with clinical data with enough knowledge and understanding of clinical trial design to evaluate extensive, long-range scientific programs, and their implications on the drug development process. Prior human subject research experience is desired, but not required.

TO APPLY

Please send a current CV/resume and cover letter to ond-employment@fda.hhs.gov for consideration.
Please reference source code: #21-011EG in the subject line.

FDA IS AN EQUAL OPPORTUNITY EMPLOYER WITH A SMOKE FREE ENVIRONMENT

CONGENITAL CARDIOLOGY TODAY

CORPORATE OFFICE

11500 Elk Horn Drive
Clarksburg, MD 20871 USA

CORPORATE TEAM

EDITORIAL BOARD

OFFICIAL PUBLICATION OF
THE CHiP NETWORK

ISSN 1554-7787 print. ISSN 1554-0499 electronic.
Published monthly.