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Corticosteroid Therapy as an Effective Treatment for Primary Pulmonary Hypertension in Children: A Case Report

Mina Farshidgohar, MD; Reza Abbaszadeh, MD; Behzad Alizadeh, MD

Keywords: Corticosteroid Therapy, Primary Pulmonary Hypertension, Child

Abstract

Primary Pulmonary Hypertension (PPH) is a rare disease, characterized by sustained elevations of pulmonary artery pressure without a demonstrable cause. We report the first case of PPH, in which we used prednisolone to reduce Pulmonary Arterial Pressure (PAP). Our patient was a 4-year-old girl who presented with dyspnea and exercise intolerance. We diagnosed her as a case of PPH based on careful physical examination, lab data, Doppler echocardiography, and heart catheterization. Cardiac cath revealed severe pulmonary hypertension with PAP of 120/70 mmHg, and Mean PAP of 88 mmHg. Medical therapy was initially started with sildenafil and Bosentan. After one month, the mean PAP was estimated 70 mmHg on TTE.

Prednisolone 1 mg/kg daily was added afterward. After four weeks the pulmonary artery pressure fell from a mean value of 70 mmHg to 41 mmHg, and there was a corresponding clinical response.

This case suggests that in patients with pulmonary hypertension of unknown origin, an immunopathogenetic factor may be present and immunosuppressive therapy should be considered. We describe a patient with PPH who, after treatment with systematic corticosteroid therapy, showed clinical improvement and significant reduction of pulmonary arterial pressure.

Introduction

Primary pulmonary hypertension, currently known as Idiopathic Pulmonary Arterial Hypertension (IPAH), is a rare disease characterized by sustained elevations of pulmonary artery pressure without a demonstrable cause. The diagnostic criteria used by the registry of the National Institutes of Health (NIH), an agency of the United States Department of Health and Human Services, include: a mean pulmonary artery pressure of more than 25 mm Hg at rest, or more than 30 mm Hg with exercise, and the exclusion of left-sided cardiac valvular disease, myocardial disease, congenital heart disease, and any clinically important respiratory, connective-tissue, or chronic thromboembolic diseases. After all the known causes of pulmonary hypertension have been ruled out, the diagnosis becomes idiopathic pulmonary arterial hypertension (IPAH). This unexplained disease in which a structural abnormality is found, either in the arteries or in the veins, occurs both in children and adults and sometimes with a familial tendency (HPAH).¹ By the time the patient becomes symptomatic, the disease is usually advanced. In the absence of

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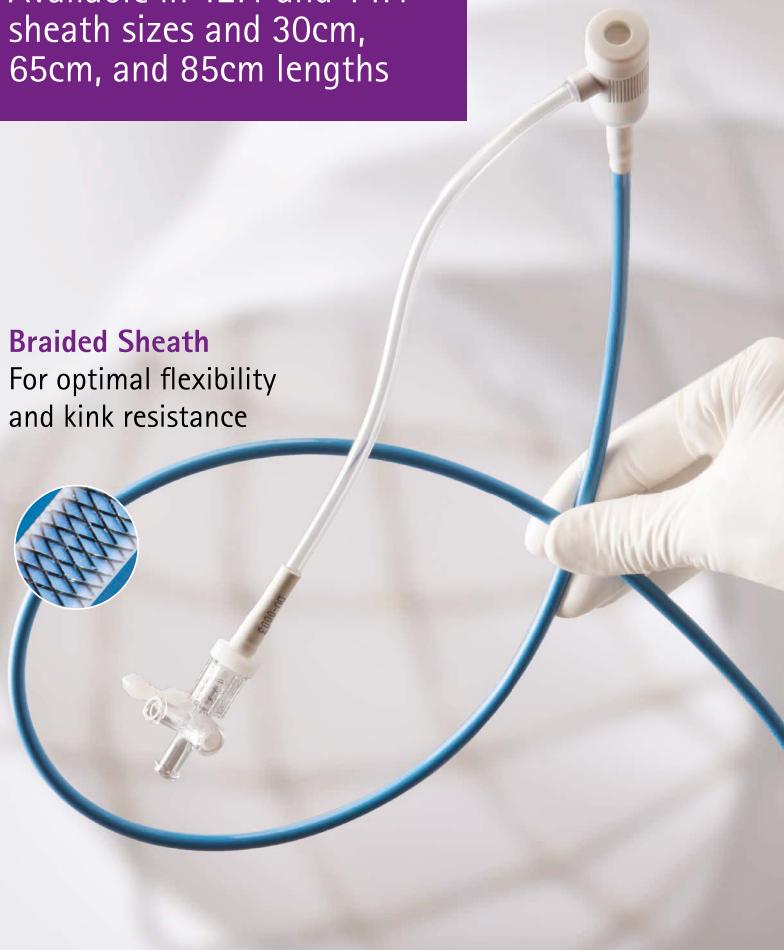
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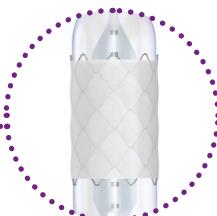
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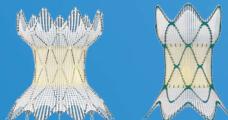
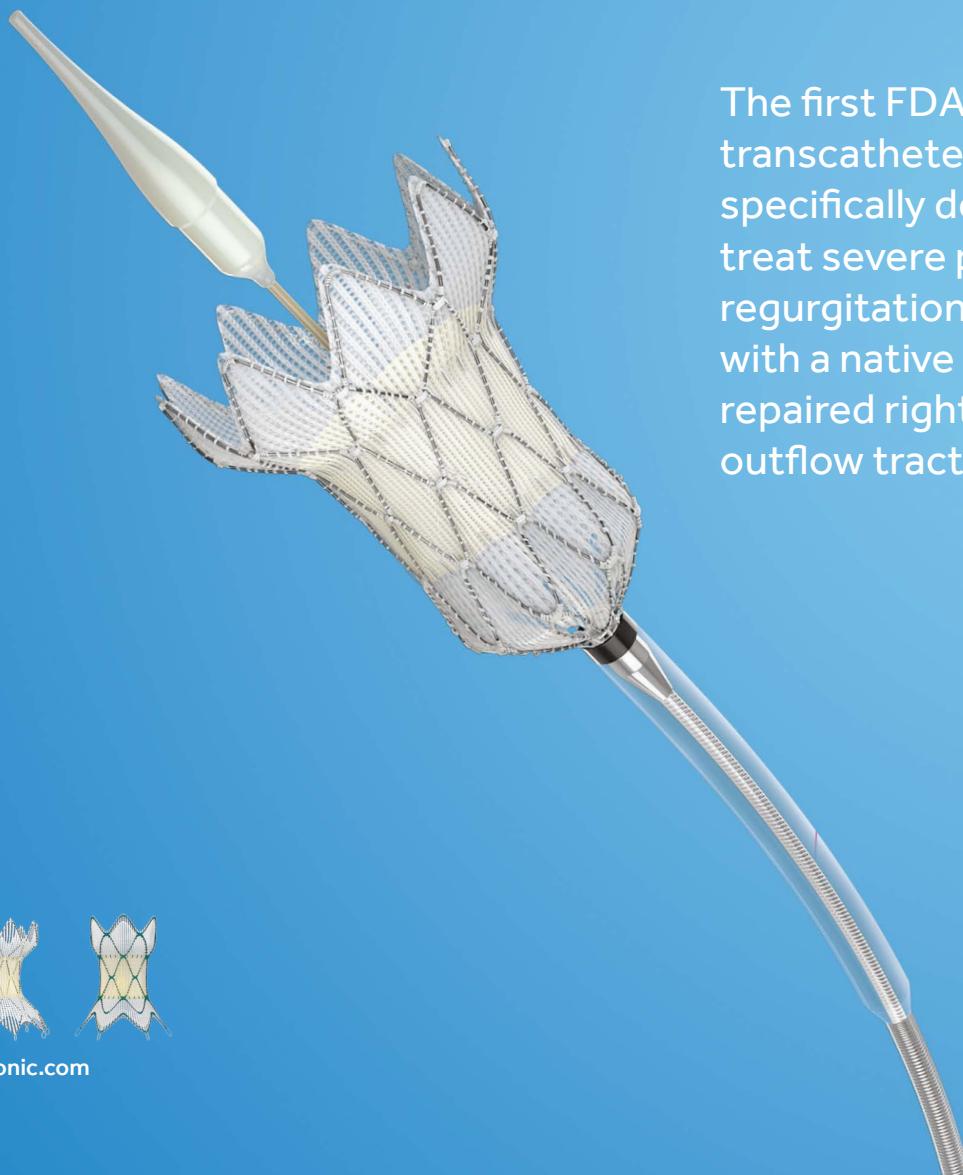
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Delivery catheter system (DCS): This device was designed for single use only. Do not reuse, reprocess, or resterilize the DCS. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not reuse or resterilize the DCS. If resistance is met, do not advance the guidewire, DCS, or any other component without first determining the cause and taking remedial action. Do not remove the guidewire from the DCS at any time during the procedure.

Precautions

General: Clinical long-term durability has not been established for the Harmony TPV. Evaluate the TPV performance as needed during patient follow-up. The safety and effectiveness of Harmony TPV implantation in patients with pre-existing prosthetic heart valve or prosthetic ring in any position has not been demonstrated. The Harmony TPV system has not been studied in female patients of child-bearing potential with positive pregnancy.

Before use: Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the chemical vapor. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water (for a minimum of 15 minutes) and seek medical attention immediately. The TPV and the glutaraldehyde storage solution are sterile. The outside of the TPV container is nonsterile and must not be placed in the sterile field. The TPV and DCS should be used only in a sterile catheterization laboratory (cath lab) environment. Ensure that sterile technique is used at all times. Strictly follow the TPV rinsing procedure. For TPV 25: Ensure that all green sutures have been removed from the attachment suture loops on the TPV before loading onto the DCS. Prevent contamination of the TPV, its storage solution, and the DCS with glove powder. Verify the orientation of the TPV before loading it onto the DCS. The inflow end of the TPV

with attachment suture loops must be loaded first. Do not place excessive pressure on the TPV during loading. Inspect the sealed DCS packaging before opening. If the seal is broken or the packaging has been damaged, sterility cannot be assured. Proper functioning of the DCS depends on its integrity. Use caution when handling the DCS. Damage may result from kinking, stretching, or forceful wiping of the DCS. This DCS is not recommended to be used for pressure measurement or delivery of fluids. Carefully flush the DCS and maintain tight DCS connections to avoid the introduction of air bubbles.

During use: The TPV segment is rigid and may make navigation through vessels difficult. Do not advance any portion of the DCS under resistance. Identify the cause of resistance using fluoroscopy and take appropriate action to remedy the problem before continuing to advance the DCS. Careful management of the guidewire is recommended to avoid dislodgement of the TPV during DCS removal. Once deployment is initiated, retrieval of the TPV from the patient is not recommended. Retrieval of a partially deployed valve may cause mechanical failure of the delivery catheter system or may cause injury to the patient. Refer to the section below for a list of potential adverse events associated with Harmony TPV implantation. During deployment, the DCS can be advanced or withdrawn prior to the outflow struts protruding from the capsule. Once the TPV struts contact the anatomy during deployment, it is not recommended to reposition the device. Advancing the catheter forward once the TPV struts make contact with the anatomy may lead to an undesired deployment or may cause damage to or failure of the TPV and injury to the patient. Refer to the section below for a list of potential adverse events associated with the Harmony TPV implantation. Physicians should use judgment when considering repositioning of the TPV (for example, using a snare or forceps) once deployment is complete. Repositioning the bioprosthesis is not recommended, except in cases where imminent serious harm or death is possible (for example, occlusion of the main, left, or right pulmonary artery). Repositioning of a deployed valve may cause damage to or failure of the TPV and injury to the patient. Refer to the section below for a list of potential adverse events associated with the Harmony TPV implantation. Ensure the capsule is closed before DCS removal. If increased resistance is encountered when removing the DCS through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and harm to the patient. If the cause of resistance cannot be determined or corrected, remove the DCS and introducer sheath as a single unit over the guidewire, and inspect the DCS and confirm that it is complete. If there is a risk of coronary artery compression, assess the risk and take the necessary precautions. Endocarditis is a potential adverse event associated with all bioprosthetic valves. Patients should make their healthcare providers aware that they have a bioprosthetic valve before any procedure. Post-procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. Prophylactic antibiotic therapy is recommended for patients receiving a TPV before undergoing dental procedures. Post-procedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment and/or institutional protocol. Excessive contrast media may cause renal failure. Preprocedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long term.

Potential Adverse Events

Potential risks associated with the implantation of the Harmony TPV may include, but are not limited to, the following:

- death
- valve dysfunction
- tissue deterioration
- hematoma
- heart failure
- cerebrovascular incident
- perforation
- rupture of the right ventricular outflow tract (RVOT)
- compression of the aortic root
- compression of the coronary arteries
- sepsis
- pseudoaneurysm
- erosion
- stent fracture
- arrhythmias
- device embolization or migration
- pulmonary embolism
- occlusion of a pulmonary artery
- laceration or rupture of blood vessels
- device misorientation or misplacement
- valve deterioration
- regurgitation through an incompetent valve
- physical or chemical implant deterioration
- paravalvular leak
- valve dysfunction leading to hemodynamic compromise
- residual or increasing transvalvular gradients
- progressive stenosis and obstruction of the implant
- hemorrhage
- endocarditis
- thromboembolism
- thrombosis
- thrombus
- intrinsic and extrinsic calcification
- bleeding
- bleeding diathesis due to anticoagulant use
- fever
- pain at the catheterization site
- allergic reaction to contrast agents
- infection
- progressive pulmonary hypertension
- progressive neointimal thickening and peeling
- leaflet thickening
- hemolysis

General surgical risks applicable to transcatheter pulmonary valve implantation:

- abnormal lab values (including electrolyte imbalance and elevated creatinine)
- allergic reaction to antiplatelet agents, contrast medium, or anesthesia
- exposure to radiation through fluoroscopy and angiography
- permanent disability

Please reference the Harmony TPV system instructions for use for more information regarding indications, warnings, precautions, and potential adverse events.

Caution: Federal law (USA) restricts these devices to the sale by or on the order of a physician.

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TABLE 1 Heart Catheterization Data

Parameter	Before O ₂ Inhalation	After O ₂
sPAP (systolic)	120 mm Hg	105
dPAP (diastolic)	70 mm Hg	60
mPAP (mean)	88 mm Hg	78
Aortic pressure (mean)	60 mm Hg	60
PVR	26 wood	22
CI	3 L/min/m ²	3

Systolic Pulmonary Arterial Pressure (sPAP) and diastolic Pulmonary Arterial Pressure (dPAP) and mean Pulmonary Arterial Pressure (mPAP). PAP (Pulmonary Artery Pressure), PVR (Pulmonary Vascular Resistance), CI (Cardiac Index).

treatment, it may be rapidly progressive and ultimately fatal, although rare cases of spontaneous regression have been reported. The incidence and prevalence of IPAH and HPAH are lower in children than in adults. However, children still represent a significant proportion of PAH cases.²

Case Report

A 4-year-old girl with 15 kg weight, non-diabetic, normotensive, referred to us in October 2019. She had shortness of breath and exertional intolerance without any remarkable medicine history. She lives in Tehran.

Her family history was negative for PPH. On physical examination, she was neither cyanosed, nor clubbed, respiratory rate was 50 breaths/min.

Pulse rate was 110 beats/min in regular rhythm. Blood Pressure (BP) measured 100/70 mmHg. S1 was normal, but P2 was very loud and there was an early diastolic murmur along the left sternal border and a systolic murmur in the tricuspid area. Respirations were regular and the rest of her examination revealed no abnormalities. Complete Blood Count (CBC), electrolytes, urine analysis, renal and Liver Function Tests (LFT) were normal, rheumatoid factor, and

Anti-Nuclear Antibody (ANA) were negative. Chest radiography revealed cardiomegaly and prominent pulmonary arteries.

Echocardiography (ECG) showed normal sinus rhythm, right axis deviation, and right ventricular hypertrophy. Transthoracic Doppler echocardiogram showed a dilated right ventricle. Interatrial and interventricular septa were intact with no patent ductus arteriosus flow. Mitral and aortic valves were normal. LVEF was 65%. There was no pericardial effusion, no vegetation or thrombus. Doppler study showed severe Tricuspid Regurgitation (TR). Pulmonary artery systolic pressure was estimated to be 100 mmHg. Cardiac catheterization revealed severe pulmonary hypertension with pulmonary artery pressure (120-70) mmHg and mean pulmonary artery pressure of 88 mmHg (Table 1).

Computed tomography ruled out a possible pulmonary embolism. The treatment was initially started with sildenafil and Bosentan. Sildenafil administered as 15 mg per day in three parts and Bosentan administered 1/4 Tab orally once daily. After two months TransThoracic Echocardiography (TTE) showed moderate TR. PAP was 50-76 mmHg. Prednisolone with dose of 1 mg/kg/day (in three parts) added to sildenafil and Bosentan. After two weeks of initial prednisolone, PAP had dramatically decreased and TTE showed mild TR (PPG=45 mmHg), and mild PI (PPG=29 mmHg).

The patient was followed up for PAP evaluation with transthoracic echocardiography every week. Prednisolone was administered for two months and tapered off within two weeks.

Discussion

In young children with PAH, the pathophysiology suggests the failure of the neonatal vasculature to open and a striking reduction in arterial number. In older children, intimal hyperplasia and occlusive changes are found in the pulmonary arteries, plexiform lesions, and thickening of the pulmonary adventitia and venous hypertrophy as well as endothelial cell hyperplasia. Immunohistochemical changes include increased expression of TGF-B matrix Protein and macrophages,³ as well as the molecules observed with advanced lesions in congenital heart defect patients, that are fibronectin, tenascin C, and S100 A4/MtS1.

TABLE 2 Echocardiographic Data

Parameter	Before Vasodilator Therapy	1 Month after Sildenafil and Bosentan	2 Weeks after Prednisolone (15 mg/day)	4 Weeks after Prednisolone (15 mg/day)	2 Weeks after Tapering of Prednisolone (5 mg/day)	1 Month after Discontinuance of Prednisolone
TR (PPG)	83	71	45	40	42	70
PI (PPG)	57	45	29	30	40	50
RV TAPSE (cm)	1.8	1.8	2	1.8	1.6	1.6
RVsm (cm/s)	12	12	12	12	12	12
RV MPI	0.98	0.94	0.66	0.60	0.60	0.7

TR (Tricuspid Regurgitation), PI (Pulmonary Insufficiency)



TABLE 3 PAP Before and After Prednisolone Therapy

Parameter	Pre-Prednisolone Therapy	4 Weeks after Prednisolone
sPAP	80	45
dPAP	50	35
mPAP	70	41

sPAP (systolic Pulmonary Artery Pressure), dPAP (diastolic Pulmonary Artery Pressure), mPAP (mean Pulmonary Artery Pressure)

An inflammatory response is also seen in idiopathic PAH, with heightened circulating cytokines and their receptors. They increase Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) in pulmonary arteries of patients with IPAH. Neutrophil elastase expression in cultured pulmonary artery smooth muscle cells and is localized to neointimal lesions in lungs from patients with idiopathic pulmonary artery hypertension (IPAH).⁴

Prednisolone can suppress neutrophil elastase expression and suppress the inflammatory response that is seen in idiopathic PAH through inhibiting the production of pro-inflammatory and proliferative fibrogenic cytokines, and controlling both immunologically induced intimal hyperplasia, and the general immune response.

This case is unique as it is the first reported case that used prednisolone to reduce PAH in PPHTN. In this study, after two weeks of initial prednisolone, pulmonary artery pressure reduced from a mean value of 70 mmHg to 41 mmHg (Table 3), and one month after discontinuing prednisolone it increased to 70 mmHg.

Immunosuppression might theoretically arrest and even relieve vascular obstruction and systematic symptoms. However, patients with PPH may have an immune-mediated disease.⁵ We suggest further study of the effect of systematic corticosteroid therapy in the subgroup of patients with severe and uncontrollable PPH.

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Illustrated Field Guide to Congenital Heart Disease and Repair

4th Edition - 2021

Authors: Allen Everett, MD & Scott Lim, MD

Publisher: Scientific Software Solutions, Inc. Charlottesville, VA

Reviewed by John Moore, MD, MPH

Does anyone buy medical books anymore? No, of course not. Everything is readily available on line. Right?

And, who carries manuals in their lab coat these days? Are you kidding? All you need is a working smart phone. It's all on UpToDate. Yes?

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Scientific Software Solutions' *Illustrated Field Guide to Congenital Heart Disease and Repair* is extraordinary. This manual is comprehensive yet concise; organized intuitively according to actual practice of pediatric cardiology; and timely in all aspects (treatments, procedures, pharmacy, and ICU). It is truly a useful "lab coat reference" for cardiology fellows, residents, and medical students; and it is a great "hand carry" tool for pediatric cardiology nurses, physician assistants and technologists of all stripes. The *Field Guide* also provides numerous figures which attending cardiologists will find to be outstanding visual aids for teaching patients, families and students. You will want a hard copy.

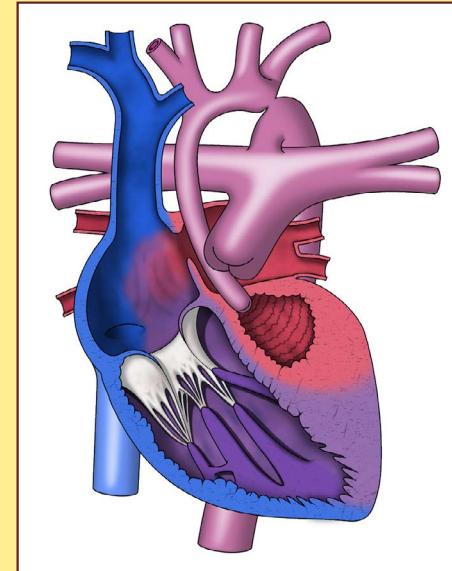
The *Field Guide* provides content on the Normal and Fetal Heart, Congenital Heart Defects, Echocardiography, Catheterization Lab Interventions, Percutaneous Valve Insertion, Hybrid Therapies, Congenital Heart Surgeries, Cardiac ICU Topics, Electrophysiology, and Cardiac Pharmaceuticals. It includes a useful table giving the *Guide's* contents in detail. In this table, where applicable, individual topics are presented in alphabetical order (e.g., for Defects, Surgeries, and Pharmaceuticals). This allows readers to find topics of interest very quickly and efficiently.

"The facts, ma'am, just the facts." That's how I regard the text in this guide. For example, each of the common defects is described with brief paragraphs summarizing anatomy, pathophysiology and therapy. These descriptions are supplemented by simple, color-coded and labeled drawings which make the text very understandable. The common catheter interventions are outlined and illustrated with color figures, stills from angiograms and echocardiograms, and drawings of specialized catheters employed and/or devices implanted. Similarly, hybrid procedures and surgeries are described and illustrated by simple, labeled color figures. Evaluation and treatment of cardiac ICU patients and arrhythmias are also very well outlined and described using excellent figures which aid in understanding the concepts. The final chapter provides a practical reference about virtually all the pharmaceuticals currently used in cardiac care.

The *Field Guide* is not a comprehensive textbook of pediatric cardiology or pediatric heart surgery. Nor is it a sufficient reference for those who are learning to record and read echocardiograms or to perform cardiac catheterization. But, the *Field Guide* does describe virtually all of the important fundamentals of pediatric cardiology and heart surgery very well. If you know what's in the *Field Guide*, you will be literate in these fields, and you will be able to interact successfully with senior cardiac practitioners, the pediatric heart care team, heart patients and their families.

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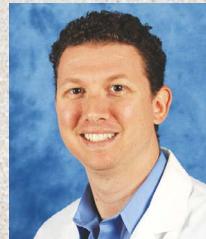
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Himanshu Adlakha, MD ★●
Fetal and Pediatric Cardiology



To discuss the needs of a prospective patient, or to schedule an appointment in Northern Broward, Palm Beach or Martin counties, please call the Nicklaus Children's Heart Institute at **561-514-7390**. We are also available to consult with other healthcare providers at any time of the day or night via our 24/7 on-call cell phone number at **561-203-1026**.

■ **Nicklaus Children's Pediatric Specialists at Coral Springs**
9750 NW 33rd Street, Suite 109, Coral Springs, FL 33065
nicklauschildrens.org/CoralSprings

★ **Nicklaus Children's Boynton Beach Care Center**
10383 Hagen Ranch Rd., Suite 200, Boynton Beach, FL 33437
nicklauschildrens.org/BoyntonBeach

♦ **Nicklaus Children's Palm Beach Gardens Outpatient Center**
11310 Legacy Ave., Legacy Place, Palm Beach Gardens, FL 33410
nicklauschildrens.org/PalmBeach

● **Nicklaus Children's Pediatric Specialists at Palm City**
3228 SW Martin Downs Blvd., Suite 33, Palm City, FL 34990
nicklauschildrens.org/PalmCity



Introducing the PICS Society

On behalf of our Board, our volunteer committees and our growing global membership, we are honored to introduce the *PICS Society*, the professional society devoted solely to specialists in minimally invasive treatment of congenital heart disease (CHD). We represent the collective voice of physicians, nurses and technologists in our growing field. We foster the highest quality of care by connecting our community and learning from one another. Join us and strengthen our voice!

Our Vision

A world where anyone who can benefit from minimally invasive techniques to treat CHD can access safe, effective care.

Our Mission

We promote the highest quality care globally for infants, children and adults with CHD through minimally invasive techniques. We partner to further knowledge and skills of all involved, fostering research, education and advocacy on behalf of you and the patients we are privileged to treat.

Background and History

We are new AND we are also celebrating our 25th silver anniversary! We have a new name (and a new logo!) but our history runs deep. Since 1997 the *PICS Foundation* has held the annual *Pediatric & Adult Interventional Cardiac Symposium*. The Symposium has a proud history of excellence in education for physicians, nurses and technologists in our field. Each year the Symposium focuses on the newest technologies, teaching via live cases, dealing with (and avoiding) challenges, tried-and-true refreshers and much more. The Symposium will continue as best-in-class for many years to come. **However...**

2020 - Transformation and Growth

In recent years, many reached out to Symposium organizers recommending that our profession needs its own medical professional society devoted solely to our maturing discipline. Common threads emerged, threads which quickly became the core values of our—**your**—new professional organization. Here are those values:

- Our perspective is truly international
- Our leadership comes from many nations
- Our commitment is to the highest quality care
- Rigorous, high standards for membership are key
- Education is year-round, available anytime
- We must lead in developing guidelines
- We are pursuing universal advocacy principles
- Respectful partnership with national societies is vital
- We take pride in working with our industry partners
- We commit to mentoring the “next generation”
- We will ensure the Symposium continues best in the field
- We are VERY affordable to all who wish to join us

As a result, in our 25th anniversary year the *PICS Foundation* has formally transformed into the *PICS Society*, the professional global “home” for those dedicated to our field. We are equally dedicated to partnering with national societies to ensure their continued growth. This signifies transformation of our global profession into a recognized, unified community of dedicated medical providers.

The *PICS Society* will continue to offer the annual *PICS Symposium* as our flagship event. As a professional society of global colleagues, we will also do more—MUCH more. Join us!



PICS Society

Pediatric **and** Congenital Interventional Cardiovascular Society

PICS Society Representative Activities

Adult Congenital Heart Disease: Our profession now treats adults of all ages who have CHD. This Committee coordinates educational programs, guidelines, advocacy, early career, quality & industry engagement in Adult CHD (led by Drs. Jamil Aboulhosn, Eric Horlick and Lars Sondergaard).

Advocacy: Patients who can be helped should not be barred from treatment due to non-medical issues. We will engage relentlessly with policymakers and payors in pursuit of that goal (Drs. John Cheatham, Hideshi Tomita and Cliff Kavinsky).

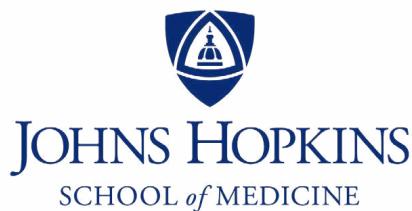
Evidence/Documents/Guidelines: The need is urgent. While other societies have produced excellent documents that address this in part, until now no international organization has focused solely on standards of care in our field. We are changing that (Drs. Doff McElhinney, Peter Ewert and Athar Qureshi).

Early Career Development: Our Fellows & Early Career Course will be August 2021 in Las Vegas, the first global program for next generation CHD interventionists. We are engaging future leaders to learn, grow & lead (Drs. Aimee Armstrong, Darren Berman, Gianfranco Butera, Vivian Dimas and Dan Gruenstein).

Industry Relations: Thanks to decades of partnership between physicians and innovative companies, our ability to treat those with CHD has advanced exponentially. The *PICS Society* is proud of those partnerships and actively partners with industry on behalf of the patients we all serve (Drs. Evan Zahn, Tom Forbes and Gregor Krings).

Membership: Our members believe it a privilege to care for patients of all ages with CHD. We are THE professional home for CHD interventional professionals globally. We welcome all physicians, nurses and technologists who commit to the highest standards of patient care (Drs. Shakeel Qureshi, Jae Yong Choi and Allison Cabalka).

Nurses, Technologists & Other Medical Professionals: Our commitment to engaging the care team into all we do is a core value. We also engage with professional societies in allied disciplines. (Dr. Sharon Cheatham and Ms. Kathleen Nolan).



Director of Outpatient Cardiology

The Blalock Taussig Thomas Pediatric and Congenital Heart Center

The Johns Hopkins University School of Medicine is seeking an experienced pediatric cardiologist to be the Director of Outpatient Cardiology. Applicants should be at least five years after fellowship training and have extensive experience as an active pediatric cardiologist in the outpatient setting.

The rank of this position will be based on clinical and academic achievements. The Bloomberg Children's Center of Johns Hopkins Hospital has ten outpatient clinic sites located across the state of Maryland servicing the needs of patients of all ages with congenital and acquired heart conditions. The successful applicant will direct the structure of the outreach sites, develop collaborations, and participate in pediatric cardiology fellow education.

Our pediatric and congenital cardiology program is medium-sized with excellent support in noninvasive imaging, electrophysiology, catheterization, heart failure, adult congenital heart disease, fetal cardiology, pulmonary hypertension, and full range of pediatric and adult subspecialties.

Our goal is to recruit a talented individual with strong interpersonal and communication skills who is committed to excellence in patient care, education, and scholarly advancement. The ability to work effectively with faculty members from a variety of clinical disciplines is particularly important.

Interested candidates should forward their CV to: skutty1@jhmi.edu

Shelby Kutty, MD, PhD, MHCM
Director, Pediatric and Congenital Cardiology

Johns Hopkins School of Medicine
Taussig Heart Center – M2315
1800 Orleans Street, Baltimore, MD 21287



PICS Annual Scientific Symposium: We (sixteen course directors) look forward to welcoming everyone from around the globe in-person September 2021 at the Aria Convention Center in Las Vegas, Nevada.

Professional Education: With the evolution of the Foundation to become the *PICS Society*, we expanded our educational offerings to include Master Class webinars and fellows-in-training courses, with much more planned (Drs. Dan Levi, Teiji Akagi and Tom Jones).

Quality Improvement: We are leading development of a major clinical document, "Standards for Cardiac Catheterization of Pediatric Patients & Patients with CHD" partnering with six other societies, the first global comprehensive guideline for quality in our field. Other Q.I. initiatives are in the queue (Drs. Ralf Holzer, Lisa Bergersen and John Thomson).

For more information, please go to www.CHDinterventions.org (click on "PICS Society") or email nlinsky@CHDinterventions.org.



PICS Society Leadership



ZIYAD M. HIJAZI, MD, MPH, FPICS

President
Doha, Qatar



DAMIEN KENNY, MD, FPICS

Vice President
Dublin, Ireland



LEE BENSON, MD, FPICS

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MARIO CARMINATI, MD, FPICS

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BHARAT DALVI, MD, DM, FPICS

Board Member
Mumbai, India



JACQUELINE KREUTZER, MD, FPICS

Board Member
Pittsburgh, Pennsylvania USA

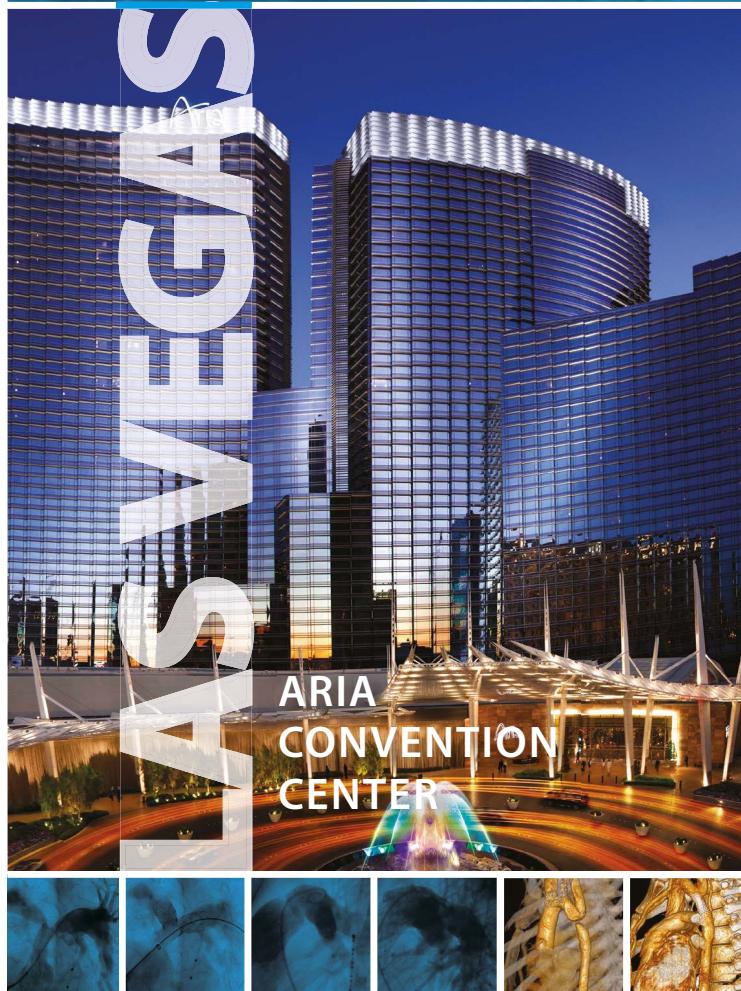


CARLOS PEDRA, MD, PHD, FPICS

Board Member
Sao Paulo, Brazil



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DATE 2021



Focusing on the latest interventional catheter strategies for congenital and structural heart disease in children and adults.

www.picsymposium.com

www.CHDinterventions.org



Atrium Health

Pediatric Imaging Cardiologist

Sanger Heart & Vascular Institute / Levine Children's Hospital

The Congenital Heart Center at Levine Children's Hospital (LCH) and **Sanger Heart & Vascular Institute (SHVI)**, seeks to recruit a **Pediatric Imaging Cardiologist** to join their existing faculty.

- Candidates will have completed an ACGME accredited fellowship in pediatric cardiology and be BC/BE by the American Board of Pediatrics; expertise in echocardiography and congenital heart disease, which includes transthoracic, transesophageal, and fetal echocardiography; responsibilities will include both outpatient and inpatient cardiology. Minimum five (5) years of post-fellowship experience preferred, with potential to join as Medical Director of the Echocardiography Program.
- Team includes: 13 cardiologists, 5 cardiac intensivists, 4 pediatric cardiac anesthesiologists, 2 pediatric cardiac radiologists, 18 APPs (includes 2 surgical APPs), 3 Surgeons, 13 sonographers, 4 nurse navigators and 5 dedicated RNs.

The Congenital Heart Center, established in 2010, has been ranked as one of the top-50 pediatric heart centers in the country by U.S. News and World Report for the last nine years. Our comprehensive services include cardiac imaging, diagnostic and interventional catheterization, electrophysiology, dedicated cardiovascular intensive care staff, and regional referral programs in heart failure / transplantation, adult congenital heart disease, and fetal echocardiography. Program volume has been growing secondary to increased referral patterns and regional population growth. Our new outpatient suite will be opening in December 2020, designed to treat all from fetal cardiology to ACHD. Our state-of-the-art two lab cardiac catheterization and electrophysiology suite opened in February of 2017, with dedicated staffing and anesthesia teams. We have one of the most comprehensive Cardiac Neurodevelopment programs in the region, providing a multitude of specialty services to our congenital heart population in the same office suite. Participation in investigator initiated and multi-center industry sponsored studies is ongoing within the Heart Center, with the support of an active clinical research department.

Levine Children's Hospital (LCH) is a state-of-the-art facility open since 2007 in beautiful Charlotte, North Carolina. LCH has 11 floors and 234 inpatient beds, including an on-site PICU and CVICU covered 24/7 by in-house intensivists, Progressive Care Unit, Inpatient Observation Unit, Pediatric Rehab Unit and Pediatric Emergency Department. We are committed to being the region's leading provider of pediatric health care services.

LCH and SHVI are both premier referral facilities within Atrium Health and one of the nation's leading and most innovative healthcare systems. Atrium Health employs nearly 2,500 system-employed physicians, more than 60,000 employees, and more than 7,460 licensed beds across the Carolinas and Georgia.

Sanger Heart & Vascular Institute is one of the Southeast's largest cardiac and vascular programs providing the highest quality care available to patient with cardiovascular disease throughout North and South Carolina. Sanger employs more than 110 physicians in a network of more than 25 locations to provide the highest quality care available to patients with cardiovascular disease throughout North and South Carolina. Sanger has more than 50 years of experience providing world-class, comprehensive acute and chronic cardiovascular services including the region's only heart transplant center and pediatric heart surgery program.

To apply or for more information, please contact:

Kathrine Hatcher
Physician & APP Recruiter
Kathrine.hatcher@atriumhealth.org



Coronary Anomalies Research Education to Develop a Patient Centered Outcomes Research Agenda to Engage Children Living with Anomalous Aortic Origin of the Coronary Artery

On behalf of the CARE Collaborative (Coronary Anomalies Research Education), we hope this letter finds you well. Our team received exciting news at the close of 2020 about the proposal we submitted to the Patient-Centered Outcomes Research Institute (PCORI). The awarded proposal aims to engage children living with Anomalous Aortic Origin of the Coronary Artery (AAOCA) and their parents, along with clinicians and relevant stakeholders such as you and your group, to develop a patient-centered outcomes research agenda. Since the proposal was awarded, we have diligently been working to develop our tools for identifying the patient reported outcomes which will form the research agenda.

Our team is composed of enthusiastic clinicians from pediatric care centers (University of Texas/Dell Children's Medical Center, Boston Children's Hospital, Children's Hospital of Philadelphia, and Texas Children's Hospital) and parents of children who have been diagnosed with AAOCA, a congenital coronary artery anomaly and the second leading cause of sudden cardiac death in the youth. We are formally referred to as the CARE Collaborative and look forward to engaging with relevant stakeholders such as you and your organization, and the lives you touch that positively support the quality of life of these children and their families.

As you may know, children and young adults with congenital coronary anomalies are at an increased risk of sudden cardiac death, especially during exercise. Your organization has been engaged in preventing sudden death in the young, including athletes, and has advocated for continued efforts to prevent such a devastating event. The mechanism of sudden cardiac death, the actual risk for individual patients, and the effectiveness of different therapies are unknown in patients with coronary anomalies. Despite the anxiety and anguish faced by patients and families, there has been no patient/family engagement to define research priorities and the most relevant outcomes to be measured. Our collaborative is deeply invested in engaging a wide range of stakeholders to develop a patient-centered research agenda, creating a network of stakeholder collaborators for future research initiatives, and identifying and

prioritizing patient-centered questions and gaps in care. The success of this project hinges upon a series of focus groups, surveys, and webinar workshops with different stakeholders, in particular patients and families.

Through this communication, we want to express our hope that you and your organization desires to and has the capacity to partner with us in this project. Our team will distribute a study summary report. We truly believe our findings will be helpful to other cardiovascular conditions in which patients and families face challenges living with.

We would be happy to discuss the project further by phone, video conference, or additional email communication. You can also reach us directly at info@carecollaborative.net.

Thank you for your time and please let us know how we can be of any assistance or provide any additional information.

Sincerely,

Silvana Molossi, MD, PhD, on behalf of the CARE Collaborative
Associate Chief, Section of Cardiology
Medical Director, Coronary Anomalies Program
Associate Professor, Department of Pediatrics
Texas Children's Hospital
Baylor College of Medicine
6651 Main St. MC E1920
Houston, Texas 77030
smolossi@bcm.edu
sxmoloss@texaschildrens.org
P. 832.826.5600
F. 832.826.4290

To participate in the survey, please follow the link below:
https://utexas.qualtrics.com/jfe/form/SV_cCodozyThXdZMVv



Pediatric and Congenital Interventional Cardiovascular Society



Announcing the First Annual
PICS Fellows & Early Career Course

August 30 & 31, 2021

ARIA CONVENTION CENTER, LAS VEGAS



**Nicklaus
Children's
Hospital**

Heart Institute

Outstanding Opportunity for Director of Adult Congenital Heart Disease in Miami

Nicklaus Children's Hospital, a 309-bed freestanding children's hospital, and Nicklaus Children's Pediatric Specialists, the physician multispecialty group practice of Nicklaus Children's Health System, have an exceptional opportunity for an adult congenital heart disease specialist to direct the Adult Congenital Heart Disease (ACHD) Program.

The Nicklaus Children's Hospital Heart Institute is a world leader in cardiology and cardiovascular surgery for the care of patients with congenital heart disease. Nicklaus Children's Hospital is expanding its services to the growing number of adult congenital heart disease patients in partnership with top-ranked adult specialists in the region. Interested candidates for the ACHD directorship should have completed a residency in either pediatrics, internal medicine or a combined med/peds program, followed by a three-year fellowship in either pediatric or adult cardiology. Either completion of a two-year ACGME accredited ACHD fellowship or a career demonstrating clinical and academic leadership in the field of ACHD is required. The candidate should be board certified in ACHD.

Nicklaus Children's Hospital is an affiliate of the Florida International University Herbert Wertheim College of Medicine. Our state-of-the-art Advanced Care Pavilion houses a 34-bed cardiac in-patient unit with an adjustable acuity model that allows all rooms to accommodate critically ill patients with heart disease. The Heart Institute offers a full range of services, including the management of patients following congenital heart surgery, interventional catheterization and invasive electrophysiology. Our cardiac surgical program, led by Dr. Redmond Burke, is one of the most transparent in the world. It remains the only cardiovascular surgical program to offer real-time outcomes reporting <https://rto.nicklauschildrens.org>.

Competitive compensation and benefits package.

Qualified candidates please contact:

Lourdes Prieto, MD
Interim Chief, Cardiology
Lourdes.Prieto@nicklaushealth.org

Joyce Berger
Physician Recruiter
Joyce.Berger@nicklaushealth.org
786.624.3510



Children's Minnesota Receives Heart Transplant Certification

Launches Heart Transplant Program Dedicated to Pediatric Patients

Children's Minnesota announced that it received the Centers for Medicare and Medicaid Services (CMS) certification of its Heart Failure and Heart Transplant program. Children's Minnesota launched its heart transplant program in 2018 after receiving Organ Procurement and Transplantation Network (OPTN) certification. OPTN certification allowed the organization to begin performing heart transplants, and the first heart transplant occurred later that year. Children's Minnesota provides cardiac care to the majority of pediatric cardiovascular patients in the region. The dedicated pediatric heart transplant program at Children's Minnesota is among the most comprehensive pediatric cardiology services in the region.

"We knew we needed to add heart transplant capabilities in order to better serve and care for our patients," said Dr. Erik Edens, medical director of the Heart Failure and Heart Transplant program. "Our program is dedicated to treating pediatric cardiovascular patients; we will now be able to offer the specialized expertise needed to care for patients throughout every stage of their journey."

Learn more about Children's Minnesota's heart transplant program:

<https://www.childrensmn.org/services/care-specialties-departments/cardiovascular-program/conditions-and-services/heart-failure-therapy-and-heart-transplant/>

Since the first heart transplant at Children's Minnesota in 2018, six heart transplants have been successfully performed. The program also provides advanced heart failure therapies including medical management and ventricular assist device (VAD) placement which provides a bridge to heart transplant for children waiting for a donor heart to become available.

"Our cardiovascular program is dedicated to advancing the field of cardiac care through research and innovation," said Dr. Robroy MacLver, congenital heart surgeon and Surgical Director of Transplantation. "We are proud of the team's work to launch this program and look forward to helping children across the region in need of cardiovascular care."

About Children's Minnesota

Children's Minnesota is the seventh largest pediatric health system in the United States and the only health system in Minnesota to provide care exclusively to children, from before birth through young adulthood. An independent and not-for-profit system since 1924, Children's Minnesota serves kids throughout the Upper Midwest at two free-standing hospitals, 12 primary and specialty care clinics and six rehabilitation sites.

Find us on Facebook [@childrensmnnesota](#) or on Twitter and Instagram [@childrensmn](#). Please visit [childrensmn.org/](https://www.childrensmn.org/)





Combined Cath Approach No Match for Surgery for Aortic Stenosis, CAD

Pacemakers Increasingly an Issue in TAVR Plus PCI

The percutaneous-only approach to aortic stenosis and coronary artery disease (CAD) left patients with higher rates of cardiac and vascular complications compared with surgery, researchers reported. Data from the National Inpatient Sample (NIS) showed that in-hospital mortality in 2012-2017 reached 5.1% after transcatheter aortic valve replacement (TAVR) plus percutaneous coronary intervention (PCI), which was not significantly higher than the 3.5% after surgical aortic valve replacement (SAVR) plus coronary artery bypass grafting (CABG; adjusted OR 1.09, 95% CI 0.95-1.26). Even so, complication rates favored SAVR plus CABG over the combined transcatheter approach when it came to pacemaker implants, cardiac arrest, and vascular complications, reported Sri Patlolla, MBBS, of the Mayo Clinic in Rochester, Minnesota, at the Society of Thoracic Surgeons (STS) virtual meeting.

On the other hand, TAVR plus PCI was associated with less hemodialysis and prolonged ventilation. Stroke was comparable between groups. Patlolla reminded attendees that 60% of patients receiving aortic valve interventions have CAD, and that guidelines recommend concomitant CABG at the time of SAVR to avoid the risk of repeat sternotomy. Notably, NIS data showed that the proportion of people getting TAVR plus PCI increased from 1.1% in 2012 to 9.6% in 2017, with corresponding losses in SAVR plus CABG. The good news for the transcatheter approach was that mortality fell from more than 16% to below 4% over the same period ($P<0.001$). However, the rise of pacemaker implants after TAVR plus PCI was a worrying trend (4.8% in 2012 to 13.5% in 2017).

Study findings confirm that the transcatheter field is improving rapidly, whereas surgery is already a mature procedure, commented STS discussant Michael Reardon, MD, of Houston Methodist DeBakey Heart & Vascular Center. What's more, the study ended in 2017, when TAVR was still being performed in higher-risk patients who may not be comparable to peers getting surgery. Since TAVR's FDA approval for low-risk patients in 2019, young patients are increasingly opting for TAVR in contemporary practice. Randomized data stratified by the two combined approaches are scarce but do exist, Reardon said, citing SURTAVI as one example showing the transcatheter method to be a reasonable alternative to surgery.

In the present study, participants were split between the combined surgical group ($n=106,510$) and the transcatheter group ($n=4,850$). Patlolla's group excluded people with other concomitant major cardiac procedures and those getting CABG and PCI during the same hospitalization. Compared with those receiving the combined percutaneous treatment, the surgical cohort was significantly younger (mean 72.7 vs 80.5), more likely to be male (72.7% vs 53.0%), and had a lower comorbidity index score (4.8 vs 6.6). Compared with their surgical peers, the transcatheter cohort was significantly more likely to be discharged home. These patients also had shorter lengths of hospital stay (7 vs 8 days), but consistently higher hospitalization costs (median \$272,000 vs \$175,000).

Stratifying patients by how their dual procedures were staged, Patlolla reported that the 145 people who received PCI after TAVR had especially high complication rates (24.1% mortality, 10.3% vascular complications, 3.4% stroke). Yet it was the 1,665 people with PCI staged before TAVR that had the highest pacemaker rate, at 12%. The authors acknowledged that their analysis relied on the NIS data being accurate. Moreover, the dataset lacked information on CAD severity or important procedural characteristics such as type of valve, the group cautioned. Thus, the investigators attempted to adjust for differences between surgical and percutaneous groups, but left room for bias and confounding; a center's heart team would have decided what is the best therapy for a patient with aortic stenosis and CAD, and adjusting for such judgment is difficult if not impossible, Reardon said. Reardon's suggestion to perform propensity score matching would require more granular data than what was at hand, Patlolla said.



Joe DiMaggio Children's Hospital

Join a Leading Children's Hospital in South Florida



Pediatric Cardiac Imaging Physician Career Opportunity

Joe DiMaggio Children's Hospital, located in South Florida, is recruiting for a board certified pediatric cardiologist with specialty training and experience in advanced cardiovascular imaging for pediatric and congenital heart disease. Primary responsibilities will be for children and adults with congenital heart disease in need of cardiac imaging, including transthoracic and transesophageal echocardiography as well as cardiac magnetic resonance imaging. Additional responsibilities will include related outpatient clinic evaluations, sharing inpatient night and weekend call and occasional coverage of the inpatient service. Candidate will participate in research opportunities with supportive resources.

Cardiac imaging volume has been steadily increasing specifically for CMR cases. Currently there are four available Siemens 1.5T scanners with state of the art clinical and research sequences, including 4D flow, turbo flash first pass perfusion with perfusion quantification post-processing capabilities, myomaps (T1, T2 and ECV analysis) and many others. The candidate must hold a cardiac MRI level II or III certification by the Society of Cardiovascular Magnetic Resonance.

The CMR Stress Perfusion Program at Joe DiMaggio Children's Hospital is the only one available in the region and has grown in the last couple of years. In our Heart Transplant Program, CMR has also become one of the non-invasive imaging modality of choice for patients with suspected allograft rejection and/or coronary vasculopathy.

Our echo lab is equipped with state of the art GE E95 machines for transthoracic and transesophageal echocardiography and Voluson E10 for fetal echocardiography. Echo images are manipulated in raw data using ViewPoint (ECHOPAC) software for post-processing.

This is a full-time employed position with the multispecialty Memorial Physician Group. The position offers competitive benefits and a compensation package that is commensurate with training and experience. Professional malpractice and medical liability are covered under sovereign immunity.

About Joe DiMaggio Children's Hospital

Joe DiMaggio Children's Hospital (JDCH) is a 226-bed free-standing children's hospital located in Hollywood, Broward County, Florida. As one of six hospitals in one of the largest public health systems in the country, Memorial Healthcare System, JDCH delivers nearly 14,000 babies per year and has 132 Neonatal Intensive Care Unit beds in three of its hospitals. Memorial also has three pediatric emergency departments.

JDCH has robust high-risk and congenital programs including a US News and World Report ranked pediatric Cardiology and Heart Surgery Program, one of only two in the state who do heart transplants. JDCH's Orthopedic and Sports Medicine program is ranked by US News as number one in Florida and is one of the largest programs in the southeastern United States.

JDCH serves over 375,000 children per year and our services continue to grow with our new specialty center/ambulatory surgery center in Palm Beach County. JDCH combines leading-edge clinical excellence with a child- and family-friendly environment that emphasizes the Power of Play. JDCH offers a comprehensive range of healthcare services – delivered with kindness, dedication and compassion.

About South Florida

South Florida offers a dynamic urban/suburban lifestyle with an abundance of cultural and recreational amenities, miles of beautiful beaches, top-rated golf courses, zoos and wildlife refuges, a vibrant arts community, museums and world-class dining. South Florida's high quality of life – including year-round summer weather, exciting multiculturalism and no state income tax – attracts new residents from all over the country and around the world.

To submit your CV for consideration, please visit memorialphysician.com. Additional information about Joe DiMaggio Children's Hospital can be found at jdch.com.

LIVE. WORK. PLAY.
memorialphysician.com



**Nicklaus
Children's
Hospital**

Heart Institute

Immediate Opportunity for a Pediatric Cardiologist to Join a Thriving Practice in Palm Beach County, Florida

Nicklaus Children's Hospital, a 309-bed freestanding children's hospital and Level I trauma center, and Nicklaus Children's Pediatric Specialists, the physician multispecialty group practice of Nicklaus Children's Health System, have an exceptional opportunity for a BC/BE fellow-trained pediatric cardiologist.

Join a thriving and expanding group in Palm Beach County, Florida. The candidate will provide comprehensive outpatient and inpatient consultative services and should be highly skilled in noninvasive imaging, including fetal cardiology. This role presents a unique and exciting opportunity for a motivated candidate to flourish in a burgeoning market and reside in one of the most sought-after neighborhoods in Florida.

The Nicklaus Children's Hospital Heart Institute is a world leader in pediatric cardiology and cardiovascular surgery for the care of children with congenital heart disease and serves as a beacon to families confronting the reality of a child or newborn with a heart defect. The institute offers a full range of services, including the management of patients following congenital heart surgery, interventional catheterization and invasive electrophysiology. Our cardiac surgical program, led by Dr. Redmond Burke, is one of the most transparent in the world. It remains the only cardiovascular surgical program to offer real-time outcomes reporting (<https://rto.nicklauschildrens.org>).

With a historic legacy a century in the making, Palm Beach County, located just north of Miami and Fort Lauderdale, is home to 38 cities and towns and offers an array of cultural and outdoor events. Enjoy abundant sunshine and activities such as golfing, swimming, hiking and sport fishing, all year round.

Competitive compensation and benefits package.

Qualified candidates please contact:

David Drossner, MD

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David.Drossner@nicklaushealth.org

Lourdes Prieto, MD

Interim Chief, Cardiology
Lourdes.Prieto@nicklaushealth.org

Joyce Berger

Physician Recruiter
Joyce.Berger@nicklaushealth.org
786.624.3510

NicklausChildrens.org/NCPS

DFW

Canon Medical Receives FDA Clearance on One-Beat Spectral Cardiac CT

Aquilion ONE / PRISM Edition Now Offers AI Powered Spectral Capabilities for Cardiac Exams

Meeting the growing cardiovascular needs of healthcare providers today, Canon Medical Systems USA, Inc. announces that its Deep Learning Spectral CT has received 510(k) clearance for expanded capabilities into cardiovascular applications. Available on the company's Aquilion ONE / PRISM Edition CT system, <https://us.medical.canon/products/computed-tomography/aquilion-one-prism/>, healthcare providers can now acquire whole-heart spectral images in one beat thanks to the system's 16 cm wide area detector, 0.275 second whole-heart acquisition with rapid kVp switching and Deep Learning Spectral Reconstruction.

Designed for deep intelligence, the Aquilion ONE / PRISM Edition integrates artificial intelligence (AI) technology to maximize conventional and spectral CT capabilities while providing deep clinical insights to assist physicians in making more informed decisions across the patient's care cycle. To make it even easier for clinicians, the fully integrated end-to-end workflow is easy to use and can be incorporated into routine protocols.

"By integrating AI into spectral imaging, Canon Medical is bringing innovative technology to the market that can make an immediate impact for clinicians, empowering them to make definitive diagnoses," said Erin Angel, Managing Director, CT Business Unit, Canon Medical Systems USA, Inc. "With Deep Learning Spectral CT, we have leveraged the power of AI to overcome several of the barriers that are otherwise associated with dual energy and spectral imaging."

About Canon Medical Systems USA, Inc.

Canon Medical Systems USA, Inc., headquartered in Tustin, Calif., markets, sells, distributes and services radiology and cardiovascular systems, including CT, MR, ultrasound, X-ray and interventional X-ray equipment. For more information, visit Canon Medical Systems' website at <https://us.medical.canon>.

About Canon Medical Systems Corporation

Canon Medical offers a full range of diagnostic medical imaging solutions including CT, X-Ray, Ultrasound and MR, across the globe. In line with our continued Made for Life philosophy, patients are at the heart of everything we do. Our mission is to provide medical professionals with solutions that support their efforts in contributing to the health and wellbeing of patients worldwide. Our goal is to deliver optimum health opportunities for patients through uncompromised performance, comfort and safety features.

At Canon Medical, we work hand in hand with our partners - our medical, academic and research community. We build relationships based on transparency, trust and respect. Together as one, we strive to create industry-leading solutions that deliver an enriched quality of life. For more information, visit the Canon Medical website: <https://global.medical.canon>.





Edwards RESILIA Tissue Aortic Valve Demonstrates Favorable Safety and Efficacy at Five Years

Edwards Lifesciences announced new data from the COMMENCE clinical trial that demonstrate Edwards' bioprosthetic surgical aortic valve with the company's novel RESILIA tissue platform show favorable safety and hemodynamic performance through a median of five years follow-up. The data were presented at the 57th annual meeting of the Society of Thoracic Surgeons.

"There continues to be a significant focus placed on tissue valve durability given the increase in life expectancy and lifestyle implications for more active patients who historically would receive mechanical valves," said Joseph E. Bavaria, MD, lead enroller and site principal investigator for the COMMENCE study and the Brooke Roberts-William M. Measey professor of surgery and vice chief of the division of cardiovascular surgery, University of Pennsylvania. "The latest data from the COMMENCE study are encouraging and speak to the promise of RESILIA tissue as a significant advancement in technology for patients with valve disease."

There were no incidences of structural valve deterioration (SVD) at the five-year review mark, a key safety outcome. SVD can be caused by a buildup of calcium on the valve's tissue or by other damage that impacts long-term durability of the valve. RESILIA tissue is specially formulated using a proprietary integrity-preservation technology that may eliminate a key factor in calcification leading to valve deterioration.

"Beyond the COMMENCE study, Edwards continues to invest in research to examine different outcome measures to further validate the long-term performance and durability of RESILIA tissue," said Daveen Chopra, Edwards' corporate vice president, surgical structural heart. "Evidence from the COMMENCE trial adds to the growing body of research that demonstrates the value of innovative, RESILIA tissue-based technologies in transforming care for patients, especially more active patients."

Current technologies utilizing this novel tissue include the INSPIRIS RESILIA aortic valve and the KONECT RESILIA aortic valved conduit, the first ready-to-implant solution for bio-Bentall procedures. In addition to its anti-calcification properties, RESILIA tissue also allows the valve to be stored under dry packaging conditions, facilitating ease of use in the operating room.

The COMMENCE study is a prospective, non-randomized, multicenter, single-arm investigational device exemption (IDE) trial comprised of 689 patients at 27 clinical sites across the United States and Europe. The trial evaluated the safety and effectiveness of Edwards' RESILIA tissue aortic valve in patients ages 18 and older with diagnosed aortic valve disease and scheduled to undergo aortic valve replacement surgery. Data were collected for a total of five years and a subset of these patients will continue to be evaluated through 10 years. At this stage, the study has recorded data equivalent to 2,989 patient-years of follow-up.

Additional RESILIA tissue studies include:

- European feasibility study: a prospective, single-arm observational clinical trial that evaluated SVD in a cohort of 133 patients. There were no events of structural valve deterioration throughout the study period of five years.
- RESILIENCE clinical trial: an ongoing, first-of-its-kind study designed to assess calcium deposits as a way to potentially predict long-term bioprosthetic valve durability. The study will enroll up to 250 patients under the age of 65 at the time of surgery to examine incidence of valve deterioration from year five to 11 after surgery.

Dr. Bavaria is a consultant to Edwards Lifesciences.



Pediatric Cardiologists

The Children's Heart Institute is a diverse and thriving practice located in Maryland and Northern Virginia that is recruiting multiple pediatric cardiologists. Candidates will be joining a group of additional cardiologists providing a full spectrum of clinical pediatric cardiology services and must be eligible for licensure within the States of Maryland and Virginia. Candidates should have completed an ACGME accredited fellowship in pediatric cardiology and be BC/BE by the American Board of Pediatrics. Renumeration for these positions will be commensurate with qualifications and experience including bonus income based on clinical success. Expected duties will include patient clinics M-F including echocardiograms, stress tests and remote patient monitoring devices while helping with hospital consults and rotating call.

Multiple positions in Northern Virginia and Maryland are being filled. They are both beautiful places to live and raise a family. The schools are highly rated and many large Tech companies are located or moving into the area making it a popular place to live. The communities are located next to our nation's capital yet have their own character reminiscent of colonial times with quaint taverns, shops and historical places to live or visit. There are countless museums, performance venues, and natural wonders. One to two hours in any direction there are diverse activities for personal enjoyment including beautiful beaches and mountain venues for hiking, camping, biking and skiing during the year. Multiple professional and collegial sports are also close by for enthusiasts in every area. Collaboration with multiple subspecialties are easily obtained within some of the top institutions in the country including Children's National, Johns Hopkins, the University of Maryland, INOVA healthcare, and the University of Virginia. Clinical research is also possible through the same venues as well as the National Institutes of Health which is located nearby in Bethesda, Maryland.

<http://childrensheartinstitute.org/>

Interest applicants should forward their CV and letters of recommendation to:

Robert Barlow, MD, PhD
rbarlow@chiva.us

We have an opening waiting to be filled immediately!



SCAI 2021: Harmony TPV Could 'Fundamentally Alter' Care for Patients with Congenital Heart Disease

Michael Walter, Structural Heart Disease

Medtronic's Harmony transcatheter pulmonary valve (TPV) is a safe and effective treatment option for patients with congenital heart disease and severe pulmonary regurgitation, according to new one-year data presented at the Society for Cardiovascular Angiography & Interventions 2021 Scientific Sessions.

The analysis included 67 patients who received the valve due to an abnormality in their right ventricular outflow tract (RVOT). Harmony TPVs in two different sizes—one with a 22-mm valve and one with 25-mm valve—were included in the team's research.

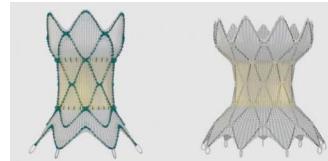
Overall, one-year findings showed that there were no instances of mortality, endocarditis, major stent fractures or surgical intervention among patients who received the Harmony TPV. More than 90% of patients had either no pulmonary regurgitation (PR) at all or just trace amounts of PR when they returned for follow-up appointments.

Two patients did require catheter reinterventions. Several patients also had stable ventricular tachycardia after the procedure, but that resolved in every instance and was not associated with any significant issues.

"This is a brand-new class of cardiac devices designated to help a very specific patient population where no less-invasive, percutaneous treatment options were available until now," Thomas Jones, MD, the study's principal investigator and director of cardiac catheterization laboratories for Seattle Children's Hospital, said in a prepared statement. "Unlike any other TPV, this novel technology is designed to expand into the enlarged RVOT in these patients while simultaneously deploying a suitable bioprosthetic pulmonary valve. The Harmony TPV system has the potential to fundamentally alter the lifetime management of CHD patients from here on out."

The Harmony TPV gained FDA approval back in March. The agency issued a press announcement to highlight the news.

"The Harmony TPV provides a new treatment option for adult and pediatric patients with certain types of congenital heart disease." Bram Zuckerman, MD, director of the Office of Cardiovascular Devices in the FDA's Center for Devices and Radiological Health, said at the time. "It offers a less-invasive treatment alternative to open-heart surgery to patients with a leaky native or surgically-repaired RVOT and may help patients improve their quality of life and return to their normal activities more quickly, thus fulfilling an unmet clinical need of many patients with congenital heart disease."



New Grants Fund Research on Congenital Heart Defects

The American Heart Association and The Children's Heart Foundation are jointly funding eight new research projects to help health care professionals better understand, identify and treat congenital heart defects.

The grants, totalling \$917,426, have been awarded to:

- Barbara Gonzalez Teran at the J. David Gladstone Institutes in San Francisco, California
- Benjamin Streeter at Emory University in Atlanta, Georgia
- Dulguun Amgalan at the Stanford University School of Medicine in Stanford, California
- Mingkun Wang at Cornell University in Ithaca, New York
- Devin Laurence at the University of Oklahoma in Norman, Oklahoma
- Sathiyanarayanan Manivannan at The Research Institute at Nationwide Children's Hospital in Columbus, Ohio
- Alexis Leigh Krup at the University of California, San Francisco
- Jennifer Klein at Children's National Medical Center and Children's Research Institute in Washington, D.C.

This is the eighth round of co-funding for the Congenital Heart Defects Research Awards program. The two organizations have pledged \$14.3 million to fund CHD research over 10 years.

"By funding research directly related to advancing the prevention, diagnosis and treatment of congenital heart defects, we are investing critical resources for more children to survive into healthy adulthoods," said Dr. Mitch Elkind, president of the AHA and professor of neurology and epidemiology at Columbia University in New York City.

"Research is the foundation of the American Heart Association. Supporting innovative research saves and improves the lives of children, and that is of utmost importance to us."

Each year, nearly 40,000 infants in the U.S. are born with congenital heart defects – the No. 1 birth defect in the country. About 25% of babies with a heart defect require invasive treatment in their first year of life, and more than 800,000 American adults are living with a CHD.

"At The Children's Heart Foundation, funding the most promising CHD research is our sole mission," said Kevin Slawin, chairman of The Children's Heart Foundation's board of directors. "Through this collaboration and our ongoing commitment to this important work, we strive to make a lasting impact in the lives of CHD patients and their families."

Scientists conducting research to advance knowledge on preventing and treating congenital heart defects are encouraged to submit applications for the next round of funding.





**More
THAN A Hospital**



Outpatient Pediatric Cardiologist Opportunity – Northeast Ohio

Ohio-based Akron Children's Hospital seeks a **Pediatric Clinical Cardiologist** to join its expanding Heart Center. Akron Children's Hospital is the largest pediatric healthcare system in Northeast Ohio and is ranked among the best children's hospitals by *US News and World Report*.

This integrated healthcare delivery system includes:

- Two free-standing pediatric hospitals
- More than 800 providers, who manage over 1.1 million patient visits annually
- A network of more than 60 primary and specialty care locations
- Robust research and innovation endeavors

The successful candidate will provide Cardiology care at the Beegly campus, expanding the services of the dedicated Heart Center team, which includes 16 pediatric cardiologists, 5 nurse practitioners and 2 cardiothoracic surgeons who provide a complete spectrum of coordinated, compassionate, cardiac care to over 10,000 patients annually. Services include: advanced diagnostics, complex surgical procedures, an adult congenital heart disease program, a fetal imaging program and a cardiac MRI program. Enjoy practicing in a comfortable community setting.

This position offers opportunities for:

- Partnership with an established team of Cardiologists affording exceptional work-life balance
- Active involvement in medical student and resident education; academic appointment at Northeast Ohio Medical University is available and commensurate with experience
- An attractive compensation plan that includes bonus compensation

Requirements include board eligibility/certification in Pediatric Cardiology and the ability to obtain an active medical license in the state of Ohio.

The Mahoning Valley is an exciting and vibrant place to live...outstanding parks, museums, theaters, art galleries, sport events, golf courses, country clubs, live concert and event venues, biking and hiking trails, lakes and much more provide residents with a dynamic choice of recreational opportunities. This area is successfully transitioning to a technology and knowledge-based economy by leveraging its industrial and academic strengths. In just the last two years, 107 businesses have invested \$682 million here, creating over 4500 new jobs!

Interested candidates may contact Jane Hensley, Physician Recruiter at 330-543-3015 or jhensley@akronchildrens.org. To learn more, visit our website at www.akronchildrens.org.



Low Radiation Possible During Cardiac Cath in Children

NYC Center Reports Encouraging Results with ALARA Radiation Protocol

Nicole Lou, Staff Writer, MedPage Today

Pediatric cardiac catheterization could be performed with low levels of radiation exposure using one center's "as low as reasonably achievable" (ALARA) protocol, researchers reported.

The strategy employed by Lisa Goto, MD, and colleagues at the Children's Hospital at Montefiore in New York City, resulted in favorable radiation levels across 95 catheterizations in 77 children weighing 20-40 kg (approximately 44-88 lbs):

- Median fluoroscopy time: 11.9 minutes
- Total air Kerma product: 38 mGy
- Dose air product (DAP): 175 μ Gym²
- DAP by weight: 7 μ Gym²/kg

Based on these findings, radiation exposure during cardiac catheterization with ALARA seems to compare favorably against published values, as Goto cited prior reports of air Kerma reaching 370-400 mGy and DAPs exceeding 2,000 μ Gym² in similar patients. She presented her group's abstract at the virtual meeting of the Society for Cardiovascular Angiography and Interventions (SCAI).

"Given the epidemiological evidence we already have that strongly suggests an increased cancer risk from medical ionizing radiation exposure to children, such findings are potentially important," commented Andrew Einstein, MD, PhD, of Columbia University Irving Medical Center in New York City.

"However, while these findings are encouraging in terms of the low radiation doses, minor complications were noted in the small sample and the study was not randomized and in fact did not even include a historical control group," he warned.

Goto asserted that ALARA did not change image quality and complication rates from standard of care. However, she did report three minor complications that were self-limited: one accelerated junctional rhythm, two broken balloons with stent placement, and one hemoptysis.

The study included children (median age 9 years, median weight 60.6 lbs) who underwent cardiac catheterization at Goto's center in 2015-2020. Excluded were transplant patients who had routine endomyocardial biopsy or biopsy with coronary angiography.

Interventions most frequently performed in these patients were atrial septal defect device closure, pulmonary artery dilation, and patent ductus arteriosus closure.

The investigators used the ALARA protocol consisting of ultra-low frame rates (2-3 frames per second) and low fluoroscopy dose (10-18 nGy/frame), plus the air gap technique (i.e., removal of anti-scatter grid, with the flat panel detector placed 110 cm from the patient).

"ALARA is especially important in pediatrics, where patients are more radiosensitive with higher rates of mitosis compared to adults," Goto said, emphasizing that children tend to be smaller and have longer life expectancies. Patients with congenital heart disease in particular may stand to benefit, as they undergo multiple catheterizations and have an increased lifetime risk of radiation exposure per year, she added.

"While Goto and Sutton's study demonstrates promise for the air gap technique, this technique cannot yet be regarded as definitive but rather warrants further investigation," Einstein concluded.



MEETING CALENDAR

JULY

16-17

CITI 2021 Complex Interventional Cardiovascular Therapy 14th Annual Conference: A Case Based Workshop

Chicago, IL, USA

<https://cictsymposium.com/>

17-18

8th Congress of the Asia-Pacific Pediatric Cardiac Society

Taipei, Taiwan

<http://www.appcs2020.org/>

AUGUST

27-30

ESC Congress 2021 – The Digital Experience

Virtual

<https://www.escardio.org/Congresses-&-Events/ESC-Congress>

30-31

Frist Annual PICS Fellows & Early Career Course

Las Vegas, NV, USA

Kimberly_ray@chdinterventions.org



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