

July 2017; Volume 15; Issue 7  
International Edition

## IN THIS ISSUE

### Echocardiographic Diagnosis of Left Ventricular Pseudoaneurysm Presenting Two Months after Arterial Switch Operation - A Rare Complication

By Enas Shanshen, MD, FAAP; Joan Hoffman, MD; Chawki EL Zein, MD  
~Page 1

### Clinical Trials

~Page 8

### Medical News, Products & Information

~Page 10

### Medical Meeting

~Page 14

## Echocardiographic Diagnosis of Left Ventricular Pseudoaneurysm Presenting Two Months after Arterial Switch Operation - A Rare Complication

By Enas Shanshen, MD, FAAP; Joan Hoffman, MD; Chawki EL Zein, MD

### Introduction

Left ventricular (LV) pseudoaneurysms form when myocardium rupture is contained by adherent pericardium or scar tissue. It is well described in the adult literature as an uncommon complication of acute myocardial infarction, occurring in about 0.1% of patients. It is more common in adults than children, most likely given the higher incidence of Coronary Artery Disease. There is a spectrum of clinical presentations from asymptomatic to symptoms related to congestive heart failure. LV pseudoaneurysm is very rare in the pediatric population. As such, the diagnosis is difficult without a high index of suspicion given the nonspecific symptoms and the ambiguous clinical presentation. The diagnosis is more frequently seen in the adult population described as a complication after trauma, infection and myocardial infarction. The natural history is unknown owing to scarcity in the medical literature, and likewise, LV pseudoaneurysms are rare in the pediatric population. Nonetheless, it is a potentially critical complication following pediatric cardiac surgery, particularly in infants because of immature myocardium that may be more prone to rupture.<sup>1</sup> In pediatric patients, Trezzi et al described that it is seen as a complication after ventricular surgical repair of Ventricular Septal Defect (VSD).<sup>2</sup> It was also described after infective endocarditis of the mitral valve.<sup>3</sup> High clinical suspicion and urgent surgical management are crucial for improved outcome. We present a case of LV pseudoaneurysm that occurred in an infant with d-Transposition of the Great Vessels (D-TGA) two months after the arterial switch operation.

### Clinical Case

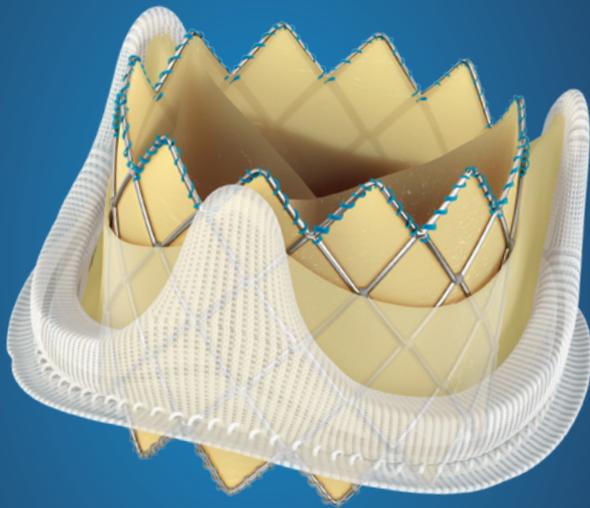
The patient had a postnatal diagnosis of D-TGA and Wolff Parkinson White (WPW) and underwent an arterial switch operation at five days of age. During the procedure, a 7-French LV sump was inserted through the right superior pulmonary vein into the left atrium and across the mitral valve into the LV cavity to

keep a dry field for surgical repair. Gentle suction was continuously applied to the sump by the roller pump of the cardiopulmonary bypass machine. The sump catheter was pulled out before weaning the heart off bypass. The intraoperative course was uncomplicated. The post-operative course was complicated by episodes of supraventricular tachycardia treated with antiarrhythmic medications. The patient was discharged home three weeks after surgery. The pre-discharge echocardiogram showed normal LV systolic function with no wall motion abnormality or pericardial effusion. At two months of age, the patient was admitted with history of poor feeding, respiratory distress and nasal congestion. On examination, the patient was afebrile with a heart rate of 162 beats per minute, respiratory rate of 45 breaths per minute, and blood pressure of 65/42 mmHg in the right lower extremity. Oxygen saturation was 97% on room air. He had normal pulses in the upper and lower extremities with no blood pressure differential. The precordium was hyper dynamic. Auscultation revealed normal first and second heart sounds with a third heart sound, and a grade 1/6 murmur at the left lower sternal border. The liver edge was just palpable below the costal margin. Breath sounds were normal and equal bilateral. The patient was on telemetry which showed significant ST depression that prompted performing electrocardiogram (ECG). The ECG showed ST depression and T wave inversion in the inferior and lateral leads that were not present after the initial surgical repair. Echocardiogram revealed a 10 x 15 mm cystic structure connected to the posterior-inferior LV cavity near the anterolateral papillary muscle with to and fro flow (Figures 1, 2, 3). As the LV systolic function was normal with no regional wall motion abnormality, coronary insufficiency was not suspected. Cardiac catheterization was not done because the anatomy of the pseudoaneurysm was clear enough by echocardiogram to guide the surgeon for management.

The patient underwent surgical repair on cardiopulmonary bypass. The LV pseudoaneurysm was well contained by an old organized thrombus reinforced by pericardial adhesions. There was no myocardial wall surrounding the pseudoaneurysm cavity. The fistulous communication was located at the

# CE MARK RECEIVED

# FOR USE IN FAILED SURGICAL BIOPROSTHETIC PULMONARY VALVES



## Melody™

Transcatheter Pulmonary  
Valve (TPV) Therapy

Reaching even  
more patients  
with Melody™ TPV

- The first commercially available TPV
- A breakthrough non-surgical option to treat failing pulmonary valve conduits
- Has treated more than 11,000 patients globally over the last 10 years

[Melody-TPV.com](http://Melody-TPV.com)

## Medtronic

Further. Together

## Melody™ Transcatheter Pulmonary Valve, Ensemble™ II Transcatheter Valve Delivery System

### Important Labeling Information for Geographies Outside of the United States

**Indications:** The Melody™ TPV is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

### Contraindications:

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture\*, stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

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

For additional information, please refer to the Instructions For Use provided with the product or available on <http://manuals.medtronic.com>.

The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.

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.cstechsupport@medtronic.com](mailto:rs.cstechsupport@medtronic.com)

Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic. All other brands are trademarks of a Medtronic company.

# Medtronic

# CHIIP NETWORK

CONGENITAL HEART INTERNATIONAL PROFESSIONALS

## Get involved with CHIIP (Congenital Heart International Professionals Network)

We need your help:

- Finding news stories.
- Creating journal watch.
- Keeping track of upcoming meetings.
- Building our presence on LinkedIn, Facebook, and Twitter.
- Creating more value for our readers/subscribers.
- Engaging our partner organizations.
- Fundraising to support our activities.

Step up! Here's how to contact us:

[www.chipnetwork.org/Contact](http://www.chipnetwork.org/Contact)

We'd like to know WHO you are, WHERE you are, and WHAT you do.

Please go to [www.chipnetwork.org](http://www.chipnetwork.org) and let us know more about you. It only takes two minutes. Then we'll be able to send you messages targeted to your interests.

I hope you will consider joining the CHIIP Network and help foster a strong congenital heart care community.

Sincerely,

Gary Webb, MD  
**CHIIP Network**  
215-313-8058  
[garywebb6@gmail.com](mailto:garywebb6@gmail.com)



The CHIIP Network, the Congenital Heart Professionals Network, is designed to provide a single global list of all CHD-interested professionals.

## CONGENITAL CARDIOLOGY TODAY

### CALL FOR CASES AND OTHER ORIGINAL ARTICLES

Do you have interesting research results, observations, human interest stories, reports of meetings, etc. to share? Submit your manuscript to: [RichardK@CCT.bz](mailto:RichardK@CCT.bz)

junction of the septum and the diaphragmatic wall of the left ventricle and well epithelialized. This was repaired using multiple interrupted 5-0 Prolene pledged sutures. The patient had an uneventful recovery. Echocardiogram showed near normal LV systolic function, and the patient was discharged home after 3 days.

## Discussion

LV pseudoaneurysm has been reported following myocardial infarction in the adult population. To our knowledge, there have been no reported cases of LV pseudoaneurysms in pediatric patients after arterial switch operation.

It has been described following prosthetic mitral valve replacement<sup>4</sup> and at the ventriculotomy site in per ventricular repairs. The proposed mechanism of LV pseudoaneurysm development following arterial switch operation is unclear. Arterial switch operation with coronary translocation has been the procedure of choice for correction of D-TGA for several decades now. The procedure has low mortality and morbidity rates as 90% of patients now reach adulthood. Post-surgical coronary artery thrombosis, embolism or spasm creating an infarcted area with subsequent LV wall weakening and pseudoaneurysm formation is a possibility. This was described as a complication of the coronary artery procedures in cases with intramural coronary artery course.<sup>5</sup> Coronary lesions were detected in up to 5% of patients, at a mean interval of  $33 \pm 38$  months (1 month - 10 years) after arterial switch operations.<sup>6</sup> Myocardial ischemia was demonstrated involving territories of the left main coronary artery, the left anterior descending artery, and the right coronary artery. The patients presented with signs of coronary ischemia and myocardial infarction, but none of them developed LV pseudoaneurysm. Our patient developed post-operative SVT which might have been an enhancing factor that compromised coronary blood flow. However there were no clinical symptoms of myocardial ischemia throughout the hospital stay such as ventricular arrhythmia or Low Cardiac Output Syndrome. The location of the pseudoaneurysm in the thick posterior-inferior wall of the LV, as well as the proximity of the pseudoaneurysm from the diaphragm might have provided time for chronic formation as well as thrombus organization.

The natural history of pseudoaneurysms in the pediatric population is unknown. In the adult literature, it is estimated that 30–45% of ventricular pseudoaneurysms will rupture. Furthermore the mortality reaches 48% after medical therapy and up to 23% after surgical repair.<sup>7,8</sup>

The etiology of the pseudoaneurysm was presumed to be chronic progressive weakening and ultimately rupture of the LV free wall secondary to the sump catheter

pressing on the wall during the course of the initial surgical repair. The sump catheter likely caused pressure on the LV wall with progressive chronic thinning and ultimately

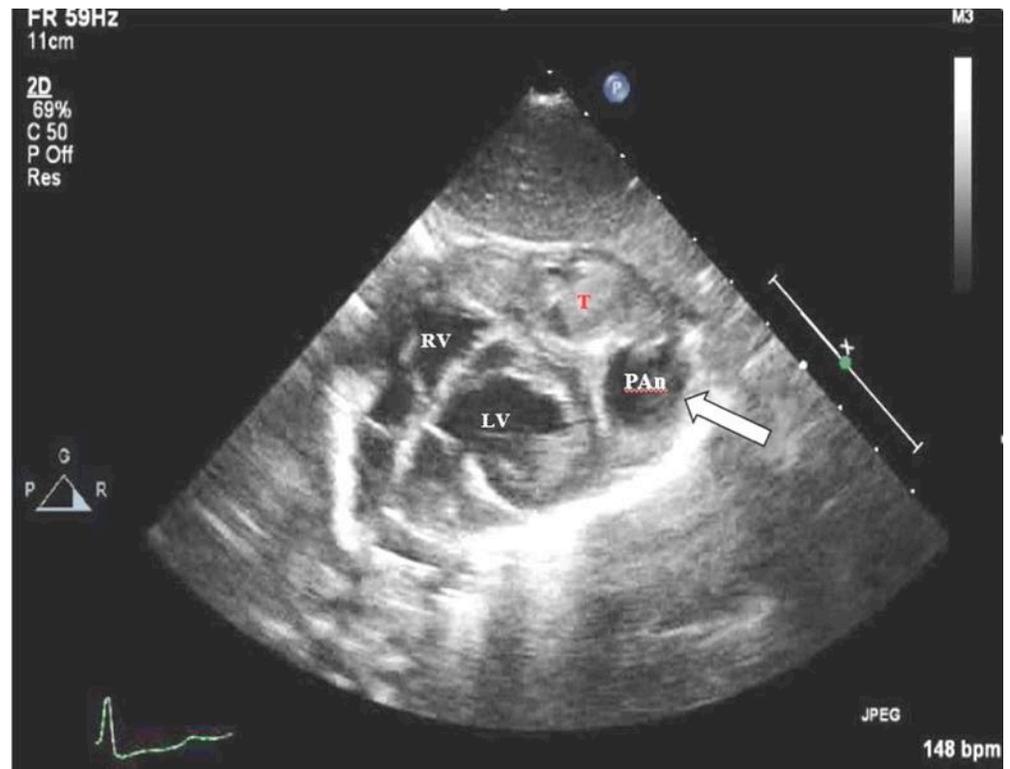


Figure 1. Subcostal coronal view showing both right ventricle (RV), left ventricle (LV) and the well contained LV pseudoaneurysm (arrow) surrounded by the organized thrombus in the pericardial space (T).

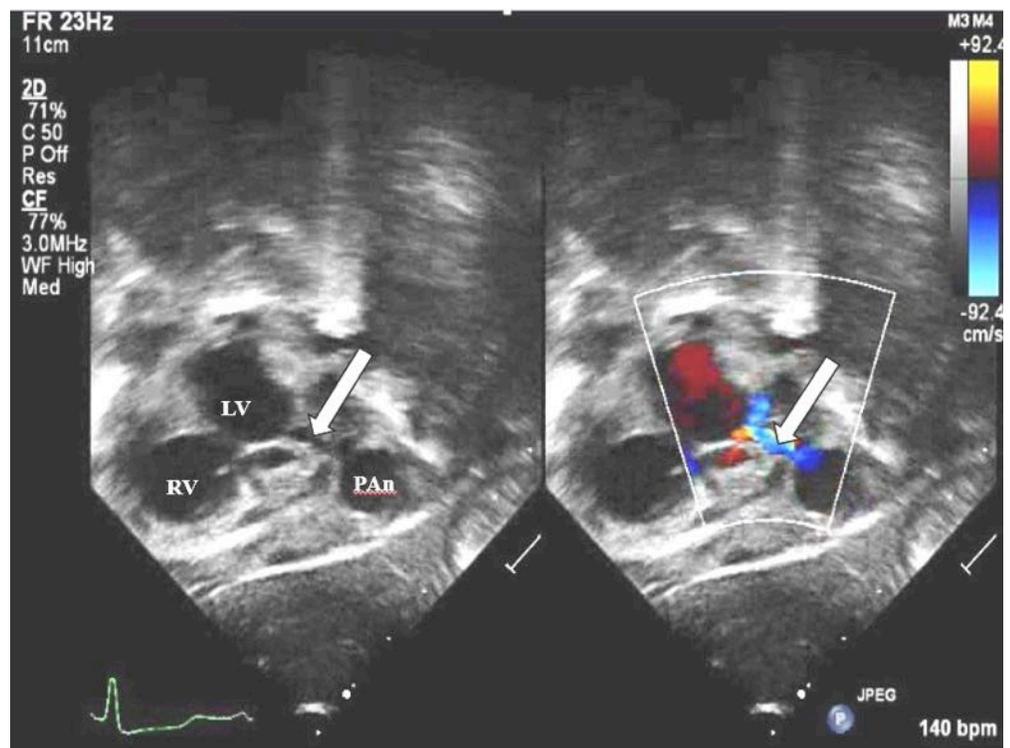


Figure 2. Echocardiogram; subcostal coronal views showing right ventricle (RV), and left ventricle (LV) communication with the LV pseudoaneurysm (PAn) through a fistulous connection (arrow).

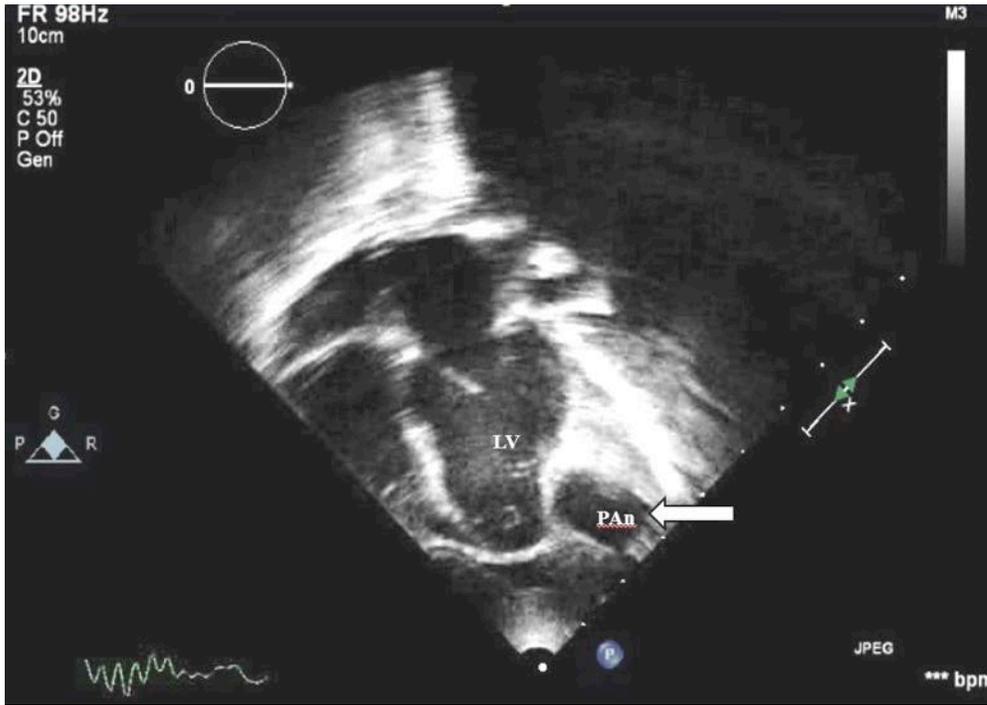


Figure 3. Apical four chamber view in 2-D showing the LV pseudoaneurysm size and location (PAN) (arrow).

rupture of the myocardium with continuous contraction late after the patient was discharged home. The possibility of coronary ischemia and infarction was very unlikely in view of the absence of LV wall motion abnormalities on pre-discharge echocardiography after the arterial switch operation. Endocarditis with myocardial abscess formation and LV wall weakness were unlikely causes as the patient had no infectious concerns.

In our patient, the clinical symptoms and exam were vague, and it was likely related to coincidental viral syndrome. ECG displayed ST segment depressions and T wave inversions which were concerning for the LV pathology. This prompted performing echocardiogram study. The echocardiography was diagnostic, and gave all the information needed before planning surgical repair. We did not pursue further imaging, as the echocardiogram clearly delineated the pathology. After LV pseudoaneurysm resection, the patient recovered and was discharged in three days with no complications.

To our knowledge, there have been no reported cases of LV pseudoaneurysms in pediatric patients after arterial switch operation or after any other cardiac surgery. This might be related to improper positioning of the LV sump during cardiopulmonary bypass, or coronary artery accident after the arterial switch operation. However, even though this was not previously reported, it can certainly be a preventable complication. Specific mortality data for this repair is

unknown, but anticipated to be significant and comparable to “redo” operations in general.

### Conclusion

Left ventricular pseudoaneurysm is a rare, but serious complication after cardiac surgery in infants. The etiology is often iatrogenic and suspected to be due to chronic LV wall thinning leading to eventual rupture due to myocardial ischemia. The initial insult can occur as a complication of surgeries that require coronary interventions, or may be secondary to myocardial blood supply compromise due to direct and prolonged pressure of the surgical equipment on the LV endocardium. Imaging via echocardiogram can provide valid information pertaining to diagnosis, as well as prognostic data required for appropriate management. Surgery is the main stay of treatment. Pediatric cardiologists and congenital cardiac surgeons should be aware of this potential complication.

### References

1. Frances C, Romero A, Grady D. Left ventricular pseudoaneurysm. J Am Coll Cardiol. 1998; 32:557–561.
2. Trezzi M, Kavarana MN, Hlavacek AM, Bradley SM. Left ventricular pseudoaneurysm after periventricular ventricular septal defect device closure. J Card Surg. 2014 Mar; 29(2):186-8.
3. Sachdeva R, Imamura M. Left ventricular pseudoaneurysm: a rare complication of infective endocarditis.

- World J Pediatr Congenit Heart Surg. 2011 Oct 1; 2(4):644-7.
4. Carlson EB, Wolfe WG, Kisslo J. Subvalvular left ventricular pseudoaneurysm after mitral valve replacement: two-dimensional echocardiographic findings. J Am Coll Cardiol. 1985; 6(5): 1164-1166.
5. Thrupp SF, Gentles TL, Kerr AR, Finucane K. Arterial switch operation: early and late outcome for intramural coronary arteries. Ann Thorac Surg. 2012 Dec; 94(6):2084-90.
6. Raisky O et-al. late coronary artery lesions after neonatal arterial switch operation: results of surgical coronary revascularization. Eur J Cardiothorac Surg. 2007 May; 31(5): 894-8.
7. Brown SL, Gropler RJ, Harris KM. Distinguishing left ventricular aneurysm from pseudoaneurysm. A review of the literature. Chest. 1997; 111:1403–9.
8. Si D, Shi K, Gao D, Yang P. Ruptured left ventricular pseudoaneurysm in the mediastinum following acute myocardial infarction: A case report. Eur J Med Res. 2013; 18:

### CCT

#### About the Author

Dr. Enas Shanshen, MD, FAAP is a third year Pediatric Cardiology Fellow at Advocate Children’s Heart Institute.

#### Memberships:

American Society of Echocardiography  
American College of Cardiology  
American Academy of Pediatrics

Joan Hoffman, MD  
Lutheran Children’s Hospital  
Park Ridge, IL USA

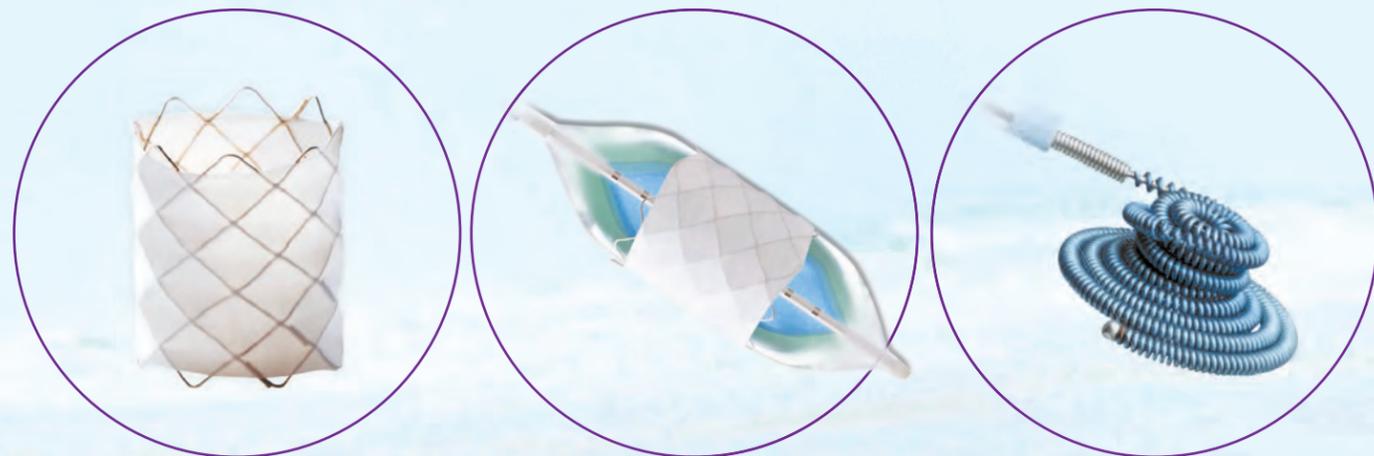
Chawki EL Zein, MD  
Advocate Children’s Hospital  
Oak Lawn, IL 60453 USA

#### Corresponding Author

Enas Shanshen, MD, FAAP  
Advocate Children’s Hospital  
4440 West 95th St.  
Oak Lawn, IL 60453 USA  
Phone: 708-684-8790

Enas.Shanshen@advocatehealth.com  
or  
md.enasms@gmail.com

# MAKING A DIFFERENCE



CP STENT™ UNMOUNTED OR PRE-MOUNTED ON A BIB® CATHETER  
 FOR TREATMENT OF COARCTATION OF THE AORTA

NIT-OCCLUD® PDA COIL SYSTEM  
 FOR TREATMENT OF PATENT DUCTUS ARTERIOSUS



**INDICATIONS FOR USE:**

The CP Stent™ is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving a compliant aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery and the balloon angioplasty is contraindicated or predicted to be ineffective. **WARNINGS / PRECAUTIONS:** Coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta should be confirmed by diagnostic imaging. The CP stent has not been evaluated in patients weighing less than 20kg. As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess. Over-stretching of the artery may result in rupture or aneurysm formation. Crimping the stent on a balloon catheter smaller than 12mm may cause damage to the stent. This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross-contamination. **CONTRAINDICATIONS:** Patients too small to allow safe delivery of the stent without compromise to the systemic artery used for delivery. Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty. Curved vasculature. Occlusion or obstruction of systemic artery precluding delivery of the stent. Clinical or biological signs of infection. Active endocarditis. Known allergy to aspirin, other antiplatelet agents, or heparin. Pregnancy.

**INDICATIONS FOR USE:**

The Covered CP Stent™ is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery associated with one or more of the following: Acute or chronic wall injury; Nearly atretic descending aorta of 3 mm or less in diameter; A non-compliant stenotic aortic segment found on pre-stent balloon dilation; A genetic or congenital syndrome associated with aortic wall weakening or ascending aortic aneurysm. **WARNINGS / PRECAUTIONS:** Coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta should be confirmed by diagnostic imaging. The CP stent has not been evaluated in patients weighing less than 20kg. As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess. Over-stretching of the artery may result in rupture or aneurysm formation. Crimping the stent on a balloon catheter smaller than 12mm may cause damage to the stent. Excessive handling and manipulation of the covering while crimping the stent may cause the covering to tear off of the stent. This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross-contamination. **CONTRAINDICATIONS:** Patients too small to allow safe delivery of the stent without compromise to the systemic artery used for delivery. Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty. Curved vasculature. Occlusion or obstruction of systemic artery precluding delivery of the stent. Clinical or biological signs of infection. Active endocarditis. Known allergy to aspirin, other antiplatelet agents, or heparin. Pregnancy.

**INDICATIONS FOR USE:**

The Nit-Occlud® PDA coil is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of small to moderate size patent ductus arteriosus with a minimum angiographic diameter less than 4mm. Nit-Occlud Brief Statement: Do not implant the Nit-Occlud PDA into patients who have endocarditis, endarteritis, active infection, pulmonary hypertension (calculated PVR greater than 5 Wood Units), thrombus in a blood vessel through which access to the PDA must be obtained, thrombus in the vicinity of the implantation site at the time of the implantation or patients with a body weight < 11 lbs (5 kg). An angiogram must be performed prior to implantation for measuring length and diameter of the PDA. Only the pfm medical implantation delivery catheter should be used to implant the device. Administration of 50 units of heparin per kg body weight should be injected after femoral sheaths are placed. Antibiotics should be given before (1 dose) and after implantation (2 doses) in order to prevent infection during the implant procedure. Do not implant the Nit-Occlud PDA in an MR environment. Do not pull the Nit-Occlud coil through heart valves or ventricular chambers. Contrast media should not be injected through the implantation catheter. The catheter must not be connected to high pressure injectors. Patients may have an allergic response to this device due to small amounts of nickel that has been shown to be released from the device in very small amounts. If the patient experiences allergic symptoms, such as difficulty in breathing or swelling of the face or throat, he/she should be instructed to seek medical assistance immediately. Antibiotic prophylaxis should be performed to prevent infective endocarditis during first 6 months after coil implantation. Potential Adverse Events: Air embolism, Allergic reaction to drug/contrast, Apnea, Arrhythmia requiring medical treatment or pacing, Arteriovenous fistula, Bacterial endocarditis, Blood loss requiring transfusion, Chest pain, Damage to the tricuspid or pulmonary valves, Death, Embolization of the occluder, requiring percutaneous or surgical intervention, Endarteritis, False aneurysm of the femoral artery, Fever, Headache/migraine, Heart failure, Hemolysis after implantation of the occluder, Hypertension, Hypotension or shock, Infection, Myocardial infarction, Occluder fracture or damage, Perforation of the heart or blood vessels, Stenosis of the left pulmonary artery or descending thoracic aorta, Stroke/TIA, Thromboembolism (cerebral or pulmonary), Valvular Regurgitation, Vessel damage at the site of groin puncture (loss of pulse hematoma, etc.).

Refer to the Instructions for Use for complete indications, relevant warnings, precautions, complications, and contraindications.

CP Stent is a trademark of NuMED, Inc. BIB is a registered trademark of NuMED, Inc. Nit-Occlud is a registered trademark of pfm medical, Inc.

Rx only CV9058 - 9/16 ©2016 B. Braun Interventional Systems Inc.



Distributed by:

B. Braun Interventional Systems Inc. | 824 Twelfth Avenue | Bethlehem, PA 18018 USA

Tel 877 836 2228 | Fax 610 849 1334 | www.bisusa.org

# Clinical Trials from ClinicalTrials.gov

## The Medtronic Harmony™ Transcatheter Pulmonary Valve Clinical Study

*This study is currently recruiting participants*

**Sponsor:** Medtronic Cardiovascular

**Information provided by (Responsible Party):**  
Medtronic Cardiovascular

**ClinicalTrials.gov Identifier:** NCT02979587

**First received:** November 23, 2016

**Last updated:** April 28, 2017; **Last verified:** April 2017

**Purpose:** The purpose of this study is to evaluate the safety and effectiveness of the Harmony TPV system.

### Condition:

- Congenital Heart Disease (CHD)
- Tetralogy of Fallot (TOF)
- RVOT Anomaly
- Pulmonary Regurgitation

### Intervention:

- Device: Harmony Transcatheter Pulmonary Valve
- Device: Harmony Delivery System

**Study Type:** Interventional

**Study Design:** Intervention Model: Single Group Assignment

**Masking:** No masking

**Primary Purpose:** Treatment

### Further Study Details as Provided by Medtronic Cardiovascular:

#### Primary Outcome Measures:

- Freedom from procedure- or device-related mortality at 30 days. [Time Frame: 30 days]
- Percentage of subjects with acceptable hemodynamic function composite at 6 months. [Time Frame: 6 months] Defined as:
- Mean RVOT gradient as measured by continuous-wave Doppler  $\leq 40$  mmHg -AND-
- Pulmonary regurgitant fraction as measured by magnetic resonance imaging  $< 20\%$

#### Secondary Outcome Measures:

- Technical success at exit from catheterization lab/operating room (OR) [Time Frame: At exit from catheterization lab/operating room (OR)]
- Device Success out to 5 years [Time Frame: 5 years]
- Procedural Success at 30 days [Time Frame: 30 days]
- Freedom from TPV Dysfunction out to 5 years [Time Frame: 5 years]
- Incidence of Treatment-Emergent Adverse Events (safety) [Time Frame: 5 years] All procedure-related serious adverse events. All device-related serious adverse events. Death (all-cause, procedural, and device-related)

- Characterization of quality of life scores over time as assessed by the SF-36 [Time Frame: 5 years]
- Characterization of right ventricle remodeling following TPV implant [Time Frame: 5 years]

**Estimated Enrollment:** 40

**Study Start Date:** January 2017

**Estimated Study Completion Date:** December 2023

**Estimated Primary Completion Date:** December 2018 (Final data collection date for primary outcome measure)

### Arms:

- Harmony TPV
- Intervention Device: Harmony Transcatheter Pulmonary Valve

### Assigned Interventions:

- Device: Harmony Transcatheter Pulmonary Valve
- Device: Harmony Delivery System

**Ages Eligible for Study:** Child, Adult, Senior

**Sexes Eligible for Study:** All

**Accepts Healthy Volunteers:** No

### Inclusion Criteria:

- Subject has pulmonary regurgitation
- Subject has clinical indication for surgical placement of an RV-PA conduit or bioprosthetic pulmonary valve

### Exclusion Criteria:

- Patients with Right Ventricular Outflow Tract Obstruction (RVOTO) lesions surgically treated with an RV-to-PA conduit implant
- RVOT anatomy or morphology that is unfavorable for device anchoring

### Contacts and Locations:

**Contact:** Kristin J Boulware; 763-514-9809  
[kristin.j.boulware@medtronic.com](mailto:kristin.j.boulware@medtronic.com)

#### Locations - United States, California

Ronald Regan UCLA Medical Center  
Los Angeles, California, United States, 90095  
Contact: Daniel Levi, MD  
Contact: Rachel Bolanos  
*Recruiting*

Stanford  
Palo Alto, California, United States, 94305  
Contact: Doff McElhinney, MD  
Contact: Melissa Jenkins  
*Recruiting*



**International Workshop  
on Interventional Pediatric  
and Adult Congenital Cardiology**

**September  
28th-30th 2017**

*Crowne Plaza Linate*



#### United States, Connecticut

Yale University  
New Haven, Connecticut, United States, 06510  
Contact: Jeremy Asnes, MD  
Contact: Amanda Catucci  
*Recruiting*

#### United States, Ohio

Nationwide Children's Hospital  
Columbus, Ohio, United States, 43215  
Contact: John P Cheatham, MD, MSCAI 614-722-6124  
[John.Cheatham@nationwidechildrens.org](mailto:John.Cheatham@nationwidechildrens.org)  
Contact: Joanne L Chisolm, MSN, RN 614-355-5736  
[Joanne.Chisolm@nationwidechildrens.org](mailto:Joanne.Chisolm@nationwidechildrens.org)  
Principal Investigator: John P Cheatham, MD, MSCAI  
*Recruiting*

#### United States, Pennsylvania

The Children's Hospital of Philadelphia  
Philadelphia, Pennsylvania, United States, 19104  
Contact: Matthew Gillespie, MD  
Contact: Olivia Martino  
*Recruiting*

**Sponsors and Collaborators:** Medtronic Cardiovascular

**Principal Investigator:** John P Cheatham, MD, Nationwide Children's Hospital

**Responsible Party:** Medtronic Cardiovascular

**ClinicalTrials.gov Identifier:** NCT02979587

**Other Study ID Numbers:** Medtronic Harmony TPV Pivotal

**Study First Received:** November 23, 2016

**Last Updated:** April 28, 2017

#### Additional Relevant MeSH Terms:

- Heart Diseases
- Pulmonary Valve Insufficiency
- Respiratory Insufficiency
- Tetralogy of Fallot
- Cardiovascular Diseases
- Heart Valve Diseases
- Respiration Disorders
- Respiratory Tract Diseases
- Heart Defects, Congenital
- Cardiovascular Abnormalities
- Congenital Abnormalities

*ClinicalTrials.gov processed this record on May 17, 2017*

#### For more detailed information visit:

<https://clinicaltrials.gov/ct2/show/NCT02979587?term=harmony&rank=3>

## CONGENITAL CARDIOLOGY TODAY

### We Can Help You

#### Recruit:\*

- **Pediatric Cardiologists**
- **Pediatric Interventional Cardiologist**
- **Adult Cardiologist focused on CHD**
- **Congenital/Structural Heart Surgeons**
- **Echocardiographers,**
- **EPs**
- **Pediatric Transplant Cardiologist**

\*Reach over 6,000 BC/BE Cardiologists focused on CHD worldwide

### Your Recruitment Advertising Includes:

- Full color Recruitment ad in the issue(s)
- Your recruitment listing in the email blast for the issue(s) with a hot link
- 3-Step Special Recruitment Opportunity Website Section in three (3) areas of the website
- *We can create your recruitment ad at no extra charge!*

#### For more Information Contact:

**Tony Carlson**

+1.301.279.2005 or

[tcarlsonmd@gmail.com](mailto:tcarlsonmd@gmail.com)



## Archiving Working Group

**International Society for Nomenclature of  
Paediatric and Congenital Heart Disease**

[ipccc-awg.net](http://ipccc-awg.net)

# Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

## EchoPixel, Inc. Appoints Bill Carrano as Vice President of Sales - Industry Veteran Brings Three Decades of Experience to Visionary Medical Software

Marketwired - - EchoPixel, Inc. has pioneered True 3D, an interactive virtual reality software solution that assists healthcare professionals in detailed interpretation of medical images, both for diagnosis and surgical planning. On May 22<sup>nd</sup>, the company announced that business and marketing executive Bill Carrano will be joining the company as Vice President of Sales.



Bill Carrano, Vice President of Sales - EchoPixel

Mr. Carrano has more than 30 years of professional experience in the medical device industry and has been a driving force in the introduction of innovative technologies in the rapidly evolving area of medical imaging. Most recently, as the leader of Strategic Business Management of GE Healthcare, Mr. Carrano was responsible for developing strong collaborations with key opinion leaders to achieve rapid market adoption. In addition, he implemented strategies to significantly grow market share by leveraging National Health Systems and solutions based on rapidly changing customer workflow needs.

"My experience at GE Healthcare, Siemens, and Acuson have been invaluable in preparing me for this role," Carrano noted, "I'm thrilled to take on this new challenge and grow EchoPixel to its full potential to revolutionize medical imaging, clinical efficacy, and workflow."

In his new role as Vice President of Sales at EchoPixel, Mr. Carrano will be responsible for building and executing new business and marketing initiatives that will further advance the broad utilization of True 3D for intricate surgical planning and challenging diagnostic decisions, such as identification of colon lesions.

"Bill's addition to the company could not be coming at a more opportune time," stated Ron Schilling, EchoPixel CEO. "With our planned sales expansion and our increased clinical usage, we're charging forward on our mission to change the way healthcare professionals communicate and operate, ultimately improving patient outcomes. Bill is crucial to that success."

In February, EchoPixel introduced True 3D Print Support, designed to enhance the efficacy and accuracy of 3D-printed medical models. The system is currently used at Stanford Medical Center for the planning of congenital heart surgery in newborns, at the University of California to conduct virtual colonoscopies, as well as at luminary sites such as the Cleveland Clinic. Echopixel has FDA market clearances for its products, medical device licenses in Canada, and the CE Mark to market in the European Union.

EchoPixel is building a new world of patient care with its groundbreaking medical visualization software. The company's FDA-cleared True 3D Viewer uses existing medical image datasets to create virtual reality environments of patient-specific anatomy, allowing physicians to view and dissect images just as they would real, physical objects. The technology aims to make reading medical images more intuitive, help physicians reach diagnosis, and assist in surgical planning.

EchoPixel is a privately held, venture backed company located in Mountain View, Calif. For more information, visit: [www.echopixeltech.com](http://www.echopixeltech.com).

## The University of Maryland School of Medicine (UMSOM) and the Interdisciplinary Stem Cell Institute (ISCI) at the University of Miami Miller School of Medicine Have Begun Testing to See Whether Bone Marrow-Derived Cells Will Benefit Children with the Congenital Heart Defect HLHS

In a first-in-children randomized clinical study, the University of Maryland School of Medicine (UMSOM) and the Interdisciplinary Stem Cell Institute (ISCI) at the University of Miami Miller School of Medicine have begun testing to see whether bone marrow-derived cells will benefit children with the Congenital Heart Defect Hypoplastic Left Heart Syndrome (HLHS).

"Allogeneic Human Mesenchymal Stem Cell Injection in Patients with Hypoplastic Left Heart Syndrome: An Open Label Pilot Study" is a Phase I/IIb clinical trial to test the therapeutic effects of the allogeneic mesenchymal stem cells (MSCs) in children with HLHS. ISCI will be providing the MSCs and clinical site for the trial is at UMSOM.

Even with extensive surgical treatments, HLHS babies still do not have optimal outcomes. The researchers hope the cells will increase the babies' chances of survival as HLHS limits the heart's ability to pump blood from the heart to the body because of poor right ventricle function.

"The premise of this clinical trial is to boost or regenerate the right ventricle, the only ventricle in these babies, to make it pump as strongly as a normal left ventricle," says lead researcher Sunjay Kaushal, MD, PhD, Associate Professor of Surgery, University of Maryland School of Medicine and Director, Pediatric Cardiac Surgery, University of Maryland Medical Center. "We are hoping this therapy will be a game-changer for these patients."

This is the first HLHS research in the United States to use stem cells known as allogeneic mesenchymal stem cells (MSC). The allogeneic nature of the MSCs makes it possible for stem cells from one bone marrow donor to provide all the stem cells for this study. In adult patients, MSCs in the heart have been shown to reduce scar tissue, reduce inflammation, cause new small vessels to grow, and stimulate the heart to regenerate itself by improving ejection fraction by 7%, causing heart muscle cells and cardiac stem cells to grow.

This trial is intended to address the remaining obstacles to long-term cardiac function in HLHS patients. We propose that a stem cell-based therapy for these patients may prevent right heart failure, and therefore, improve survival outcomes and reduce the need for



**PICS-AICS** Pediatric and Adult Interventional Cardiac Symposium  
**VEGAS** MGM GRAND LAS VEGAS  
SEPTEMBER 5-8, 2018  
[www.picsymposium.com](http://www.picsymposium.com)

transplantation. The MSCs are directly injected into the right ventricular myocardium during the 2nd out of 3 standard operations (Glenn procedure/Bidirectional Cavopulmonary Anastomosis)—when the baby is about 4 months of age.

To date, our three enrolled patients are all showing early signs of safety and feasibility. This trial will be testing a total of 30 patients, and after proving that this stem cell therapy works in strengthening the heart function. If you would like more information and have a patient who might want to consider participation in this landmark trial, please contact Dr. Sunjay Kaushal at 410-328-5842 or by email: [SKaushal@som.umaryland.edu](mailto:SKaushal@som.umaryland.edu).

### Research Led by the Children's Hospital of Michigan Provides New Insights into the Management and Clinical Outcomes for Children with Cardiomyopathy

Cardiomyopathy is a heart condition involving abnormalities of the muscle fibers, which contract with each heartbeat. According to the Pediatric Cardiomyopathy Registry, one in every 100,000 children in the U.S. under the age of 18 is diagnosed with cardiomyopathy. Dilated cardiomyopathy is the most common type of cardiomyopathy in infancy, childhood, and adolescence. Many children newly diagnosed with dilated cardiomyopathy and heart failure do not have a good long-term prognosis and may need a heart transplant or other medical interventions in order to survive.

Children's Hospital of Michigan Pediatric Cardiologist Steven E. Lipshultz, MD, Senior Author and Principal Investigator of the study, explains that some children with dilated cardiomyopathy have other family members known to have dilated cardiomyopathy. This is called familial dilated cardiomyopathy, and is mostly due to a gene mutation or set of gene mutations found in family members.

Dr. Lipshultz says that children with familial dilated cardiomyopathy are generally diagnosed at a younger age than children, whose dilated cardiomyopathy is not thought to be familial, since they are more likely to be screened for heart problems at an earlier age due to known other family members affected with this condition. The children with familial dilated cardiomyopathy are more likely to receive a heart transplant or intervention, such as placement of a left Ventricular Assist Device (VAD) sooner due to earlier screening and therefore being identified as high risk.

"What this new study shows is that just because the children with familial dilated cardiomyopathy are more likely to receive a heart transplant, these heart transplants may not always be necessary since we found that these children may not die sooner or in greater numbers than children with dilated cardiomyopathy whose cause is not known to be familial. This is a critical finding since some of those children with familial dilated cardiomyopathy who received a transplant might have survived without having received a heart transplant," he says.

Dr. Lipshultz adds that the second breakthrough from this paper suggests many of the children with idiopathic dilated cardiomyopathy should have a more comprehensive assessment of whether they have a genetic cause of their dilated cardiomyopathy. The term "idiopathic" indicates that a cause for the child's cardiomyopathy has not been identified. This is because some who are classified as idiopathic may

be familial but have not been completely evaluated. This may make it a challenge for families who have a child with familial dilated cardiomyopathy since other family members who may be affected simply would not know.

"This paper suggests that genetic and echocardiographic screening of the families of all children with dilated cardiomyopathy is supported since their courses are so similar and the early identification of genetic associations or inheritance patterns may help for management, family counseling and treatment plans," Dr. Lipshultz says.

Luanne Thomas-Ewald, CEO of the Children's Hospital of Michigan, stated: "At the Children's Hospital of Michigan, life is transformed by scientific advancements to achieve a better future for our patients. With this research, we are not only changing how we most appropriately treat children with heart diseases at the Children's Hospital of Michigan, but we are also changing the way the world thinks about this important issue."

The National Heart, Lung, and Blood Institute of the NIH has funded this study as the Pediatric Cardiomyopathy Registry, which was founded by Dr. Lipshultz and his colleagues in 1990, has been funded by the NIH since 1994, and is based within the Children's Hospital of Michigan and its Children's Research Center of Michigan (CRCM). Steven Lipshultz, MD leads the Pediatric Cardiomyopathy Registry and is the Interim Director of the CRCM. James D. Wilkinson, MD, MPH, is the Associate Director of the CRCM, second author of this paper, and is the Director of the Administrative Coordinating Center of this study at the CRCM. The Children's Cardiomyopathy Foundation has also funded this paper and study. This paper included centers who cared for these children with dilated cardiomyopathy and lists study authors of this publication who come from the University of Miami Miller School of Medicine, Miami, FL (Paolo Rusconi, MD, first author); Wayne State University School of Medicine and the Children's Hospital of Michigan, Detroit, MI; New England Research Institutes, Watertown, MA; Genzyme Corporation, Boston, MA; Cincinnati Children's Hospital Medical Center, Cincinnati, OH; Boston Children's Hospital and Harvard Medical School, Boston, MA; Monroe Carell Jr. Children's Hospital at Vanderbilt, Nashville, TN; Washington University, St. Louis, MO; Indiana University School of Medicine, Indianapolis; The Children's Hospital at Montefiore, Bronx, NY; and Columbia University Medical Center, New York, NY.

For 130 years, the Children's Hospital of Michigan has been dedicated to providing high quality care to children and adolescents in a caring, efficient and family-centered environment. With more than 40 pediatric medical and surgical specialty services, the hospital draws patients from nearly every Michigan County, 39 additional states, and 22 countries annually and provides the highest level of pediatric specialty care available for children. The hospital is a national leader in cardiology and heart surgery, neurology and neurosurgery, nephrology, and orthopedics. It is ranked as one of America's best hospitals for children and sees more children than any hospital in the state. Children's Hospital of Michigan is one of eight hospitals operated by the Detroit Medical Center (DMC). For more information: [www.childrensdmc.org](http://www.childrensdmc.org).

CITATIONS  
Circulation: Heart Failure, Feb-2017; R01 HL53392, R01 HL111459, R01 HL109090



**Barth Syndrome (ICD-10: E78.71)**  
Symptoms:  
Cardiomyopathy, Neutropenia, Muscle Weakness,  
Exercise Intolerance, Growth Delay, Cardiolipin Abnormalities  
[www.barthsyndrome.org](http://www.barthsyndrome.org)

## Patients from Age 15-to-90 Have Benefited from Robotic-Assisted Cardiac and Thoracic Surgery

Newswise – Surgeons on the medical staff at The Heart Hospital Baylor Plano\* achieved a major milestone when they performed that hospital's 1,000th robotic surgery March 31<sup>st</sup>, nearly six years after initiating the program in November 2011.

Robotic-assisted cardiac and thoracic surgery pairs a surgeon's skills with advanced robotic technology. Surgeons use minimally invasive techniques, meaning large surgical incisions are not required. The technology translates the surgeon's hand, wrist and finger movements into precise, real-time movements of surgical instruments inside the patient.

According to the maker of robotic-assisted technology used by The Heart Hospital Baylor Plano, the hospital's cardiothoracic robotic program leads Texas in number of cardiothoracic robotic operations.\*\* Cardiovascular and thoracic procedures that can be performed with the robotic surgical system include coronary artery bypass grafting, heart valve repair and all thoracic surgical procedures.

Fifteen-year-old Camden Thrailkill, a talented football and baseball player, benefitted from robotic surgery for mitral valve replacement at The Heart Hospital Baylor Plano last October. Traditionally, surgeons cut through the patient's breastbone to access the mitral valve within the heart and the breastbone is wired together to heal. This approach would not have allowed Thrailkill to withstand direct hits to his chest during sporting events.

By choosing the robotic-assisted surgery, Camden only missed three weeks of school. He returned to a limited workout routine in November 2016 and successfully tried out for spring baseball at his high school.

"The surgeon has a lot more maneuverability with the robot compared to other minimally invasive techniques using long instruments that don't have wrists," said Robert L. Smith II, MD, a cardiovascular surgeon on the medical staff and cardiovascular surgical services vice chair at THHBP. "There are small instruments at the end of each wrist which provide a much greater degree of freedom when using sutures and other devices around the heart. It's almost like having the surgeon's hands in there."

Kimble Jett, MD, Medical Director of Thoracic Surgery, notes how the robotic-assisted surgery can impact length of hospital stay positively. "If we take out a lobe of the lung robotically, most patients go home the next day," Jett said. "By using the robotic-assisted surgical system, we can significantly reduce the trauma to the body that is associated with open chest cardiothoracic procedures. Having this technology allows surgeons to be less invasive, usually resulting in quicker patient recovery. It's truly a win-win."

Benefits to surgeons using the technology over traditional approaches may include greater surgical precision, increased range of motion, improved agility, enhanced visualization and improved access to the surgical site. The robotic-assisted surgery system integrates 3-D, high-definition (10 times magnification) endoscopy and four robotic arms that wield cameras and complex surgical equipment into the surgical field, all controlled from a nearby console by a trained surgeon on the medical staff at The Heart Hospital Baylor Plano.

## CONGENITAL CARDIOLOGY TODAY

### We Can Help You

#### Recruit:\*

- **Pediatric Cardiologists**
- **Pediatric Interventional Cardiologist**
- **Adult Cardiologist focused on CHD**
- **Congenital/Structural Heart Surgeons**
- **Echocardiographers,**
- **EPs**
- **Pediatric Transplant Cardiologist**

\*Reach over 6,000 BC/BE Cardiologists focused on CHD worldwide

### Your Recruitment Advertising Includes:

- Full color Recruitment ad in the issue(s)
- Your recruitment listing in the email blast for the issue(s) with a hot link
- 3-Step Special Recruitment Opportunity Website Section in three (3) areas of the website
- *We can create your recruitment ad at no extra charge!*

### For more Information Contact:

**Tony Carlson**

+1.301.279.2005 or

[tcarlsonmd@gmail.com](mailto:tcarlsonmd@gmail.com)



**PICS-AICS**  
Pediatric and Adult Interventional Cardiac Symposium

**VEGAS**  
MGM GRAND LAS VEGAS  
SEPTEMBER 5-8, 2018

[www.picsymposium.com](http://www.picsymposium.com)

The Heart Hospital Baylor Plano (THHBP), joint ownership with physicians, is a physician-owned cardiovascular specialty hospital with the highest cardiac surgery volume in Texas and the DFW Metroplex\*\*\*. Part of Baylor Scott & White Health, THHBP is nationally ranked in key surgical specialties based on volume: #4 in heart valve surgery\* and #7 in heart surgery. Highly trained physicians on the medical staff and skilled clinicians, including a nationally recognized nursing staff, consistently deliver quality outcomes. In 2016, The Heart Hospital received a national ranking of 18<sup>th</sup> in the Nation in "Cardiology & Heart Surgery" by *U.S. News & World Report*, and was rated "High Performing" in five Adult Procedures/Conditions. Additionally, in 2014, THHBP became a member of a network affiliation with the Cleveland Clinic's Sydell and Arnold Miller Family Heart and Vascular Institute. As part of this affiliation, the two hospitals share best practices, coordinate care and develop programs to improve quality and patient safety.

The hospital has been recognized more than a dozen times by Press Ganey® for outstanding patient satisfaction (Inpatient, Emergency Department), including receiving, in November 2016, the prestigious Pinnacle of Excellence Award® on the basis of extraordinary achievement for patient experience.

Baylor Scott & White Health formed from the 2013 merger between Baylor Health Care System and Scott & White Healthcare, the system referred to as Baylor Scott & White Health. It is the largest not-for-profit health care system in the state of Texas, with total assets of \$10.8 billion\*. The system now includes 48 hospitals, more than 1,000 access points, 5,500 active physicians, and 44,000 employees, plus the Scott & White Health Plan, Baylor Scott & White Research Institute and Baylor Scott & White Quality Alliance — a network of clinical providers and facilities focused on improving quality, managing the health of patient populations, and reducing the overall cost of care. For more information visit: [bswhealth.com](http://bswhealth.com).

Based on audited 2016 fiscal year statements

\*Joint ownership with physicians

\*\* Based on volume data provided by Intuitive Surgical.

\*\*\*MedAssets Performance Management Solutions, Inc. (as successor in interest to The Reilly Group, LLC d/b/a TRG Health Care Solutions, LLC), a Delaware corporation

### Mayo Clinic Researchers Demonstrate Value of Second Opinions

Newswise — Many patients come to Mayo Clinic for a second opinion or diagnosis confirmation before treatment for a complex condition. In a new study, Mayo Clinic reports that as many as 88% of those patients go home with a new or refined diagnosis — changing their care plan and potentially their lives. Conversely, only 12% receive confirmation that the original diagnosis was complete and correct.

#### Why Get a Second Opinion?

When people are sick, they look to their doctor to find solutions. However, physicians don't always have the answers. Often, because of the unusual nature of the symptoms or complexity of the condition, the physician will recommend a second opinion. Other times, the patient will ask for one.

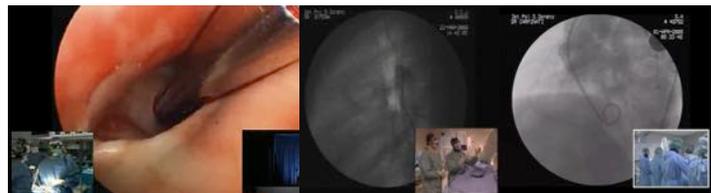
## Watch over 300 Live Case Videos, Presentations and Workshops Online from Leading Congenital and Structural Medical Meetings from Around the World

[www.CHDLiveCases.com](http://www.CHDLiveCases.com)



- Transseptal Access Workshop from Cook Medical
- Workshop: Past Present and Future of Pediatric Interventions Cardiology - St. Jude & AGA Medical
- Symposium on Prevention of Stroke Clinical Trials at the Heart of the Matter - WL Gore Medical
- Imaging in Congenital & Structural Cardiovascular Interventional Therapies
- Morphology of The Atrial Septum
- Morphology of The Ventricular Septum
- Pre-Selection of Patients of Pulmonic Valve Implantation and Post-Procedural Follow-up
- Echo Paravalvular Leakage (PVL)
- ICE vs TEE ASD Closure in Children - PRO & CON ICE
- 3D Rotational Angiography - Why Every Cath Lab Should Have This Modality
- PICS Doorway to the Past - Gateway to the Future
- Follow-up From PICS Live Cases 2010 Presentation
- Intended Intervention - Transcatheter TV Implantation - *Live Case*
- Intended Intervention - LAA Closure Using Amplatzer Cardiac Plug Under GA & Real Time 3D
- Provided Intervention - LPA Stenting / Implantation of a Sapien Valve
- Intended Intervention - PV Implantation
- Intended Intervention - COA Stent Using Atrium Advanta V12 Covered Stent - *Live Case*
- Intended Intervention - ASD Closure - *Live Case*
- Intended Intervention - Transcatheter VSD Device Closure - *Live Case*
- Intended Intervention - COA Stenting Using Premounted Advanta V12 Covered Sten - *Live Case*
- Stunning Revelation - The Medical System is Changing - What Can You Do To Show Patients That Your Practice Does It Right? Patient Perspective
- Percutaneous Paravalvular Leak Closure Outcomes
- Intensive Management of Critically Ill Infants Undergoing Catheterization
- **and many more....**

Presented by **CONGENITAL CARDIOLOGY TODAY**



## 27<sup>th</sup> International Symposium on Adult Congenital Heart Disease

Sep. 14-16, 2017 | Cincinnati, Ohio USA



[www.cincinnatichildrens.org/ACHDsymposium](http://www.cincinnatichildrens.org/ACHDsymposium)



This second opinion could lead to quicker access to lifesaving treatment or stopping unnecessary treatments. And a second opinion may reduce stress in a patient's extended family, when they learn the new diagnosis does not carry dire genetic implications. These scenarios can result from diagnostic error.

### **Odds Are Good the Diagnosis Will Be Adjusted**

To determine the extent of diagnostic error, the researchers examined the records of 286 patients referred from primary care providers to Mayo Clinic's General Internal Medicine Division in Rochester over a two-year period (Jan. 1<sup>st</sup>, 2009 to Dec. 31<sup>rd</sup>, 2010). This group of referrals was previously studied for a related topic. It consisted of all patients referred by nurse practitioners and physician assistants, along with an equal number of randomly selected physician referrals.

The team compared the referring diagnosis to the final diagnosis to determine the level of consistency between the two and, thus, the level of diagnostic error. In only 12% of the cases was the diagnosis confirmed.

In 21% of the cases, the diagnosis was completely changed; and 66% of patients received a refined or redefined diagnosis. There were no significant differences between provider types.

"Effective and efficient treatment depends on the right diagnosis," says Dr. Naessens. "Knowing that more than 1 out of every 5 referral patients may be completely [and] incorrectly diagnosed is troubling — not only because of the safety risks for these patients prior to correct diagnosis, but also because of the patients we assume are not being referred at all."

### **Risks of Cost Containment**

To manage costs in a health care environment with ever-increasing costs, health insurers often limit access to care outside their network, effectively limiting referrals. Further, primary care providers may be more confident in their diagnostic expertise than warranted in a particular case, or patients may lack the knowledge or assertiveness to request a referral.

## MEDICAL MEETINGS

### **CSI at UCSF - Catheter Interventions in Structural, Valvular & Congenital Heart Disease, Atrial Fibrillation & Heart Failure**

Sep. 8-9, 2017; San Francisco, CA USA  
[www.csi-congress.org](http://www.csi-congress.org)

### **27<sup>th</sup> International ACHD Advanced Symposium, 2017**

Sep. 14-16, 2017; Cincinnati, OH USA  
[cincinnatichildrens.org/service/a/congenital-heart/achd-annual-symposium](http://cincinnatichildrens.org/service/a/congenital-heart/achd-annual-symposium)

### **50<sup>th</sup> Anniversary Southeast Pediatric Cardiovascular Society Conference**

Sep. 28-30, 2017; Atlanta, GA USA  
[choa.org/medical-professionals/professional-events/50th-anniversary-southeast-pediatric-cardiovascular-society-meeting](http://choa.org/medical-professionals/professional-events/50th-anniversary-southeast-pediatric-cardiovascular-society-meeting)

### **11<sup>th</sup> IPC Workshop**

Sep. 28-30, 2017; Milan, Italy  
[www.workshopipc.com/main.php](http://www.workshopipc.com/main.php)

### **33<sup>rd</sup> Annual Echocardiography in Pediatric and Adult Congenital Heart Disease Symposium**

Oct. 8-11, 2017; Rochester, MN USA  
[cveducation.mayo.edu/marketing/echocardiography-in-pediatric-and-adult-congenital-heart-disease-case-studies--2#overview](http://cveducation.mayo.edu/marketing/echocardiography-in-pediatric-and-adult-congenital-heart-disease-case-studies--2#overview)

### **LAA - How to close the Left Atrial Appendage**

Nov. 17-18, 2017; Frankfurt, Germany  
[www.csi-congress.org/laa-workshop.php?go=0](http://www.csi-congress.org/laa-workshop.php?go=0)

### **CSI Africa**

Dec 1-2, 2017; Nairobi, Kenya  
[www.csi-congress.org/csi-africa.php?go=0](http://www.csi-congress.org/csi-africa.php?go=0)

## CONGENITAL CARDIOLOGY TODAY

© 2017 by Congenital Cardiology Today (ISSN 1554-7787-print; ISSN 1554-0499-online). *Published monthly. All rights reserved.*

[www.CongenitalCardiologyToday.com](http://www.CongenitalCardiologyToday.com)

### Publication Company Address:

11502 Elk Horn Dr. Ste. 201  
Clarksburg, MD 20871 USA  
Tel: +1.301.279.2005

### Publishing Management:

- Tony Carlson, Founder, President & Sr. Editor - [TCarlsonmd@gmail.com](mailto:TCarlsonmd@gmail.com)
- Richard Koulbanis, Group Publisher & Editor-in-Chief - [RichardK@CCT.bz](mailto:RichardK@CCT.bz)
- John W. Moore, MD, MPH, Group Medical Editor - [JMoore@RCHSD.org](mailto:JMoore@RCHSD.org)
- Allan Berthe, Contributing Editor-Special Projects

**Editorial Board:** Teiji Akagi, MD; Zohair Al Halees, MD; Mazeni Alwi, MD; Felix Berger, MD; Fadi Bitar, MD; Jacek Bialkowski, MD; Mario Carminati, MD; Anthony C. Chang, MD, MBA; John P. Cheatham, MD; Bharat Dalvi, MD, MBBS, DM; Horacio Faella, MD; Yun-Ching Fu, MD; Felipe Heusser, MD; Ziyad M. Hijazi, MD, MPH; Ralf Holzer, MD; Marshall Jacobs, MD; R. Krishna Kumar, MD, DM, MBBS; John Lamberti, MD; Gerald Ross Marx, MD; Tarek S. Momenah, MBBS, DCH; Toshio Nakanishi, MD, PhD; Carlos A. C. Pedra, MD; Daniel Penny, MD, PhD; James C. Perry, MD; P. Syamasundar Rao, MD; Shakeel A. Qureshi, MD; Andrew Redington, MD; Carlos E. Ruiz, MD, PhD; Girish S. Shirali, MD; Horst Sievert, MD; Hideshi Tomita, MD; Gil Wernovsky, MD; Zhuoming Xu, MD, PhD; William C. L. Yip, MD; Carlos Zabal, MD

**Free Subscription to Qualified Professionals:** Send your name, title(s), hospital or practice name, work address and url, phone, fax and email to: [sub@cct.bz](mailto:sub@cct.bz).

*Official publication of the CHIP Network*

*Statements or opinions expressed in Congenital Cardiology Today reflect the views of the authors and sponsors, and are not necessarily the views of Congenital Cardiology Today.*

## Master Class in Congenital Cardiac Morphology

With world renowned cardiac pathologist Professor Robert Anderson, MD, FRCPath

Oct. 11 to 13, 2017 • Children's Hospital of Pittsburgh of UPMC • Pittsburgh, PA

This activity has been approved for AMA PRA Category 1 Credit™ • The University of Pittsburgh is an affirmative action, equal opportunity institution.

Learn more at [www.chp.edu/MasterClassCCM](http://www.chp.edu/MasterClassCCM)



Children's  
Hospital of Pittsburgh  
of UPMC