CONGENITAL CARDIOLOGY TODAY
Timely News & Information for Congenital/Structural Cardiologists & Cardiothoracic Surgeons Worldwide
North American Edition
Vol. 20 - Issue 1
January 2022

## Table of Contents



# Pulmonary Artery Occlusion for Palliation of Unilateral Total Pulmonary Vein Obstruction: Procedure Results and Mid-term Follow-up

*Asimina Courelli; Stephen Nageotte, MD, MBA; Kanishka Ratnayaka, MD, FAAP, FACC, FPICS; Frank Ing, MD, FACC, MSCAI; Howaida El-Said, MD, PhD; John W. Moore, MD, MPH*

**Key Words:** occlusion, transcatheter, outcomes, hemoptysis, flow reversal

## Abbreviations

| | |
|---|---|
| 1V | single ventricle anatomy |
| 2V | double ventricle anatomy |
| AP | aorto-pulmonary |
| bPA | branch pulmonary artery |
| PVO | pulmonary vein occlusion |
| RV | right ventricle |

## Abstract

**Objectives:** Report efficacy and mid-term outcomes for transcatheter occlusion of ipsilateral branch pulmonary artery (bPA) to palliate unilateral total pulmonary vein obstruction (PVO).

**Background:** Patients with PVO who are acutely symptomatic and not eligible for surgery have limited transcatheter treatment options. Few palliative catheter-based treatments exist for patients with unilateral PVO who are acutely symptomatic and are not eligible for surgery.

**Methods:** Procedure results and follow-up were reviewed for patients who underwent transcatheter ipsilateral bPA occlusion to treat pulmonary artery flow reversal or hemoptysis caused by unilateral total PVO at Rady Children's Hospital San Diego between 2003 and 2020.

**Results:** Seven patients were identified who underwent bPA occlusion with implantation of occluder devices and/or coils. All patients presented with total unilateral PVO, (six left and one right). Three patients had single ventricle anatomy (1V) and four patients had biventricular circulation (2V). Indications for intervention included bPA blood flow reversal ipsilateral to PVO and pulmonary hemorrhage. Procedures were successful in all patients; flow reversal and hemoptysis resolved, and hemodynamic stability was maintained after device placement. There was no difference in pulmonary artery pressure (2V), Fontan pressure (1V), and systemic oxygenation. Systemic blood pressure was not different in 2V

# JANUARY 2022

North American Edition Vol. 20 - Issue 1

## TABLE OF CONTENTS

patients, whereas it increased in 1V patients. Most recent follow-up ranged from 4 months to 16 years (median = 2.8 yrs). All 1V patients were being evaluated for transplant at most recent visit. Two patients were lost to follow-up.

**Conclusion:** In patients with unilateral total PVO, device occlusion of the ipsilateral bPA may offer palliative benefits.

## Introduction

Despite advances in endovascular and surgical techniques for pulmonary vein repair, few interventional techniques exist to treat acutely symptomatic patients with pulmonary vein obstruction (PVO) who are not candidates for surgery.

PVO can arise either as a primary congenital cardiac lesion, which occurs in conjunction with other cardiac abnormalities in 50% of patients, or as a complication secondary to surgical manipulation of the pulmonary veins, as seen in TAPVR repair.[1,2] Although the mechanism behind PVO is poorly understood, its sequelae have been previously documented in the literature.[1,2] PVO causes congestion of the ipsilateral pulmonary and bronchial vasculature, resulting in damage to the lung parenchyma and the pulmonary vasculature. Parenchymal and vascular damage manifests as: alveolar hemorrhage, pulmonary hypertension, friable endobronchial mucosa, recurrent respiratory tract infections, and cyanosis.[1,2,3] In the presence of aortopulmonary (AP) collaterals, as seen in single ventricle patients, PVO can also manifest itself with flow reversal into the contralateral lung, which can be visualized on angiography.[4] As a result of the damage to the lung parenchyma and vasculature or significant alterations in pulmonary artery hemodynamics, patients typically present with acute exertional dyspnea, cough, chest pain, and/or hemoptysis.[1,2]

Current first-line interventions for PVO consist primarily of pulmonary vein surgical reconstruction or recanalization and endovascular balloon angioplasty or stenting.[5] Despite the development of multiple treatment approaches, limited success has been noted in maintaining patency of the pulmonary veins.[6,7] Nevertheless, pulmonary vein rehabilitation can be pursued whenever feasible, particularly prior to progression from stenosis to occlusion.[8] The progressive stenosis leads to occlusion in a sub population of patients who will become symptomatic from lung parenchyma damage caused by chronically high pressures in the ipsilateral lung from diminished prograde blood flow. In cases where primary pulmonary vein repair has failed or may not be feasible, a definitive approach to addressing the symptoms associated with PVO is ipsilateral lobectomy or pneumonectomy.[9] However, a pneumonectomy is a highly invasive procedure associated with significant morbidity and may not be suitable for all patients.[9] Palliating the sequelae of PVO is a critical step to bridging the patient to transplant, which offers a definitive treatment for PVO. Therefore, a minimally invasive treatment is needed for palliating patients suffering from the clinical consequences of unilateral total PVO, who have failed primary transcatheter vein repair and/or are not surgical candidates.

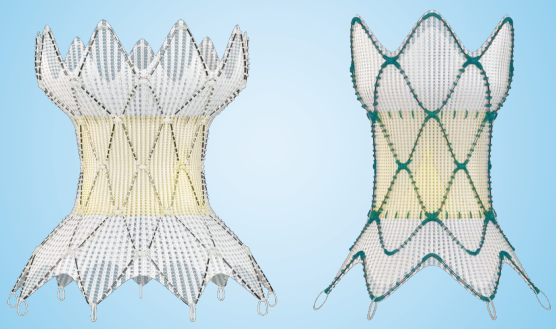
At our institution, a novel procedure has been employed for treating PVO involving the isolation of the branch pulmonary artery (bPA), which corresponds to the obstructed pulmonary veins (e.g. left bPA occluded in case of left PVO), by implanting occluding devices into that pulmonary artery. Despite complexity of the physiological variables controlling both pulmonary and arterial pressures, as well as differences between pulmonary and arterial resistance reserves, we propose that hemodynamic isolation of the ipsilateral bPA prevents both prograde flow into a lung with damaged lung parenchyma and retrograde flow through AP collaterals. This approach may be helpful in cases where patients are acutely symptomatic from PVO and not eligible to undergo transcatheter or surgical repair. As a palliative treatment for PVO, bPA occlusion has rarely been reported. We were able to identify only two case reports in which selective occlusion of a pulmonary artery branch was used to treat PVO in three patients.[11,12]

The aims of this report are to describe the efficacy and outcomes of bPA occlusion as a palliative treatment for PVO. We reviewed the procedures and devices used for bPA occlusion and evaluated the efficacy of this novel treatment by analyzing hemodynamic data, clinical impact of interventions, and mid-term sequelae. We report patients with both single and two ventricle anatomy and physiology who had ipsilateral bPA occlusion.

## Methods

This study was approved by the Institutional Review Board of the University of California, San Diego. The study was conducted by reviewing the clinical databases of Rady Children's Hospital San Diego. The study included all patients who had transcatheter occlusion of an ipsilateral bPA to treat unilateral total PVO between January 2003 and June 2020.

The procedures involved right heart catheterization, confirmation of total unilateral PVO via pulmonary angiography **(Figure 1A)**, and implantation of occlusion device(s) **(Figure 1B)**. Patients' clinical presentation, cardiac anatomy and physiology, occlusion devices implanted, hemodynamic measurements, clinical sequelae, and follow-up were reviewed. Systemic blood pressure, pulmonary artery pressure (for two ventricle patients), Fontan pressure (for single ventricle patients), and oxygen saturation before and after the placement of the occlusion device were analyzed for single and two ventricle patients to identify hemodynamic differences. Hemodynamic data of single ventricle and two ventricle patients were analyzed separately. Descriptive statistics were used to analyze hemodynamic data (mean ± standard deviation), and statistical analysis using a paired t-test in MS-Excel (Microsoft 2010, Redmond, WA) was conducted. A p-value $\leq 0.05$ was considered the threshold for statistical significance. The effects of bPA branch occlusion were analyzed either intra-operatively, where flow reversal was observed to be eliminated after bPA occlusion via angiography, or clinically by the resolution of hemoptysis.



# ONE. PARTNER.

Every step of the way

## Harmony™

Transcatheter Pulmonary Valve (TPV)

Backed by our commitment to providing solutions and support to you and your CHD patients, we offer dedicated clinical experts who can provide guidance in all stages of the therapy.

medtronic.com

Medtronic

**Indications**
The Harmony™ transcatheter pulmonary valve (TPV) system is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction ≥ 30% as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.

**Contraindications**
The following are contraindications for the use of this device: active bacterial endocarditis or other active infections, known intolerance to Nitinol (titanium or nickel), or an anticoagulation/antiplatelet regimen.

**Warnings**
*General:* Implantation of the Harmony TPV system should be performed only by physicians who have received Harmony TPV system training. The transcatheter pulmonary valve (TPV) is to be used only in conjunction with the Harmony delivery catheter system (DCS). This procedure should only be performed where emergency pulmonary valve surgery can be performed promptly. Do not use any of the Harmony TPV system components if any of the following has occurred: it has been dropped, damaged, or mishandled in any way, or if the use-by date has elapsed.

*Transcatheter pulmonary valve (TPV):* This device was designed for single use only. Do not reuse, reprocess, or resterilize the TPV. 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 resterilize the TPV by any method. Exposure of the device and container to irradiation, steam, ethylene oxide, or other chemical sterilants renders the device unfit for use. The device is packaged with a temperature sensor. Do not freeze the device. Do not expose the device to extreme temperatures. Do not use the device if the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded. Do not use the device if any of the following have occurred: the tamper-evident seal is broken, the serial number tag does not match the container label, the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded, or the device is not completely covered by the storage solution. Do not contact any of the Harmony TPV system components with cotton or cotton swabs. Do not expose any of the Harmony TPV system components to organic solvents, such as alcohol. Do not introduce air into the catheter. Do not expose the device to solutions other than the storage and rinse solutions. Do not add or apply antibiotics to the device, the storage solution, or the rinse solution. Do not allow the device to dry. Maintain tissue moisture with irrigation or immersion. Do not attempt to repair a damaged device. Do not handle the valve leaflet tissue or use forceps to manipulate the valve leaflet tissue. Do not attempt to recapture the device once deployment has begun. Do not attempt to retrieve the TPV if any one of the outflow TPV struts is protruding from the capsule. If any one of the outflow TPV struts has deployed from the capsule, the TPV must be released from the catheter before the catheter can be withdrawn. Do not attempt post-implant balloon dilatation (PID) of the TPV during the procedure, which may cause damage to or failure of the TPV leading to injury to the patient resulting in reintervention.

*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.

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879
Toll-free: (800) 328-2518

**LifeLine**
**CardioVascular Technical Support**
Tel: (877) 526-7890
Tel: (763) 526-7890
Fax: (763) 526-7888
rs.structuralheart@medtronic.com



UC202112006 EN
03/2021

**medtronic.com**

Medtronic

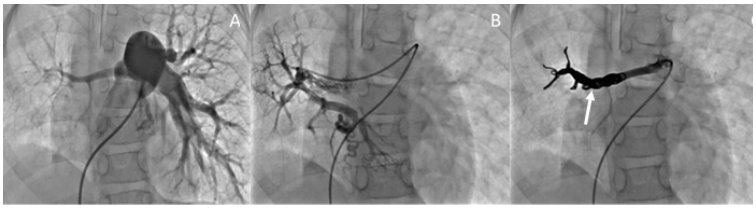



**FIGURE 1** *AP view of cardiac fluoroscopy during bPA (branch pulmonary artery) Occlusion Procedure: **(A)** fluoroscopy demonstrating left lung without pulmonary venous occlusion, **(B)** fluoroscopy demonstrating right lung with pulmonary venous occlusion and **(C)** fluoroscopy in the same patient post-occlusion of the right pulmonary artery with the white arrow indicating the occlusion device.*

## Results

### *Patient Characteristics and Patient Selection*

During the study period, seven patients underwent transcatheter ipsilateral bPA occlusion. Patient ages ranged from 1.3 to 12.5 years, with the average age at intervention of 5.2 years **(Table 1)**. Congenital cardiac diagnoses varied among patients, but all patients had undergone prior surgical intervention with palliation to either single (n = 3) or two ventricle (n= 4) physiology **(Table 1)**. Prior interventions involving pulmonary veins had been performed among three patients: two had angioplasty of the left and right pulmonary veins and the third had stenting of the left upper pulmonary vein. None had prior pulmonary vein surgery. All patients ultimately developed total obstruction of left pulmonary veins (n = 6) or right pulmonary veins (n = 1). The indications for performing ipsilateral bPA occlusion were either the presence of blood flow reversal in the bPA ipsilateral to the PVO, noted during prior catheterization (n=3) or pulmonary hemorrhage presenting with hemoptysis (n=4) **(Table 1)**. Additionally, all patients were evaluated for surgical intervention at the time of presentation to Rady Children's Hospital but were not good surgical candidates. Patients 1, 4, 6, and 7 presented with hemoptysis, while patients 2, 3, and 5 were asymptomatic other than the flow reversal present on catheterization. Patient 1 experienced three episodes of hemoptysis prior to bPA occlusion. Patient 4 experienced two episodes of hemoptysis and bPA occlusion was conducted as treatment for the second hemoptysis episode. Patient 6 had at least two episodes of hemoptysis with the second involving cardiac arrest and urgent catheterization. Patient 7 underwent bPA occlusion after the first episode of hemoptysis due to persistent pulmonary hemorrhage.

**TABLE 1** *Patient Cardiac Anatomy, Presenting Symptoms, and Age at Time of Intervention*

| Patient | Age at Procedure (yrs) | Anatomy | Number of Ventricles | PVO Laterality | Presentation |
|---|---|---|---|---|---|
| 1 | 3.4 | PA/IVS s/p Fontan | 1 ventricle | Left | Pulmonary Hemorrhage |
| 2 | 12.5 | HLHS s/p Fontan | 1 ventricle | Left | Flow Reversal |
| 3 | 4.0 | Heterotaxy, unbalanced AV canal s/p Glenn | 1 ventricle | Left | Flow Reversal |
| 4 | 3.1 | PA, VSD MAPCAs s/p unifocalization and VSD closure | 2 ventricles | Left | Pulmonary Hemorrhage |
| 5 | 3.3 | Scimitar, occluded right pulmonary veins | 2 ventricles | Left | Flow Reversal |
| 6 | 8.7 | Goldenhar Syndrome, Hypoplastic right lung | 2 ventricles | Right | Pulmonary Hemorrhage |
| 7 | 1.3 | DORV, DMGA s/p ASO, VSD closure | 2 ventricles | Left | Pulmonary Hemorrhage |

**TABLE 2** *bPA Occlusion Procedural Details and Follow-Up*

| Patient | Device Used | Additional AP Collateral Coiling | Symptom Resolution | Transplant Evaluation | Lost to Follow-Up | Follow-up (months) |
|---|---|---|---|---|---|---|
| 1 | 10/8 ADO (Abbott, Santa Clara, CA) | No | Yes | Yes | No | 192 |
| 2 | 12 mm AVP II (Abbott, Santa Clara, CA) | No | Yes | Yes | No | 83 |
| 3 | 10 mm AVP I (AGA Med Corp, Plymouth, MN) | Yes | Yes | Yes | Yes | 4 |
| 4 | 15 mm ASO (Abbott, Santa Clara, CA) | Yes | Yes | No | No | 147 |
| 5 | Two 8 mm AVP IVs (Abbott, Santa Clara, CA) | No | Yes | No | No | 26 |
| 6 | Six 0.035 Azur coils (Terumo Interv Sys, Somerset, NJ) | No | Yes | No | No | 34 |
| 7 | 12 mm AVP II (Abbott, Santa Clara, CA) | No | Yes | No | No | 1 |

## Devices and Hemodynamic Data

bPA occlusion was accomplished with a variety of transcatheter occluder devices and/or coils **(Table 2)**. In a subset of patients (n= 2), coil occlusion of AP collaterals was also performed **(Table 2)**. Patients underwent concurrent AP coiling if coiling was indicated and considered feasible during catheterization. In all patients, prograde and retrograde pulmonary artery flow in the lung corresponding to the obstructed pulmonary veins was successfully terminated with bPA occlusion.

To assess changes in the pulmonary circulation, the Fontan pressure or the pulmonary artery pressure (for two ventricle patients) were analyzed. Among single ventricle patients, comparison of pre-bPA to post-bPA occlusion Fontan pressures showed no difference (pre: 20±6 mmHg, post: 19±2 mmHg, p = 0.30; **Figure 2A**). In two ventricle patients, there was no difference in systolic (pre: 34±10 mmHg, post: 33±8 mmHg, p = 0.42; **Figure 2C**), mean (pre: 21±2 mmHg, post: 22±3 mmHg, p = 0.37; **Figure 2B**), or diastolic (pre: 11±6 mmHg, post: 12±3 mmHg, p = 0.40; **Figure 2D**) pulmonary artery pressures. Of note, pulmonary artery pressures were available for three of four patients with two ventricle cardiac anatomy.

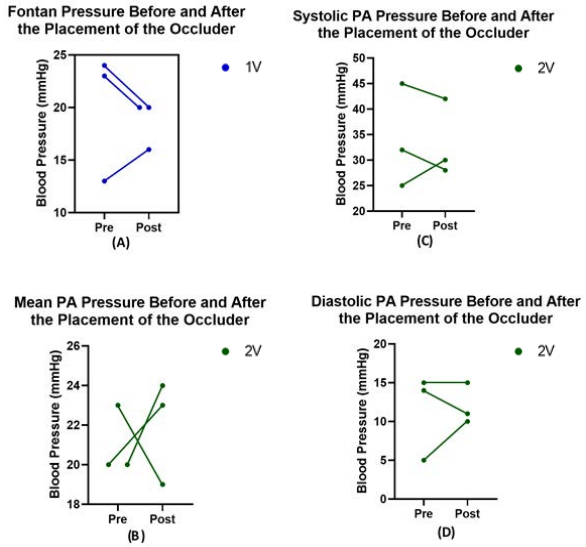



**FIGURE 2** *Plots of **(A)** Fontan Pressure in one ventricle heart anatomy, and **(B)** Mean Pulmonary Pressure, **(C)** Systolic Pulmonary Pressure, and **(D)** Diastolic Pulmonary Pressure in two ventricle heart anatomy before and after the placement of the occluding device in the pulmonary artery. Filled circles denote individual patient measurements and lines indicate trends. **(1V)** Single ventricle heart anatomy and **(2V)** Biventricular heart anatomy.*

To assess changes in the arterial circulation, systemic blood pressure and oxygen saturation were analyzed. In single ventricle patients, comparison of pre-bPA occlusion to post-bPA occlusion blood pressures showed a significant increase in mean BP (pre: 46±6 mmHg, post: 58±6 mmHg, p = 0.04); **Figure 3A**, systolic BP (pre: 67±15 mmHg, post: 85±12 mmHg, p = 0.05); **Figure 3C**, and diastolic BP (pre: 34±2 mmHg, post: 42±2 mmHg, p = 0.01). For two ventricle patients, comparison of pre-bPA occlusion to post bPA occlusion blood pressures showed no difference, mean BP (pre: 62±4 mmHg, post: 65±4 mmHg, p = 0.31); **Figure 3A**, systolic BP (pre: 83±9 mmHg, post: 92±7 mmHg, p = 0.21) and **Figure 3D,** diastolic BP (pre: 46±4 mmHg, post: 48±6 mmHg, p = 0.57). No significant change was noted in systemic oxygen saturation before and after bPA occlusion in single (pre: 68 ± 17%, post: 81±14 %, p = 0.33); **Figure 3B** and two (pre: 99±1%, post: 98±2%, p = 0.55); **Figure 3B** ventricle patients. Right ventricle assessment by pre- and post-procedural echocardiography did not show a difference in RV size or function.

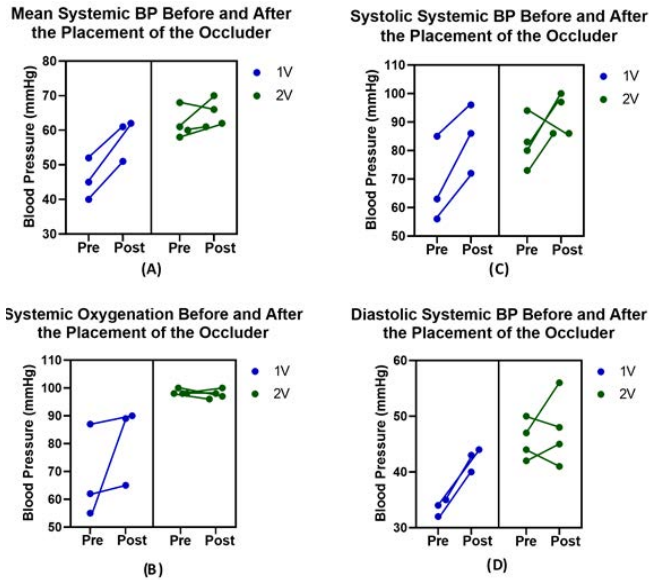



**FIGURE 3** *Plots of **(A)** Mean Blood Pressure, **(B)** O2 Saturation, **(C)** Systolic Blood Pressure, and **(D)** Diastolic Blood Pressure before and after the placement of the occlusion device in the pulmonary artery. Filled circles denote individual patient measurements and lines indicate trends. **(1V)** Single ventricle heart anatomy and **(2V)** Biventricular heart anatomy.*

## Immediate Post-Procedural Period and Follow-Up

All patients tolerated the procedure well and experienced resolution of pulmonary artery flow reversal or hemoptysis **(Table 2)**. Post procedure follow-up ranged from one month to sixteen years, median follow-up 2.8 years **(Table 2)**. Two patients were lost to follow-up. At the time of last follow-up, all single ventricle patients had been referred for a heart-lung transplant evaluation, but none had completed transplantation **(Table 2).** Of the patients who presented with hemoptysis, all patients, except for patient 4, had complete resolution of their hemoptysis. Patient 4 continued to have intractable hemoptysis to the point where he underwent pneumonectomy with complete resolution of hemoptysis. No procedural complications, major adverse events or mortality related to bPA occlusion had been noted at time of the most recent follow-up evaluations.

## Discussion

In this study, we demonstrated that occlusion of the ipsilateral bPA in patients with unilateral total PVO can serve as a minimally invasive, effective treatment in palliating symptoms associated with PVO without any major complications. The study showed that hemodynamic stability and systemic oxygenation saturation was maintained both acutely and in mid-term follow up and that a variety of devices and/ or coils may be implanted to achieve complete bPA occlusion. The study also suggests that occlusion of the ipsilateral bPA serves as an alternative to pneumonectomy or other major surgical interventions in cases where the patient is acutely symptomatic and not a candidate for surgery.

All patients in this study experienced immediate clinical resolution of bPA flow reversal or hemoptysis. No patients had experienced any serious adverse events related to the procedure or occlusion devices at the time of last follow-up. Acutely, there was no recurrence of hemoptysis or flow reversal. However, in the follow-up period, one patient who presented with hemoptysis underwent pneumonectomy for intractable hemoptysis recurrence. None of the patients who presented with flow reversal underwent subsequent pneumonectomy.

Overall hemodynamic stability was maintained following bPA occlusion. No significant changes were observed in systemic oxygen saturation, whereas systemic blood pressure increased (1V) or remained the same (2V). Systemic oxygen saturation, Fontan pressure and pulmonary artery pressure were unchanged by the procedure in all patients. The maintenance of systemic oxygenation and lack of significant change in pulmonary artery pressure is most likely due to the limited contribution provided by the affected lung to oxygenation prior to the procedure. If most of the RV output were being directed to the unaffected lung as a result of lower pressure, bPA occlusion may not significantly impact pulmonary artery pressure or oxygenation. In single ventricle patients, post-procedure systemic blood pressure increased by elimination of run off through the lung via AP collaterals thereby increasing systemic blood flow.

Although one of seven patients experienced recurrence of hemoptysis, in general, bPA occlusion successfully treated hemoptysis and flow reversal by hemodynamically isolating the lung ipsilateral to the PVO. We propose that bPA occlusion treats flow reversal from AP collaterals by preventing reverse flow into the contralateral lung. Occlusion of the bPA may increase pressure within the AP collaterals as the pulmonary artery circulation becomes isolated with occlusion of both the branch pulmonary artery and pulmonary vein. The increased pressure within the AP collaterals may prevent flow from the aorta into the collateral vessels. Limiting flow through the ipsilateral lung is responsible for hemoptysis resolution. Since the pulmonary artery delivers over 90% of the blood volume to the lungs, bPA occlusion significantly limits blood delivery to friable lung parenchyma and thereby decreases further parenchymal damage as well as available blood which can leak into the alveolar space.[12] However, even with bPA occlusion, we have observed one case of hemoptysis recurrence in patient 4. One can postulate two conditions in which hemoptysis

could recur after bPA occlusion: 1) formation of new AP collaterals or 2) extensive pre-existing damage to the lung parenchyma such that tissue is prone to significant bleeding for an extended time post-intervention even if only supplied by the bronchial vasculature.

Application of ipsilateral bPA occlusion is intended for patients who are acutely symptomatic from PVO and not candidates for surgery or other catheter interventions. Currently, first line treatment for PVO involves primary pulmonary vein repair by either surgical (e.g. pericardial patch venoplasty, intrapulmonary artery separation) or catheter based approaches (e.g. balloon angioplasty or stenting).[1,2,6,13] While primary repair eliminates the initial occlusion/stenosis, re-stenosis is consistently observed regardless of approach.[6] High rates of re-stenosis highlight the progressive nature of pulmonary vein stenosis to occlusion, which can lead to a need for lung transplant or pneumonectomy in patients who become acutely symptomatic or develop pulmonary hypertension.[6] However, at the time of presentation, not all patients are eligible for a surgical intervention or catheter-based intervention. Some patients, as seen in this study, may have failed multiple primary interventions and continue to experience symptoms from PVO. Therefore, ipsilateral bPA occlusion constitutes a means of palliating the symptoms associated with unilateral PVO without major manipulation of pulmonary vasculature or lung parenchyma.

Compared to pneumonectomy, ipsilateral bPA occlusion has a low, side-effect profile, while functionally achieving a similar end result. Pneumonectomy and lobectomy have been used in the treatment of hemoptysis associated with PVO and the resulting functionality is similar to bPA occlusion.[14,15,16] Pneumonectomy and lobectomy are highly invasive procedures and subject patients to peri-operative morbidities such as bronchopleural fistula, ARDS, pneumothorax, and post-pneumonectomy syndrome and are limited to patients who are able to tolerate surgery.[17] When ipsilateral bPA occlusion is employed, further damage or inflammation of the lung parenchyma is unlikely as the bPA is coiled proximally and perfusion for lung tissue viability is maintained via the bronchial circulation. Additionally, the relatively high incidence of post-operative arrhythmias (approximately 20%) associated with pneumonectomy was not observed in the patients who underwent bPA occlusion, included in this study.[18] bPA occlusion acts as a type of "functional pneumonectomy", since blood volume is no longer oxygenated by the occluded lung. It provides the functionality of pneumonectomy without the associated invasiveness and post-operative morbidity. However, "functionally" removing the affected lung compared to physically removing the affected lung may interfere with compensatory lung growth seen after pneumonectomy. The mechanical strain on lung tissue caused by mediastinal shift and increased alveolar inflation due to lung removal are key factors in stimulating lung tissue proliferation.[18,19] Increase of perfusion of the remaining functional lung, as would be in the case of bPA occlusion, may not exercise the same magnitude effect of promoting compensatory lung growth.[20] While bPA occlusion does not correct PVO, it can be employed as a palliative measure in patients who are not eligible for surgery and are experiencing the clinical consequences of PVO to help bridge them to transplant.

Limitations of this report include the small number of patients and the retrospective nature of the study from a single institution. The small number of patients is attributed to the fact that these are rare and challenging patients. The constraint to a single center study is due to the fact that this a novel treatment that has been largely unique to our institution. Future applications of this technique will need to be mindful of emerging treatments for primary and secondary pulmonary vein stenosis and obstruction, such as hybrid pulmonary venous repair and refined endovascular interventions. Due to the retrospective nature of the study, there were limitations in the available quantitative and imaging data for meaningful comparison across cases, as the diagnostic and treatment needs of each patient were evaluated on a case specific basis.

## Conclusion

In this study, we report that adverse clinical consequences of total unilateral PVO may be palliated with ipsilateral bPA occlusion. This procedure can effectively resolve pulmonary artery flow reversal or hemoptysis without major complications. Compared to pneumonectomy, ipsilateral bPA occlusion serves as a less-invasive treatment option that can be employed as long-term palliation and a bridge to transplantation for patients who are not eligible for surgery.

## References


1. Pazos-López Pablo. Pulmonary Vein Stenosis: Etiology, Diagnosis and Management. World Journal of Cardiology. 8(1):81, 2016.
2. Latson LA, Prieto LR. Congenital and acquired pulmonary vein stenosis. Circulation. 2007 Jan 2;115(1):103-8. doi: 10.1161/CIRCULATIONAHA.106.646166. PMID: 17200453.
3. Braun Silke. Platzek Ivan. Zophel Klaus. Weise Matthias. Kloditz Martin. Halank Michael. Hoeffken Gert. Haemoptysis Due to Pulmonary Venous Stenosis. Eur Respir Rev. 23(133):170-179, 2014 Sept.
4. Latson Larry. Qureshi Athar. Techniques for Transcatheter Recanalization of Completely Occluded Vessels and Pathways in Patients with Congenital Heart Disease. Annals of Pediatric Cardiology. 3(2):140, 2010.
5. Rachel D. Vanderlaan. Jonathan Rome. Russel Hirsch. Dunbar Ivy.Christopher Caldarone. Pulmonary Vein Stenosis: Treatment and Challenges. Congenital: Pulmonary Vein: Expert Review. 161 (6): 2169-2176.
6. Song Mi Kyoung. Clinical Characteristics and Prognostic Factors of Primary Pulmonary Vein Stenosis or Atresia in Children. The Annals of Thoracic Surgery. 95(1):229-234, 2013 Jan.
7. Place DiLorenzo Michael P. Pulmonary Vein Stenosis: Outcomes in Children with Congenital Heart Disease and Prematurity. Seminars in Thoracic and Cardiovascular Surgery. 31 (2):266-273, 2019.
8. Othman A. Aljohani, Duncan Mackie, Jeffrey Frazer, Hyeri You, Stephen J. Nageotte, Kanishka Ratnayaka, John W. Moore, Howaida G. El-Said, Pulmonary vein rehabilitation, Progress in Pediatric Cardiology, 60.

9. Giubergia V, Alessandrini F, Barrias C, Giuseppucci C, Reusmann A, Barrenechea M, Castaños C. Risk factors for morbidities and mortality in children following pneumonectomy. Respirology. 2017 Jan;22(1):187-191. doi: 10.1111/resp.12867. Epub 2016 Aug 10. PMID: 27511212.
10. Yamauchi Melissa. Selective Pulmonary Artery Occlusion to Treat Hemoptysis Associated with Pulmonary Venous Obstruction. Respiratory Medicine Case Reports. 22: 280-282. 2017.
11. Bondanza Sara. Derchi Maria. Marasini Maurizio. Selective Pulmonary Artery Embolism in Two Patients with Single Ventricle and Acquired Pulmonary Vein Occlusion. Catheterization and Cardiovascular Interventions. 80(1):101-106, July 2012.
12. Christopher Walker. Melissa Rosado-de-Christienson. Santiago Martinez-Jimenez. Jeffrey Kunin. Brandt Wible. Bronchial Arteries: Anatomy, Function, Hpertrophy, Anomalies. RadioGraphics. 35(1),2015.
13. Ishidou M, Ota K, Watanebe K, Koshiyama H, Kanno K, Ito H, Murata M, Hirose K, Ikai A, Sakamoto K. Impact of intrapulmonary-artery septation to pulmonary vein obstruction for two-lung Fontan. Eur J Cardiothorac Surg. 2020 Jul 1;58(1):177-185.
14. Alison Halpern. Michael Weyant. Video-Assisted Thoracoscopic Pneumonectomy for Complications from Congenital Pulmonary Venous Stenosis. The Annals of Thoracic Surgery: Case Report. 108(6): E357-E359, 2019 December.
15. John Reid. Morgan Jamieson. Michael Cowan. Unilateral Pulmonary Vein Stenosis. British Heart Journal. 55: 599-601,1986 July.
16. Jung Yeon Lee. Gyu Rak Chon. Jong Hoon Park.Byung Joon Kang. Tae Sun Shim. Kyung-Wook Joo. Massive Hemoptysis Due to Pulmonary Vein Stenosis Following Catheter Ablation for Atrial Fibrillation. Respiratory Care: Case Reports.60 (3): 52-55, 2015 March.
17. Giubergia V, Alessandrini F, Barrias C, Giuseppucci C, Reusmann A, Barrenechea M, Castaños C. Risk factors for morbidities and mortality in children following pneumonectomy. Respirology. 2017 Jan;22(1):187-191. doi: 10.1111/resp.12867. Epub 2016 Aug 10. PMID: 27511212.
18. Christophoros N. Foroulis. Christophoros Kotoulas. Helias Lachanas. George Lazopoulos. Marios Konstantinou. Achilleas G. Lioulias. Factors associated with cardiac rhythm disturbances in the early post-pneumonectomy period: a study on 259 pneumonectomies, European Journal of Cardio-Thoracic Surgery. 23 (3): 384-389, 2003 March.
19. Connie Hsia. Signals and Mechanisms of Compensatory Lung Growth. Journal of Applied Physiology. 97:1992-1998, 2004 November.
20. H. Fehrenbach, R. Voswinckel, V. Michl, T. Mehling, A. Fehrenbach, W. Seeger, J. R. Nyengaard. Neoalveolarization contributes to compensatory lung growth following pneumonectomy in mice. European Respiratory Journal.31: 515-522,2008.



**ASIMINA COURELLI**
UC San Diego School of Medicine
San Diego, CA, USA



**STEPHEN NAGEOTTE, MD, MBA**
Division of Cardiology
Loma Linda University Children's Hospital
Department of Pediatrics
Loma Linda University School of Medicine
Loma Linda, CA, USA



**KANISHKA RATNAYAKA, MD, FAAP, FACC, FPICS**
Division of Cardiology
Rady Children's Hospital San Diego
Department of Pediatrics
UC San Diego School of Medicine
San Diego, CA, USA



**FRANK ING, MD, FACC, MSCAI**
Division of Cardiology
UC Davis Children's Hospital
Department of Pediatrics
UC Davis School of Medicine
Sacramento, CA, USA



**HOWAIDA EL-SAID, MD, PhD**
Division of Cardiology
Rady Children's Hospital San Diego
Department of Pediatrics
UC San Diego School of Medicine
San Diego, CA, USA



**JOHN W. MOORE, MD, MPH**
Division of Cardiology
Rady Children's Hospital San Diego
Department of Pediatrics
UC San Diego School of Medicine
San Diego, CA, USA
jmoore@rchsd.org

Atrium Health
Levine Children's

# Medical Director of Pediatric Echocardiography
# Pediatric Electrophysiologist

## Charlotte, NC

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

- **Imaging candidates** will have completed an ACGME accredited fellowship in pediatric cardiology and be BC/BE by the American Board of Pediatrics; with expertise in echocardiography for congenital heart disease, including transthoracic, transesophageal, and fetal echocardiography. Candidate will be recruited as echocardiography lab director or will be expected to transition into that role within one year. Responsibilities will also include both outpatient and inpatient cardiology. A minimum of 5 years of experience and 4th year imaging fellowship are preferred. Call/weekend coverage on a rotating basis including echo backup call with 5 other imaging physicians.
- **Electrophysiology candidates** will have completed an ACGME accredited fellowships in pediatric cardiology and pediatric electrophysiology and should be BC/BE by the American Board of Pediatrics and will be expected to accomplish pediatric electrophysiology certification by the International Board of Heart Rhythm Examiners. He/she should be skilled in outpatient and inpatient congenital electrophysiology with experience and interest in transcatheter ablations and device implantation/management. Days will be split between the EP lab and clinic. Responsibilities will include attending on-site/satellite EP outpatient clinics including pacemaker/ICD clinics, providing inpatient/consult service coverage, remote device management and cardiology/EP call/weekend coverage on a rotating basis. The Pediatric/Adult Congenital Electrophysiology program has grown in procedural volume over 40% in each of the last two years, and is currently staffed by a single electrophysiologist and dedicated EP APP.
- ACHD board certification will be welcomed for either position but not essential.
- Team includes: 12 cardiologists, 3 congenital heart surgeons, 5 cardiac intensivists, 4 pediatric cardiac anesthesiologists, 2 pediatric cardiac radiologists, 26 APPs (includes 3 surgical APPs), 15 sonographers, 6 nurse navigators and 9 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. Surgical and cardiac catheterization volume have been growing at a rate of 10-15% per year. Our state of the art two lab cardiac catheterization and electrophysiology suite opened in February of 2017, with dedicated staffing and anesthesia teams. Our new outpatient office complex will be opening in December 2020, designed to treat all from fetal cardiology to ACHD. 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.

**Sanger Heart & Vascular Institute** (SHVI) 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. SHVI 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.

**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 the Atrium Health (AH) one of the nation's leading and most innovative healthcare systems. AH operates nearly 2,500 system-employed physicians, more than 60,000 employees and more than 7,460 licensed beds across the Carolinas.

**For more information or to submit a CV for review, please contact:**

Phillip Christofferson
Sourcing Specialist, Physician & APP Recruitment
Peter.Christofferson@atriumhealth.org
https://careers.atriumhealth.org/

# The PICS Society Advocacy Program: Power in Numbers! Part 4

*Hideshi Tomita, MD, PhD, FPICS; Natalie Poli, Ed.S.; Kamel Shibbani, MD; Norm Linsky, MPA, MA*

As a global community dedicated to minimally-invasive treatment of Congenital Heart Disease (CHD), do we have shared policy goals regardless of where we live and where we work? If so, how can we achieve those goals? As Dr. Shibbani says, ***"Do we have Power in Numbers?"***

This month we continue our interviews with PICS Society advocacy leaders through a discussion with Professor Hideshi Tomita, Director of Pediatric and Adult CHD, Showa University, Tokyo Japan. Dr. Tomita is Co-Chair of the PICS Advocacy Committee along with Dr. John Cheatham (Chair) and Dr. Cliff Kavinsky (Co-Chair).

Dr. Tomita is recognized by his peers for working closely with the PMDA in Japan (Pharmaceuticals and Medical Devices Agency, similar to the US FDA). Thanks to the leadership of Dr. Tomita and his distinguished colleagues, progress has been made in shortening the device approval process in Japan—while maintaining the highest standards of safety and efficacy.

***Dr. Shibbani:*** Dr. Tomita, what is the single most important policy issue that faces you and your colleagues in Japan? Are there ways the PICS Society can help you address that issue?

***Dr. Tomita:*** Our biggest issue historically has been a significant time lag in having CHD interventional devices reviewed and approved by our country's regulatory system. To address this, in 2003 authorities in Japan and the USA formalized the "US-Japan Medical Device Harmonization by Doing" (HBD) agreement. Since that time, researchers, industry and others in both countries have worked diligently to plan clinical trials and data reporting standards that could be submitted both to the PMDA in Japan and to the FDA in the US.

My colleagues and I used this as an opportunity to expand our dialogue with the PMDA, urging that harmonization of device review processes internationally would benefit patients in Japan and elsewhere. We encouraged more data sharing, maintenance of the highest standards and alignment with the HBD framework wherever possible. We recognized that progress would not happen overnight, but our pediatric community believed this would be an important opportunity.

Initially we focused on adult heart disease, an example being drug-eluting stents (DES) for adults. It was critical to start "breaking the device approval lag" in our country, in this case by focusing on a condition with a relatively large patient population. We reduced the research-to-approval time difference between Japan and the US. Then we expanded to interventional devices for the pediatric and adult congenital population. We encouraged and participated in more international clinical trials, working with innovators in industry and academic medical centers, again, starting with the "Harmonization by Doing" framework.

In 2016 we took another important step: We established the "Harmonization By Doing-for-Children (HBD-for-Children) Working Group" as a global collaboration amongst academia, industry and regulatory agencies in Japan and the United States. This newer group focuses on promoting development of pediatric medical devices. One recent example is the area of transcatheter pulmonary valve replacement, focused on the Harmony™ valve. This has been very successful both clinically and in terms of application of the HBD "harmonization" framework *[Editor's Note: the term "harmony" for both this valve and the 'Harmonization by Doing' framework is coincidental].*

Building on HBD's experience regarding approval of DES for adult heart disease, we next applied that experience to reduce the time difference between our two nations in approval of this vitally-needed pulmonary valve technology. Harmony™ received FDA approval in the US in March 2021 and PMDA approval in Japan very shortly thereafter (August 2021). This is very encouraging. Real-world clinical use will start in spring 2022 when we anticipate approval by the Statutory Health Insurance System in Japan.

Clearly this shows that using international clinical trial data for approvals in Japan will be important moving forward. We must broaden international data harmonization for trials of new devices in our field. Our next goal should be to expand this to include more data from regions beyond Japan and the US.

**"Years ago the PMDA [Japanese equivalent of the US FDA] paid little attention to pediatric device approval. That has changed: progress has been made in recent years. Our next goal is for critically-needed devices to be approved in Japan and other nations simultaneously. Harmonization of review processes globally would dramatically benefit patients everywhere." *—Hideshi Tomita, MD, PhD, FPICS***

***Dr. Shibbani:*** Are you suggesting the PICS Society could play a role by providing an international platform for sharing data related to new devices, to speed up the approval process in Japan and probably elsewhere?

***Dr. Tomita:*** Yes, very much so. Regulatory body roles have important differences from country-to-country. We have to discuss uniform requirements for approval everywhere. We need to discuss the need for some uniformity in data necessary for regulatory review and approval country-to-country. BUT, we also need to adjust and accommodate for significant differences amongst nations in terms of data needed, regulatory review processes and resources available.

***Dr. Shibbani:*** Can the PICS Society help investigators understand the different processes, data requirements, reporting requirements from country-to-country?

***Dr. Tomita:*** Yes, again, very important. This would be quite helpful, through education, publications, an online clearinghouse or other means.

***Mrs. Poli:*** Very honored to meet you Dr. Tomita! I am a stroke survivor and a recipient of two of the Amplatzer™ Atrial Septal Defect devices. I was 29 when I had my stroke. Little did I know I was born with two PFO's and an atrial septal defect. One minute I was fine, the next minute I was not. If it weren't for physicians like you, Dr. Hijazi and Dr. Kavinsky, I never would have had a minimally invasive procedure, a full recovery and an extraordinarily rewarding family and professional life ever since.

***Dr. Tomita:*** I am very happy for you and so pleased to meet someone who was successfully treated through minimally-invasive means. Your story and those of so many others are precisely why our community of doctors and industry innovators works so hard to bring better devices and techniques into daily practice.

***Dr. Shibbani:*** Beyond the regulatory environment, what else do you think the PICS Society can do to assist your profession?

***Dr. Tomita:*** Industry innovation is so important, as is partnership with those who treat patients, educate the next generation of physicians, set guidelines and the like. We must partner with industry in the US, in Japan and worldwide. We must advocate for streamlined device approval processes that maintain the highest possible standards AND reduce delays in approval unrelated to the science. Such delays discourage industry from investing in product development and reduce the tools available to us to effectively treat our patients. We must work together on this.

***Dr. Shibbani:*** Should the PICS Society act as an informational clearinghouse for regulatory information around the world, and what approaches have worked in individual countries?

***Dr. Tomita:*** Yes. When innovators can better navigate the regulatory process by becoming better informed about processes, everyone will benefit—especially patients.

Remember, the field of pediatric cardiovascular devices is a relatively small market, especially within a single country. But when we work together globally, we are much larger. We need to think of ourselves as a global marketplace, which is not a small one. That would incentivize companies to expand the innovation pipeline.

***Mrs. Poli:*** Dr. Tomita, are there examples of high priority areas where more international cooperation would be important?

***Dr. Tomita:*** In Japan, continued development of transcatheter pulmonary valve devices is a very high priority. Stent design for small children is also a very high priority. Only a small number are officially approved in Japan and US, so more options are urgently needed. Industry must continue to be incentivized to develop these, and international collaboration in our field is an urgent need.

***Dr. Shibbani:*** Dr. Tomita, if I could summarize:

- There are urgent needs—and opportunities—to collaborate with regulatory agencies to streamline device review and approval. Progress is slowly being made, much effort lies ahead.
- Working on clinical trial standards, data sharing and consistent regulatory agency policies would be major contributions to the field.
- The PICS Society can play a role by fostering communication, centralizing information and educating all stakeholders regarding device approval processes globally.

***Dr. Tomita:*** I concur and thank you. Encouraging progress has been made, we have made a good start. We look forward to working with the PICS Society and our colleagues throughout the world.

**HIDESHI TOMITA, MD, PHD, FPICS**

Director and Chief Professor
Pediatric Heart Disease & Adult Congenital Heart Disease Center
Showa University Hospital
Tokyo, Japan

**NATALIE POLI, Ed.S**

*PICS Society Senior Patient Advocate*
Public Education Professional
Successfully treated interventionally for CHD, 2006
Mrs. Midwest International 2022
Former Captain of the NBA Chicago Bulls Dance Team

**KAMEL SHIBBANI, MD**

Advanced Pediatric Cardiology Fellow
University of Iowa
Iowa City, IA, USA

**NORM LINSKY, MPA, MA**

PICS Society Executive Director
Washington, DC, USA
nlinsky@CHDinterventions.org

# ATTENTION FELLOWS & RESIDENTS: Congenital Cardiology Today Provides a Great Opportunity!

*John W. Moore, MD, MPH*

Share your clinical experiences or your research projects in a well-established and widely circulated pediatric and congenital cardiology-oriented publication. The staff of Congenital Cardiology Today (CCT) is well aware that trainees have significant research and educational requirements as part of the curriculum. Congenital Cardiology Today offers the unique opportunity to fast-track clinical and research projects into publications which a large part of the pediatric and congenital cardiology community will encounter. Publication in CCT can provide excellent exposure for your work and will assist you in meeting training requirements and in securing additional training opportunities and jobs!

CCT accepts interesting case reports and case series as well as reviews of clinical topics relevant to the practice of pediatric and congenital cardiologists. Such manuscripts are generally not eligible for review and publication in standard cardiology journals. Moreover, in the few journals which consider case-centered-manuscripts, there is often a prolonged delay after submission for review and publication. In addition, there is no fee for publication, including color images, in CCT. Our editorial policies encourage these submissions, and we provide timely review and publication. On average, approximately 50% of submissions are accepted, and accepted articles are generally published within four to six months of receipt of the manuscript. Congenital Cardiology Today has found that such articles are often of considerable interest to our readership of busy practitioners.

CCT encourages you to write up the very interesting cases you encounter in training. Make sure to include some good figures, tables, etc. Send them to us for review. Also, if you have prepared a Grand Rounds or an interesting lecture for presentation in your hospital, consider writing it up and sending it for review and likely publication.

Instructions for authors are easily accessed on the website: https://www.congenitalcardiologytoday.com/editorial

Submit your article to Kate.f.Baldwin@gmail.com

I look forward to reviewing your submissions.

# Cardiologist Needed for an Adult Congenital Heart Disease Faculty Position at Cincinnati Children's

The Heart Institute (HI) at Cincinnati Children's Hospital Medical Center (CCHMC) seeks applications for a BE/BC Pediatric Cardiologist at the Assistant or Associate Professor level. The position will be clinically focused as part of the non-invasive imaging subsection with responsibilities primarily in echocardiography with fetal echocardiography responsibilities possible if desired by the candidate.

The HI is an internationally recognized academic center of excellence for Pediatric (congenital and acquired) and Adult Congenital Cardiac Care, and clinical and basic science research. The HI incorporates the Divisions of Congenital Heart Disease, Cardiothoracic Surgery and Molecular Cardiovascular Biology. It offers the full range of Pediatric Cardiac services within a free-standing not-for-profit tertiary care medical center. The HI also serves to train categorical Pediatric Cardiology and sub-specialty fellows in all areas of congenital heart disease practice (including 2 Advanced Imaging fellows). Academic appointment within CCHMC is through the Department of Pediatrics at the University of Cincinnati College of Medicine.

The Echo lab includes 13 imaging faculty and 22 cardiac sonographers and performs over 15,000 transthoracic, 500 transesophageal and 2500 fetal echocardiograms annually. The facility includes a state-of-the-art reading room as well as the necessary technology to perform all current advanced imaging techniques.

**The applicant would be expected to participate in clinical service including (but not limited to):**

- Perform/interpret transthoracic and transesophageal echocardiograms.
- Perform a single out-patient clinic on a weekly basis
- Provide limited periods of in-patient and/or consult service coverage
- Participate in all HI clinical and management conferences
- Perform teaching and instruction commensurate with the training mission of the HI/CCHMC

The Heart Institute and the Non-invasive Imaging Service pride themselves on excellent clinical outcomes. The acceptable candidate would be expected to maintain similar high standards of clinical service.

**Skills & Competencies**

- Knowledge of growth and development
- Understands and support family-centered care
- Professional knowledge and clinical ability sufficient to provide evaluation and treatment of complex patients in one or more specialty areas
- Knowledge of pathophysiology and pharmacology
- Knowledge and skill in patient and/or family education
- Understanding and showing respect and appreciation for the uniqueness of all individuals; leveraging differences in others' perspectives and ideas; appreciating cultural differences and adjusting one's approach to successfully integrate with others who are different from oneself
- Strong organizational and project management skills to handle projects independently.
- Excellent verbal, written and/or interpersonal communication skills

**Required**

- MD, DO, or equivalent degree
- Current active medical license issued by the State of Ohio or eligible for license
- Appropriate medical credentialing through the Medical Staff Services offices
- Completion of all required pre-employment activities
- Assistant or Associate Professor appointment or eligibility required

**Preferred**

- Board certification

**Interested candidates should submit a cover letter of interest and CV to:**
**Andrew Redington, MD, Co-Director**
The Heart Institute, Cincinnati Children's Hospital Medical Center
**Andrew.Redington@cchmc.org**

# Photon-Counting CT – A Quantum Leap in Computed Tomography

*After more than 15 years of development, the world's first photon-counting system is here to redefine what's possible in cardiac imaging. For cardiologists, this means the ability to scan and diagnose previously excluded patients.*

After the introduction of spiral CT in 1990, wide detector CT in 2004, Dual Source CT in 2005 and Dual Layer CT detectors in 2013, computed tomography is a mature modality that has reached a saturation phase. Despite technological progress, limitations remain for current CT technology.

With photon-counting CT, we are developing a radically new technology for clinical routine. At its core is a new kind of detector that is substantially different from a standard energy-integrating detector.

These photon-counting detectors have the potential to overcome the limitations of current CT detectors, by providing CT data at high spatial resolution, without electronic noise, with improved contrast-to-noise ratio, at lower radiation dose and with intrinsic spectral information.

## What Makes Photon-Counting Detectors Different?

All medical CT systems today are equipped with solid-state scintillation detectors. In a two-step conversion process, the absorbed X-rays are first converted into visible light in the scintillation crystal. The light is then converted into an electrical signal by a photodiode attached to the backside of each detector cell.

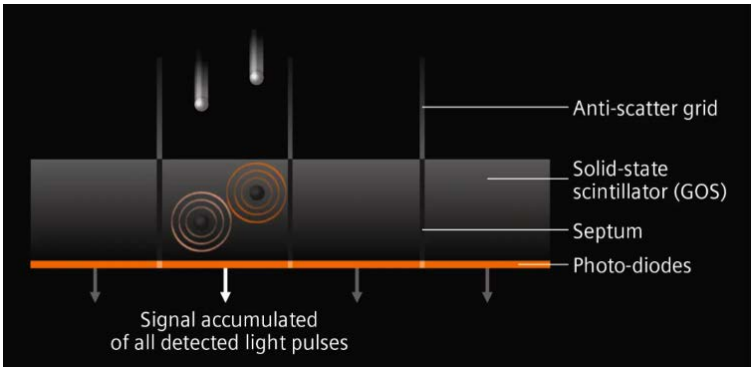



**FIGURE 1** *Energy-integrating detector*

The low-level analog electric signal of the photodiodes is susceptible to electronic noise, which sets an ultimate limit to potential further radiation dose reduction.

At the same time, it is problematic to significantly increase the spatial resolution of solid-state scintillation detectors beyond today's performance levels.

As part of this two-step conversion process, the light created by thousands of x-ray photons is accumulated over the integration time and measured as a whole, thereby losing the spectral information of the incoming signal.

Photon-counting detectors, by contrast, can directly transform X-ray photons into electrical signals.

In a direct conversion process, the absorbed X-rays create electron-hole pairs in the semiconductor. The charges are separated in a strong electric field between cathode on top and pixelated anode electrodes at the bottom of the detector.

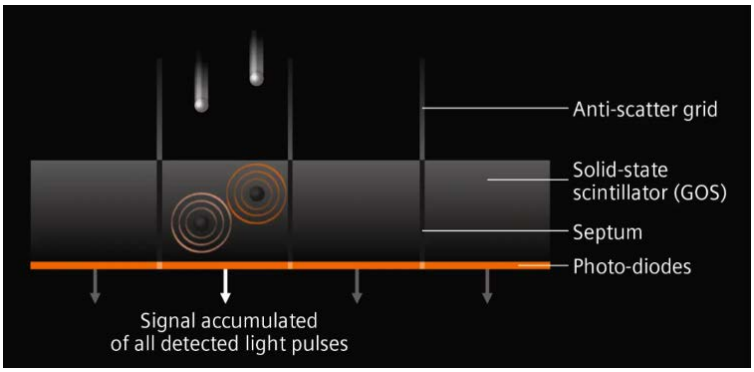



**FIGURE 1** *Photon-counting detector*

Compared to solid-state scintillation detectors, photon-counting detectors have several advantages. The individual detector cells are defined by the strong electric field between common cathode and pixelated anodes **(Figure 2)**, and there is no need for additional septa between the detector pixels to avoid optical cross-talk inherent to scintillation detectors. The geometrical dose efficiency is, therefore, better than that of scintillation detectors and only reduced by the anti-scatter collimator blades or grids that are also present in scintillation detectors. Furthermore, each "macro" detector pixel confined by collimator blades may be divided into smaller detector sub-pixels which are read-out separately to significantly increase spatial resolution.

With a photon-counting detector being able to count the charges created by individual x-ray photons as well as measuring their energy level, we now have a detector that has intrinsic spectral sensitivity in every scan.

## What Does This Mean For Computed Tomography – And For You?

The direct signal conversion of photon-counting detectors can have great impact: They are much more dose-efficient than current detectors. Also, their pixels are much smaller, which can significantly increase the spatial resolution. Based on this new technology, patients can expect even further reduction of radiation dose and less use of contrast agent. In addition, physicians can work with images that visualize even very fine tissue structures, such as the smaller bronchi of the lungs or metastases in bones.

- No downweighting of lower energy quanta: Improved image contrast
- Smaller detector pixels: High spatial resolution without losing dose efficiency
- Eliminate electronic noise: Lower radiation dose
- Intrinsic spectral sensitivity: Multi-energy information

MEDNAX National Medical Group PEDIATRIX OBSTETRIX

# Interventional Pediatric Cardiologist

## Successful Pediatric Cardiology Practice - Tropical Florida Coast

Pediatric Cardiology Associates, located in Tampa Bay on Florida's Gulf Coast, is seeking a BC Interventional Pediatric Cardiologist with advanced fellowship training and experience in Congenital Intervention.

- Ideally seeking candidates with a minimum of 5 years of experience post-fellowship
- Large, experienced, well-established team of 14 pediatric cardiologists and 3 NPs with offices and clinics located throughout the Tampa/St. Petersburg area
- Offer comprehensive congenital cardiac care from fetal life through adulthood
- The team includes members of all pediatric cardiology sub-specialties including: fetal, advanced imaging (CT, MRI, 3D echo), intervention, electrophysiology, cardiomyopathy/heart failure, prevention, and adult congenital
- The interventional team performs over 400 catheterizations per year, about 60% of which are interventions
- Recent interventional team accomplishments include:
  - implanting their 150th transcatheter pulmonary valve, Summer 2019
  - first program in Florida to implant the Gore Cardioform ASD Occluder, Fall 2019
  - only program in Tampa Bay currently offering PDA device closure for premature newborns, first implant, Winter 2016
- Sub-specialty clinics include general pediatric cardiology, intervention, pulmonary hypertension, cardiomyopathy, ACHD, electrophysiology, and prevention
- Our ACHD program is the ONLY certified Adult Congenital Heart Association program in central Florida
- This position also offers:
  - Full time interventional duties with expected procedural volume of 200+ catheterizations per year
  - No expectation of inpatient service coverage
  - 24/7 collaboration with our excellent pediatric cardiac surgical and pediatric cardiac intensive care teams at St Joseph's Children's Hospital
- Our center offers a unique depth of hospital infrastructure:
  - Two state of the art 1000+ square foot hybrid capable catheterization labs/ORs (one biplane, one single plane)
  - Two additional biplane catheterization labs
  - Two EP labs
- We have the added benefits of a children's hospital inside a large tertiary adult hospital simplifying care across all patient ages with easy access to consultants from all pediatric and adult specialties
- Pediatrix, as a national pediatric cardiology group with over 125 pediatric cardiologists, provides opportunities for quality initiatives that can have national impact
- We offer an attractive schedule allowing freedom to enjoy a great quality of life
- Generous compensation package offered

Tampa Bay's warm weather affords plenty of opportunities to relish the great outdoors year round. You will live in a region others only get to enjoy on vacation. Golf at one of nearly 100 courses or relax on one of the many pristine white-sand beaches. The area offers an assortment of family venues such as zoos, aquariums, theme parks, and state parks. Additionally Tampa Bay offers access to world-class museums, professional sporting events and the performing arts. There is a wide range of residential choices to fit every budget and lifestyle – whether you are looking for big city downtown living, golf course communities, waterfront lifestyle, majestic horse farms or historic neighborhoods.

**Benefits**

Our clinicians enjoy a competitive compensation package with many locations offering sign on bonuses, relocation and tuition reimbursement.
*Our benefits include:

- Health (various options), life, vision, dental and disability insurance
- 401(k) with annual matching program
- Advanced and continuing medical education
- Leadership training and advancement opportunities
- Employee stock purchase plan at a 15% discount
- Professional liability insurance
- Support and payment for mandatory license/s and hospital credentialing

*These benefits are for full time employees, employees in other types of employment classifications may be eligible for some of these benefits.

**Apply Here: https://www.click2apply.net/m66LAAFgxDRklkbmURbAA PI156893702**

Mednax Services, Inc. is a national medical group. Over the last 40 years, through our network of over 3,500 clinicians in 39 states and Puerto Rico, we have reshaped care delivery within women's and children's specialties and subspecialties. Our clinical teams care for the unique population of high-risk pregnancies and critically ill infants and children in both hospital and ambulatory clinical settings. Over the years, clinicians practicing as part of Pediatrix™ and Obstetrix™ Medical Groups have used evidence-based tools, continuous quality initiatives, clinical research, and telemedicine to enhance patient experience, outcomes and provide high-quality, cost-effective patient care. Our nationwide team of almost 8,000 employees, including physicians, advanced practitioners, clinical leaders, business and operational experts, work together every day to fulfill our mission to take great care of the patient®. We invite you to join the Mednax family and help shape the future of health care. Find additional information at **www.mednax.com**.

***MEDNAX is an Equal Opportunity Employer*** *All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability or veteran status.*

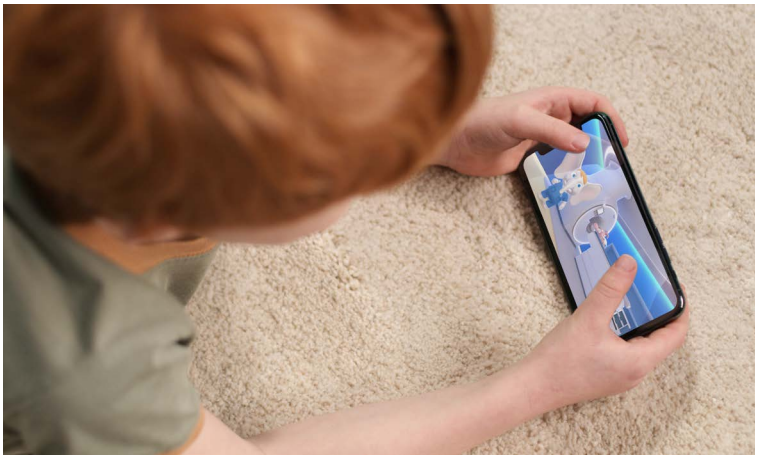
*Effective November 1st, 2021, MEDNAX will require all employees and new hires to be vaccinated against COVID-19, unless they qualify for an approved medical and/or religious exemption.*

# Philips Launches Pediatric Coaching to Enhance MR Imaging Patient Experience for Young Children at RSNA 2021

*Holistic, play-based coaching can help reduce use of general anesthesia1 and lower the risk of healthcare-induced trauma in many pediatric patients who feel anxious during MRI scans*

*Philips Ambient Experience solution uses augmented reality, gamification, and 'buddy system' techniques to engage and guide children through their entire MRI scan journey, from the home to the hospital*

Royal Philips, a global leader in health technology, today announced the launch of Philips Pediatric Coaching, a holistic solution designed to be a less stressful experience for parents and their children undergoing MRI scans. Using gamification and 'buddy system' techniques to prepare children and their parents beforehand, the solution helps guide young children through the MRI procedure to significantly enhance the patient experience. Pediatric Coaching is the latest initiative launched within the Philips Ambient Experience portfolio, featuring a wide range of dedicated solutions to help enhance the experience of patient and staff.



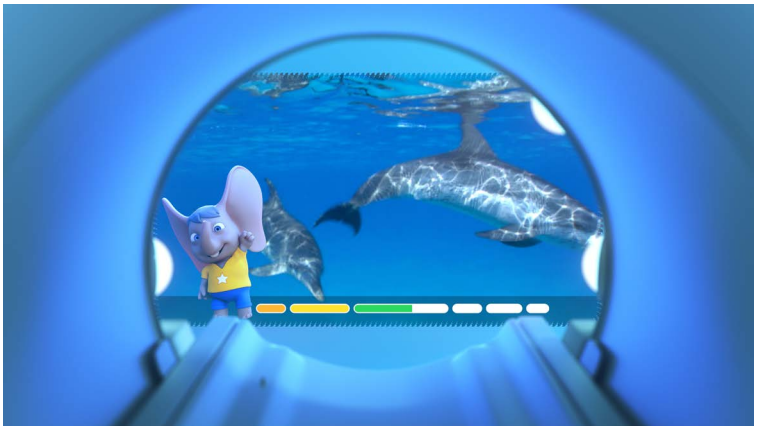
Acquiring high quality images in pediatric MRI can be challenging for both radiologists and the child undergoing the scan. Fear of the unfamiliar environment of an MRI system can be stressful for a younger child, making them agitated and unable to lie still, which is required for good image quality. As a result, scans are often performed under sedation or general anesthesia, which according to parents, carries disadvantages such as post-scan irritability for the child and concerns of repeated anesthesia exposure.[2] Having to resort to such measures or deal with a conscious but distressed child is challenging for hospital staff, increasing procedure time and costs. By helping to empower children during an MRI scan, the Philips Pediatric Coaching solution overcomes many of these issues.

"As adults, many of us can experience anxiety and stress during an MRI exam, and this is especially true for our youngest patients. By removing factors that can trigger stress, we are enhancing the patient engagement experience for pediatric patients to help improve outcomes," said Werner Satter, General Manager Philips Healthcare Environment and Experience Design. "With Philips Pediatric Coaching, we deploy gamification to help children better prepare for their MRI scan in a non-threatening environment at home, interacting with the same character and voice like Ollie the Elephant and friends, who also coaches them at the hospital, and can even coach them during the MRI procedure itself."

To prepare for their MRI scan, children are provided with a gamified mobile app that familiarizes the child and their parents with an MRI procedure in a playful way. The app also introduces the child to a virtual 'buddy' they can role-play with to perform an MRI scan - for example,


pretending to be the system operator and helping their buddy to lie still in order to get the best picture. The app also uses augmented reality to allow the child to explore the MRI system at home before entering the hospital. Many parents express a willingness to help prepare their child ahead of time, and by playing alongside their child, they can also learn more about the procedure.

When the family visits the radiology department, the same familiar virtual buddy interacts with the child as they play with Philips' newly enhanced 'Kitten Scanner' - a small scale educational scanner that allows children to scan various toy animals and view what's inside each animal for a better understanding of the upcoming procedure. When the child has their scan, their buddy's familiar voice and image are projected onto Philips' Ambient Experience in-bore Connect solution, to guide the child through the scan procedure by coaching them, for example, on when and how to hold their breath. With the new Pediatric Coaching Solution, parents are reassured, and the child is empowered and well-prepared, helping ensure the high-quality images needed for an accurate diagnosis of the child's condition are captured.



Today's announcement follows a similar child patient-centric initiative between Philips and the Walt Disney Company EMEA earlier this year to test the effects of custom-made animations, including specially made Disney stories, within Philips' Ambient Experiencehospital environments. An overview of breakthrough innovations in pediatric imaging to help improve care for younger patients, including how to reduce pediatric patients' fear and anxiety, is also discussed in a recent blog article by Dr. Julia Dmitrieva, KOL Engagement Leader for Precision Diagnosis at Philips.

The Philips Pediatric Coaching Solution is being launched at the 2021 International Pediatric Radiology Congress (IPR 2021), October 11 - 15, 2021, in Rome, Italy. Next to the MRI journey, Philips also plans to make its Pediatric Coaching available in other diagnostic imaging modalities such as CT. The solution was also demonstrated in the Philips booth at the 2021 Radiological Society of North America Annual Meeting (RSNA 2021), Nov. 28 - Dec 2, 2021, in Chicago, USA.

To see the video, please visit https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20211011-philips-launches-pediatric-coaching-to-enhance-mr-imaging-patient-experience-for-young-children.html

### References


1. Rung SB, Christensen, NL, Jensen K, Jensen IbE. Children centered care: Minimizing the need for anesthesia with a multifaceted concept for MRI in children aged 4–6. European Journal of Radiology. 2018;107:183–187.
2. Walker, B., Conklin, H. M., Anghelescu, D. L., Hall, L. P., Reddick, W. E., Ogg, R., & Jacola, L. M. (2018). Parent perspectives and preferences for strategies regarding nonsedated MRI scans in a pediatric oncology population. Supportive Care in Cancer, 26(6), 1815-1824.


CHiP NETWORK
CONGENITAL HEART INTERNATIONAL PROFESSIONALS



UCDAVIS CHILDREN'S HOSPITAL

## Pediatric Cardiac Interventionist Position

UC Davis Children's Hospital
School of Medicine
Department of Pediatric Cardiology

The Department of Pediatrics at the University of California, Davis School of Medicine is recruiting 1 full-time academic Pediatric Cardiac Interventionist within the Pediatric Cardiology specialty. We are recruiting at the Assistant/Associate/Full Professor level in the Clinical X or Health Science Clinical Series in the Section of Pediatric Cardiology, Department of Pediatrics and specifically trained and experienced in Pediatric Cardiac Interventions. Candidates must possess an M.D. or D.O. degree, be board certified in Pediatric Cardiology and must possess or be eligible for licensure in the State of California.

The interventional cardiology candidate must have at least 3 years of experience in interventions in congenital heart disease and have the desire and ability to build and grow a practice in interventional cardiology volume.

Work distribution will depend on the specific skillset of the candidate. It is expected that the candidate will share in the on-call and weekend/holiday coverage schedule.

In addition to the clinical responsibilities, the ideal candidate will be expected to participate in teaching of medical students, residents and fellows, research activities of the Department of Pediatrics, and serve on departmental committees.

The candidates must have the following qualifications:

- M.D. or D.O.
- Successful completion of an approved pediatric residency training program.
- Successful completion of an approved Pediatric Cardiology fellowship training program.
- Successful completion of a Pediatric Interventional Cardiology advanced fellowship training program.
- Board certification in Pediatric Cardiology.
- Eligibility for a California Medical License.
- Demonstrated proficiency in the teaching of students and housestaff.
- Demonstrated proficiency to perform clinical research.
- Ability to foster collegiality and work collaboratively in a diverse environment, including working closely with Adult Congenital Heart Disease services.
- Service including committees, leadership ability, and community outreach.
- Have Board Certification in Adult Congenital Heart Disease (preferred).

The Pediatric Heart Center at UC Davis Children's Hospital is inland Northern California's only full-service cardiac care facility for children and young adults, offering the latest tests and treatments for a range of congenital or acquired cardiovascular conditions. Our integrated multidisciplinary team of surgeons, specialists, physicians, nurses and researchers offer Northern California's most sophisticated specialized diagnostic, interventional and surgical expertise in comprehensive diagnostic, therapeutic, and surgical procedures for children with heart defects.

For full consideration applications should be received by December 27, 2021. However the position will remain open until filled. Completed applications include CV, Cover Letter, Statement of Contributions to Diversity, Equity, and Inclusion and contact information for 3-5 references.

**Candidates should submit their application online at:**
https://recruit.ucdavis.edu/JPF04580.

# TAVR with SAPIEN 3 Demonstrated as Economically-Dominant Treatment Strategy Compared to Surgery in Partner 3 Analysis

PRNewswire – Edwards Lifesciences has announced that a cost-effectiveness analysis comparing transcatheter aortic valve replacement (TAVR) to surgery demonstrated that TAVR with SAPIEN 3 is an economically-dominant treatment strategy, offering improved outcomes and reduced cost. This analysis from the PARTNER 3 trial was presented during the late-breaking clinical trials at the 33rd Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

The study compared healthcare costs, life expectancy and quality-adjusted life expectancy for patients with severe aortic stenosis at low risk for surgery, who were treated with TAVR or surgery in the PARTNER 3 trial.

A formal cost-effectiveness analysis conducted for the study found:

- TAVR using the SAPIEN 3 valve resulted in cost savings of greater than $2,000 per patient through the 2-year study period. This was achieved through marked reductions in hospital length of stay and substantially lower follow-up costs, which overcame higher index hospitalization and procedural costs for TAVR.
- Over the 2-year follow-up period, TAVR also led to a small but significant improvement in quality-adjusted life expectancy, driven by improved early quality of life and also survival.
- The probability that TAVR is highly cost-effective versus SAVR is approximately 95%.

"In addition to the outstanding clinical results compared with surgery, the finding that TAVR with SAPIEN 3 is also a lower cost strategy for low-risk patients empowers both cardiologists and patients with real choice in determining the right treatment option for severe aortic stenosis," said David J. Cohen, MD, MSc, Director of Clinical and Outcomes Research at the Cardiovascular Research Foundation and Director of Academic Affairs at St. Francis Hospital in New York. "TAVR is a unique technology with advantages over surgery from the perspective of both the patient and the healthcare system."

The PARTNER 3 trial randomized 1,000 patients at 71 centers between March 2016 and October 2017. Patients were assigned to undergo either TAVR with the SAPIEN 3 valve or surgery with any commercially available surgical valve. Clinical results from the PARTNER 3 trial were presented in 2019 and published in The New England Journal of Medicine.

"As we celebrate the 10-year anniversary of the SAPIEN valves' FDA approval in the United States, it is inspiring to reflect on the impact this technology has had on the treatment of patients with severe aortic stenosis," said Larry Wood, Edwards' Corporate Vice President, Transcatheter Aortic Valve Replacement. "These data add to the substantial body of evidence showing the advantages of TAVR over surgery in terms of effectiveness and cost efficiency at all surgery risk levels. We are proud that SAPIEN TAVR continues to stand out as a unique technology that extends patients' lives, improves quality of life and saves money for the healthcare system."

## About Edwards Lifesciences

Edwards Lifesciences is the global leader of patient-focused innovations for structural heart disease and critical care monitoring. We are driven by a passion for patients, dedicated to improving and enhancing lives through partnerships with clinicians and stakeholders across the global healthcare landscape. For more information, visit Edwards.com and follow us on Facebook, Instagram, LinkedIn, Twitter and YouTube.

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, but are not limited to, statements made by Mr. Wood and statements regarding expected product benefits, patient outcomes, product impacts to the healthcare system, future plans related to the product lines, objectives and expectations and other statements that are not historical facts. Forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain and difficult to predict. Our forward-looking statements speak only as of the date on which they are made, and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause results to differ materially from those expressed or implied by the forward-looking statements based on a number of factors as detailed in the company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2020, and its Quarterly Report on Form 10-Q for the quarters ended March 31, 2021, and June 30, 2021. These filings, along with important safety information about our products, may be found at Edwards.com.

Driscoll Children's Hospital

# Chief of Pediatric Interventional Cardiology

The Heart Center at Driscoll Children's Hospital is recruiting for a Chief of Interventional Cardiology to lead and guide a robust program engaged in providing the highest standard of care for its patients.

The ideal candidate will be board certified in Pediatric Cardiology with at least five years of clinical experience in pediatric interventional cardiac catheterization and a proven history in a leadership role with vision and strategic planning.

This is a full-time employed position with the multispecialty group, Children's Physician Services of South Texas (CPSST). The position offers a sign-on bonus, highly competitive compensation package, medical benefits, disability, life insurance, excellent retirement plans, generous paid vacation days, paid holidays, CME allowance and malpractice insurance.

Driscoll Children's Hospital is a freestanding children's hospital in Corpus Christi, Texas. The Driscoll Heart Center team includes inpatient and outpatient cardiologists specializing in Echo, Fetal, CMR, Imaging, electrophysiology, interventional cardiology, congenital cardiac surgeons, cardiac anesthesiologists and intensivists. Driscoll is a regional referral center for South Texas with supporting practices in Laredo, McAllen, and Brownsville.

Corpus Christi, Texas is a wonderful place to work, live and play! This is a dynamic coastal city with miles of beautiful beaches, world-class sailing, fishing and windsurfing. The mild climate allows for year-round outdoor family activities such as golf, cycling, and tennis. The cost of living is low, and there is no state income tax.

**Contact information:**

**Lori Smith**
Director of Physician Relations and Recruitment
D. 361.694.5906
M. 361.331.1311
**Lori.Smith@dchstx.org**

# Expert Consensus Update to SCAI SHOCK Stage Classification Incorporates New Data to Enhance Applicability in Clinical & Research Settings

*TCT 2021: Two-year update includes modifications and clarifications to account for the dynamic process of cardiogenic shock*

A newly-developed expert consensus statement will provide updated guidance on the use of the SCAI SHOCK Stage Classification, a five-stage system intended to facilitate communication about the diagnosis, presentation and evolving nature of cardiogenic shock (CS). The updated classification will be presented live at 9AM EST on Friday, November 5 by Srihari S. Naidu, MD, Director of the Cardiac Catheterization Laboratory at Westchester Medical Center and Trustee of SCAI, during a featured session titled New Directions in Cardiogenic Shock at the 33rd annual Transcatheter Cardiovascular Therapeutics (TCT) conference. The document was developed in collaboration with the American College of Cardiology, American College of Emergency Physicians, American Heart Association, European Society of Cardiology Association for Acute Cardiovascular Care, Cardiac Safety Research Consortium, Society of Critical Care Medicine, and the Society of Thoracic Surgeons, each of which had representation on the writing group.

Cardiogenic shock (CS) is a serious and life-threatening condition that occurs when the heart is unable to pump enough blood to the body's vital organs and is most commonly triggered by heart attack or heart failure. Mortality from cardiogenic shock complicating MI remains high, approaching or exceeding 50%, despite the development of percutaneous mechanical circulatory support technologies and the national standard of emergent angioplasty and stenting.

SCAI developed and released the SHOCK Stages classification in 2019 to provide a unified and standardized vocabulary that would translate across settings and providers from emergency room physicians and emergency medical services, to critical care physicians, heart failure physicians, interventional cardiologists and surgeons. While the system has been widely adopted for its simple and intuitive framework, and ability to discern gradations of severity of CS for the first time, recent validation studies conducted since 2019 have uncovered areas in need of refinement.

"Studies continue to validate the SCAI SHOCK Stage classification as a tool to help clinicians and researchers better understand cardiogenic shock and offer guidance on treatment pathways to improve survival," said Timothy Henry, MD, MSCAI, president of SCAI and Vice Chair of the Writing Group. "The updated expert consensus will underscore the benefit of the classification system across a broad patient spectrum and provides meaningful changes that we believe will enhance both clinical care and future research."

Key points and highlights of the updated classification include:

- SCAI SHOCK Stage is an indication of shock severity and comprises one component of mortality risk prediction in CS patients, along with etiology/phenotype and other risk modifiers; a 3-axis model of risk stratification in CS has been proposed to position SCAI SHOCK Stage in context.
- Validation studies have underscored the correlation of SCAI SHOCK Stage with mortality across all clinical subgroups, including CS with and without acute coronary syndrome, cardiac intensive 20 care unit (CICU) patients, and those presenting with out-of-hospital cardiac arrest (OHCA).
- Progression across the SCAI SHOCK stages continuum is a dynamic process, incorporating new information as available, and patient trajectories are important both for communication among clinicians and for decision-making regarding the next level of care and therapeutics.
- A hub and spoke model for transfer of higher risk patients including those with deteriorating SCAI SHOCK Stage has been proposed.
- Cardiac arrest (CA) as described herein relates to that accompanied by coma, defined as the inability to respond to verbal stimuli, most commonly associated with Glasgow Coma Scale < 9, where there is concern for significant anoxic brain injury.
- The SCAI SHOCK pyramid and associated figure now reflect gradations of severity within each stage and pathways by which patients progress or recover.
- A streamlined table incorporating variables that are most typically seen, and the revised CA modifier definition, is also provided and incorporates lessons learned from validation studies and clinician experience.
- Lactate level and thresholds have been highlighted to detect hypoperfusion but may be dissociated from hemodynamics in cases such as chronic heart failure. In addition, patients may demonstrate other manifestations of end-organ hypoperfusion with a normal lactate level and there are also important causes of an elevated lactate level other than shock.

"The new Figures and updated Table should leave less room for interpretation and enhance the standardization significantly, including placing the SCAI SHOCK Stages in context with other variables that must be evaluated when managing a patient with CS", states Dr. Naidu, who Chaired the Writing Group as well as the original one in 2019. "We also highlight new lactate thresholds and provide needed clarification for the pivotal SCAI SHOCK Stage C and the cardiac arrest modifier."

The writing group was organized to ensure a diversity of perspectives and stakeholder representation and achieve multi-specialty consensus around the updated classification scheme.

SCAI anticipates publication of the manuscript in the coming months.

## FEBRUARY

### 17-19

**CATCH: Caring for Adults and Teens with Congenital Heart Disease**
Oahu, Hawaii, USA
https://www.hawaiipacifichealth.org/CATCH

### 26-01

**CRT22**
Washington, D.C., USA
https://crtmeeting.org/Default.aspx?mkt_tok=MjcxLVJPVS0xMjQAAAGARtmr7GGCAKCWH-KPGINB9OBz_gWE70ZTgkzti5b8yjBY_CBNiT3RArF_35KpicybtR-8YhHFysgwOThFq5ffpeaYr01wsngBVdWx

## MARCH

### 15-17

**ALICE 2022 – Advanced Live Interventional Course of Essen**
Essen, Germany
https://alice-the-course.info/

### 26-27

**CSI Focus LAA & PFO**
Tokyo, Japan
https://www.csi-congress.org/laa-pfo

## APRIL

### 02-04

**ACC22**
Washington, D.C., USA
https://accscientificsession.acc.org/

### 03-05

**EHRA 2022**
Copenhagen, Denmark
https://www.escardio.org/Congresses-&-Events/EHRA-Congress

CONGENITAL CARDIOLOGY TODAY

CORPORATE OFFICE
PO Box 52316
Sarasota, FL 34232 USA

# CORPORATE TEAM



# EDITORIAL BOARD



# OFFICIAL NEWS & INFORMATION PARTNER OF

PICS Society
Pediatric *and Congenital* Interventional Cardiovascular Society




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