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# Balloon Valvuloplasty Using a New Low-Profile Balloon Catheter: Initial Clinical Experience

*By Kazuto Fujimoto, MD; Takanari Fujii, MD; Hideshi Tomita, MD; Hisashi Sugiyama, MD*

## Introduction

The requirement for larger introducing sheaths can be a limiting factor for percutaneous catheter interventions in newborns and small infants. The TMP-PED balloon catheter (Tokai Medical Products, Aichi, Japan) is a novel catheter specially designed for balloon dilatation of stenotic valves, blood vessels, as well as restrictive atrial communications in neonates and small infants. We report our experience with this catheter and a small introducing sheath in small infants.

## Materials and Methods

We performed Balloon Pulmonary Valvuloplasty (BPV), Balloon Aortic Valvuloplasty (BAV), and Balloon Angioplasty (BA) for re-coarctation of the aorta (BA) for using a new balloon catheter in our center and Tokyo Women's Medical University from September 2014 to May 2015. Informed written consent for transcatheter intervention was obtained from the patient and/or the guardian. The indications for BPV, BAV and BA complied with the Japanese Society of Pediatric Interventional Cardiology Guideline.[1] Namely, the indication for BPV and BAV was the peak right ventricle–to–pulmonary artery systolic pressure gradient estimated by Doppler echocardiography, and was above 40mmHg. The indication for BA was the peak gradient across the coarctation by catheterization above 20mmHg.

### *The TMP-PED Balloon Catheter*

The TMP-PED balloon is an 85-cm-long, over-the-wire type noncompliant balloon catheter, whose balloon is made of polyamide material, while its specification is 4.0-10.0 mm diameter and 2cm length. The special features of the balloon are its ultra-short tip, as well as tapered shoulder with extremely low profile, which can be introduced through a 3F sheath up to 10mm diameter. Its guidewire lumen accommodates a 0.014 inch guidewire (Figure 1.). Nominal pressure and rated burst

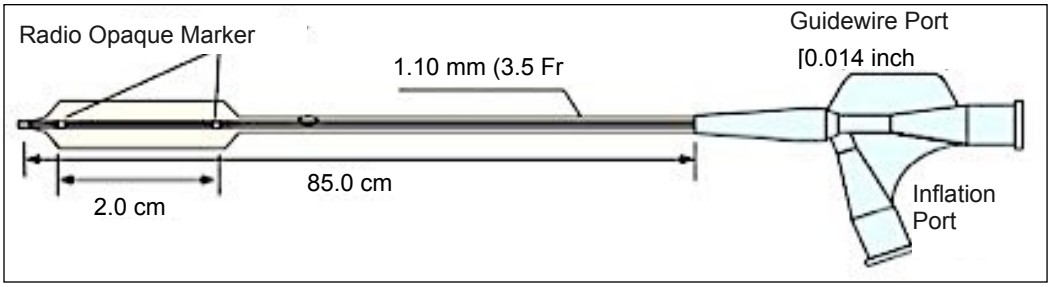
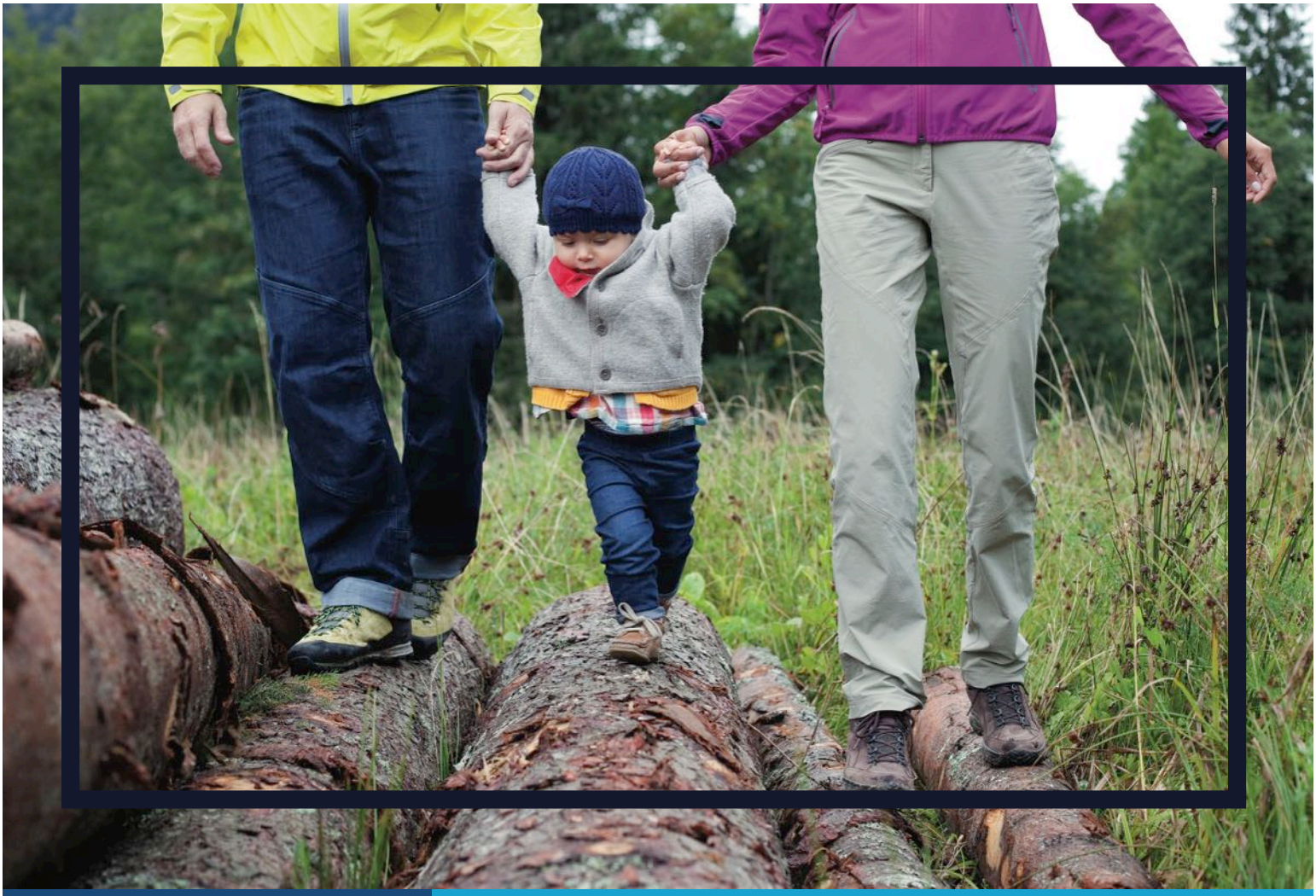



*Figure 1A. Specification.*



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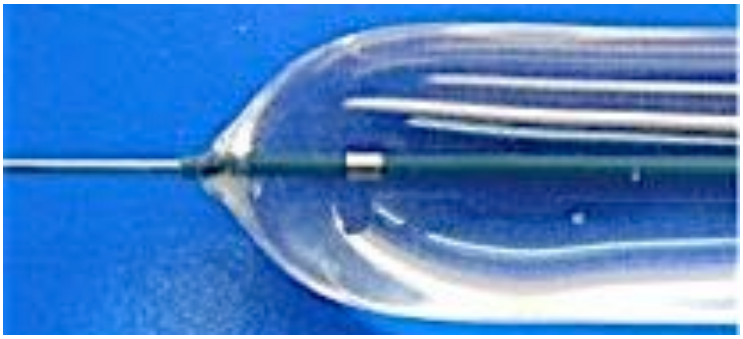

*Figure 1B. Inflated TMP-PED balloon.*

**Table I: Deflation Time Test of TMP-PED Balloon**

| Balloon Size / Type | | Outer Diameter of the Shaft (mm) | Sheath Size (Fr) | Deflation Time (sec) |
|---|---|---|---|---|
| 4×20mm | TYSHAK Mini® Balloon | 0.96 | 3 | 3 |
| | TMP PED | 1.07 | 3 | 2 |
| 10×20mm | TYSHAK Mini® Balloon | 1.23 | 4 | 4 |
| | TMP PED | 1.07 | 3 | 8 |

*Figure 2A. Pre-lateral image of right ventricular angiography in Case 3.*

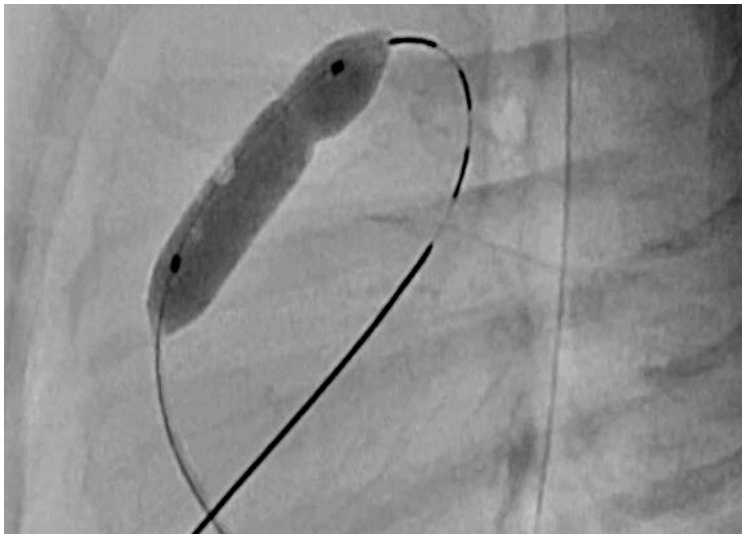

*Figure 2B. Lateral image of balloon valvuloplasty in Case 3. TMP-PED balloon engages native tissue well without slippage.*

*Figure 2C. Post-lateral image of right ventricular angiography in Case 3.*

pressure is 3.5 and 4.0 atmosphere (atm), respectively for the 4.0mm balloon and 3.0 and 3.5 atm for the 10mm balloon. In vitro, deflation time of the TMP-PED balloon was compared with an existing balloon of similar specifications, which is TYSHAK Mini® balloon, NuMed, Hopkinton, NY, USA. The deflation time of a 4 mm TMP-PED balloon was shorter than that of a 4 mm TYSHAK Mini® balloon. Meanwhile, the deflation time of a 10 mm TMP-PED balloon was longer than that of a 10mm TYSHAK Mini® balloon, as the outer diameter of the shaft in the TMP-PED balloon, which goes through 3F sheath, was smaller than that in the TYSHAK Mini® balloon, which goes through 4F sheath. However, this deflation time will be acceptable in the clinical use (Table I).

**Catheterization**

To evaluate hemodynamics, right and left cardiac catheterization was performed under general anesthesia with tracheal intubation. All patients received heparin (initial dose 100U/Kg). Balloon catheters were introduced through 3F-5F sheaths. The annular diameter of the pulmonary valve and the minimum coarctation diameter were directly measured on the lateral projection of the right ventriculogram or aortogram, respectively. Balloon diameters for BPV and BA were determined to be 120–130% of the annular diameter, and to be equal to or less than the descending Aorta at the diaphragm level. TMP-PED balloon was introduced overtly, the guidewire was (0.014 inch; Thruway® or 0.014 inch; Aguru®, Boston Scientific, Marlborough, MA, USA),

**Table II: Patient Profiles**

| Case | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Diagnosis | vPS | vPS | vPS | vAS | CoA po reCoA | HLHS po reCoA | HLHS po reCoA |
| Previous Operation | - | - | - | - | Arch repair | Norwood and Arch repair | Norwood and bil PA banding |
| Age (month) | 3 | 2 | 0.4 | 2 | 4 | 9 | 4 |
| Body Weight (Kg) | 6.9 | 6.9 | 3.3 | 3.5 | 4.6 | 4.7 | 3.7 |
| Balloon Diameter (mm) | 10 | 10 | 6 | 6 | 6 | 6,10 | 6,8 |
| Sheath Size (Fr) | 4 | 5 | 4 | 4 | 3 | 3 | 3 |
| Approach Site of Balloon | vein | vein | vein | artery | artery | artery | artery |

**Table III: Catheterization Date**

| Case | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Diagnosis | vPS | vPS | vPS | vAS | CoA po reCoA | HLHS po reCoA | HLHS po reCoA |
| Pre-intervention | | | | | | | |
| Pressure Gradient (mmHg) | 73 | 41 | - | 40 | 29 | 30 | 17 |
| Minimum Lumen Diameter | - | - | - | - | 3 | 3 | 3.7 |
| Ventricular Pressure (mmHg) | 90 (RV) | 65 (RV) | 112 (RV) | 100 (LV) | - | - | - |
| Valve Regurgitation | trivial | trivial | trivial | - | - | - | |
| Post Intervention | | | | | | | |
| Pressure Gradient (mmHg) | 20 | 24 | - | 25 | 29 | 0 | 13 |
| Minimum Lumen Diameter | - | - | - | - | 4.7 | 4.8 | 4.2 |
| Ventricular Pressure (mmHg) | 37 (RV) | 46 (RV) | 33 (RV) | 85 (LV) | - | - | - |
| Valve Regurgitation | trivial | trivial | trivial | none | - | - | - |
| Complication | none | none | IRBBB | none | none | none | none |

which had been inserted through 3F or 4F catheter.

## Results

### *Patients and Demographic Data*

Patient demographics and lesion-related data are summarized in the Table. We performed BPV in three infants, BAV in one case and BA in three infants using this new balloon catheter (Table II). The median age at the time of the procedure was 3 months (0.4 to 9 months) and median body weight was 4.6 Kg (3.3 to 6.9Kg). The median balloon diameter was 6mm (6 to 10mm). The median inserted sheath size ranged from 4F to 5F sheath in veins and 3 to 4F sheath in an artery. All interventions were performed successfully without any rupture of the applied TMP-PED balloon (Table III). In all cases, the minimum lumen diameter of reCoA was dilated, while pressure gradients were decreased except for Case 5 with reCoA. In valvular PS, the mean right ventricular pressure decreased from 89±19 to 39±5 mmHg (Figure 2). The rapid RV pacing was performed in Case 4 with valvular AS during balloon valvuloplasty. In all Cases, the TMP-PED balloon engaged native tissue well without slippage.

### *Complication*

In all the BPV cases valvular regurgitations, initially less than mild, did not deteriorate. No inflation or deflation difficulties were noticed with the TMP-PED balloon and hemodynamics were stable during procedure. No complications were recorded in all cases, except Case 3 with valvular PS, who developed temporary incomplete right bundle-branch block during BPV.

## Discussion

Balloon angioplasty and valvuloplasty have become well-established treatment options for congenital heart defects.[2, 3] Significant recent technical and material progress has made balloon pulmonary and aortic valvuloplasty, and angioplasty in children less invasive and more effective.[4] Principal findings of this report are:

1. TMP-PED balloon is a low-profile catheter, which provides a short inflation-deflation time.
2. The TMP-PED balloon catheter engages native tissue well, reducing slippage.
3. No significant procedure-related complications occurred in any infant.

To our knowledge, this balloon possesses the lowest profiles allowing introduction via a 3F sheath up to 10mm diameter. The special features of the balloon are the ultra-short tip design, as well as ultra-short tapered balloon shoulders with extremely low profile. Sugiyama et al reported that ultra-short tip design and ultra-short tapered balloon shoulders with an extremely low profile reduces vessel injury and endothelial damage in static balloon atrial septostomy.[5] The deflation time of 4mm TMP-PED balloon was shorter than that of existing balloons of similar specifications. The short inflation-deflation time is crucial in BPV, BAV and BA in helping to preserve systemic arterial blood pressure during balloon inflation. In real–world practice, acute angulation at the proximal and/or distal anastomosis may cause slippage of a balloon during the procedure. The balloon is made of polyamide elastomer, which engages native tissue well without slippage. Holzer et al reported that temporary arrhythmias and conduction anomalies were the most common adverse events in BPV (10/211 procedures, 5% of patients).[6] Although temporary incomplete right bundle-branch block occurred in one case during BPV, there were no difficulties in inflation-deflation, and retrieval of TMP-PED balloon in our patient group. We believe such a transient incomplete right bundle-branch block is a minor complication. TMP-PED balloon catheters provide an effective treatment option in BPV, BAV and balloon angioplasties in post-surgical coarctation of aorta.

### *Limitations*

Our study was limited by the small number of patients and the lack of a randomized comparison to different balloon catheters. This study was limited by its retrospective nature. Medium- and long-term outcomes have not yet been determined. Furthermore, we did not perform follow-up catheterization.

## Conclusion

The use of this new low-profile balloon catheter is safe and effective in small infants. This low-profile balloon must provide a benefit of minimizing vascular complications in the neonate or small infant, particularly when approaching the femoral or carotid artery, as in CoA or critical aortic stenosis.

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**Conflicts of Interest:** None

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## Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the institutional committees of Showa University, Northern Yokohama Hospital and Tokyo Women's Medical University.

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### Biographical Sketch

Kazuto Fujimoto is the Director of the Department of Perinatal and Pediatric Cardiology at National Cerebral and Cardiovascular Center. He is a board-certified physician of the Japanese Society of Pediatric Cardiology and Cardiac Surgery. He is certified as a sonographer of Structural Heart Disease by Japanese Society of Echocardiography. He specializes in the catheter intervention for pediatric and adult congenital heart disease, for example, stent implantation for stenotic vessel and Atrial Septal Defect (ASD) device closure.

*Corresponding Author*

*Kazuto Fujimoto, MD*
*Cardiovascular Center*
*Showa University*
*Northern Yokohama Hospital*

*5-7-1 Fujishiro-dai, Suita, Osaka*
*565-8565 Japan*
*Phone: +81-6-6833-5012, ext 4308*
*FAX: +81-6-6835-5256*
*kfkazuto@ncvc.go.jp*

*Takanari Fujii, MD*
*Cardiovascular Center*
*Showa University*
*Northern Yokohama Hospital*
*Japan*

*Hideshi Tomita, MD*
*Cardiovascular Center*
*Showa University*
*Northern Yokohama Hospital*
*Japan*

*Hisashi Sugiyama, MD*
*Department of Pediatric Cardiology,*
*Tokyo Women's Medical University*
*Japan*

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# Medical News, Products & Information

*Compiled and Reviewed by Tony Carlson, Senior Editor*

**Dr. Lock Passes the Reigns of Leadership at Boston Children's Hospital Cardiology Department to Dr. Tal Geva**

Dr. James E. Lock has stepped down as Chairman of the Department of Cardiology effective May 1st, allowing Dr. Tal Geva to assume this position earlier than the planned July 1st transition date. In making this transition, Dr. Lock has taken a part-time sabbatical, and will continue to perform catheterizations, care for patients, teach and mentor, and produce scholarly works. Dr. Lock's contributions to the field of Pediatric Cardiology and the institution have been deep and visionary.

*Dr. James E. Lock, MD*

Dr. Lock was recruited to Boston Children's Hospital in 1984 as Director of the Cardiac Catheterization Laboratory. He rose to become Cardiologist in Chief in 1993 and the Alexander S. Nadas Professor of Pediatrics at Harvard Medical School in 1995. He developed and provided the initial descriptions of nearly a dozen new techniques in interventional cardiology, and designed successful device trials for rare diseases. Along with his colleagues, he also pioneered groundbreaking fetal cardiac procedures and developed the world's largest fetal cardiac intervention program. He is the author of almost 300 original peer-reviewed publications and has been issued eight patents.

Dr. Lock's skills in interventional catheterization and development of new treatments for children with congenital heart disease have attracted patients from around the globe and inspired a generation of young pediatric cardiologists. His trainees in interventional cardiology now populate the nation and the world as department chairs and directors of pediatric cardiology divisions, cardiac catheterization laboratories and pediatric intensive care units. He conceived and established the New England Congenital Cardiac Association, solidifying the historically outstanding relationships among pediatric cardiologists in this region.

Dr. Lock has also made invaluable contributions to the Hospital. These cover a broad range from fundraising and growth of the institutional endowment to policy innovations for patient safety and quality of care. In his role as Physician-in-Chief, he conceived the principles that underlie the Hospital's Associate Attending Policy, integral to patient safety and quality of care. He helped develop a reimbursement structure to incentivize departmental adherence to regulatory requirements. He was a founder of the new Heart Center under a novel governance structure. A master fundraiser, he was the force behind raising two Harvard and four Boston Children's chaired professorships. Dr. Lock was appointed Physician-in-Chief and served on the Hospital Board of Trustees from 2002-2008; until last month, he remained on the Finance Committee.

Dr. Lock has passed the reigns of leadership in Cardiology to Dr. Tal Geva. Dr. Geva is a cardiologist of international stature who has pioneered the use of MRI for quantification of flow and hemodynamics in children with congenital heart disease. He is a passionate teacher and mentor. Under his leadership, strong sense of purpose, and high standards, the Department of Cardiology and Boston Children's look forward to continuing our tradition of excellence in patient care, innovation, and training. Please join in wishing Dr. Lock well in this next phase of his career, and Dr. Geva a bright and successful launch.

**AAN: Closure Not Recommended for People with Heart Defect and Stroke**

Newswise — An updated recommendation from the American Academy of Neurology (AAN) states that catheter-based closure should not be routinely recommended for people who have had a stroke and also have a heart defect called a Patent Foramen Ovale (PFO), a channel between the top two chambers in the heart. The practice advisory, which updates a previous AAN guideline, was published in the July 27th, 2016, online issue of *Neurology*®, the medical journal of the American Academy of Neurology (www.aan.com).

To develop the advisory, researchers reviewed all available scientific studies on people with PFO who also had an ischemic stroke, which is a stroke caused by a blood clot, or a transient ischemic attack, which is an episode of temporary stroke symptoms.

"Compared with other ways to prevent a second stroke, such as medications to reduce blood clots, the devices used to close a patent foramen ovale have limited evidence to support their use," said practice advisory author Steven R. Messé, MD, with the Perelman School of Medicine at the University of Pennsylvania in Philadelphia and a Fellow of the American Academy of Neurology. "It's still uncertain how effective these devices are in reducing stroke risk, and the procedure is associated with uncommon, but potentially serious complications."

In addition, Messé noted that the devices used for PFO closure are not available for routine use in the United States, so the procedure must be done off-label with a device approved for treating a similar heart defect or with another device that does not have strong evidence regarding its use. At the time of publication, the US Food and Drug Administration (FDA) is reviewing the one device that has the best evidence regarding closure.

"People should know that having a PFO is common—one in four people have one—and the risk of having a second stroke is low," Messé said.

When the AAN developed the earlier guideline on this topic in 2004, not enough evidence was available to make a recommendation on whether closing a PFO was effective in reducing stroke risk.

The advisory also recommends that aspirin or other antiplatelet drugs be used to prevent blood clots instead of anticoagulant drugs such as warfarin and heparin, also known as blood thinners, unless there is another reason to use blood thinners, such as a person with a history of blood clots in the legs or lungs.

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- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

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

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**The Heart-Brain Connection: The Link Between LQTS and Seizures**

Researchers at the University of Rochester Medical Center recently discovered a genetic link between Long QT Syndrome (LQTS), a rare cardiac rhythm disease, and an increased risk for seizures. The study also found that people with LQTS who experience seizures are at greater risk of sudden cardiac death.

According to research published in the July, 2016, issue of *Neurology*®, the medical journal of the American Academy of Neurology, there is a clear association between the heart and the brain of LQTS patients. Patients carrying LQTS genetic mutations were three times more likely to have experienced seizures in their past, compared to their family members who did not carry those mutations. Interestingly, LQTS patients who had a history of seizures also tended to have worse cardiac symptoms.

David Auerbach, PhD, Senior Instructor of Medicine in the Aab Cardiovascular Research Institute of the University of Rochester Medical Center, and lead author of the study found seizure status to be the strongest predictor of cardiac arrhythmias - the abnormal heart rhythms characteristic of LQTS. In fact, about 20% of the LQTS patients in the study who had a history of seizures had survived at least one lethal cardiac arrhythmia.

Auerbach's study set a new clinical precedence for the link between seizures and LQTS and provides a case for doctors to pay more attention to what is happening in LQTS patients' brains or, more broadly, to "look outside the classic organ of interest" in any disease.

As a postdoctoral fellow, Auerbach studied the heart-brain connection in a severe genetic form of epilepsy, and found that cardiac arrhythmias were one cause of sudden unexplained death in people with epilepsy. Now, he investigates the converse - whether a genetic heart disorder is also associated with issues in the brain.

With funding from the University of Rochester Clinical and Translational Science Institute, Auerbach tapped into the Rochester-based LQTS Patient Registry to answer this question. This unique resource was developed 40 years ago by the senior author of the study, Arthur Moss, MD, the Bradford C. Berk, MD, PhD, Distinguished Professor of Medicine at URMC. The registry contains information about more than 18,000 people including LQTS patients and their affected and unaffected family members, who provide a nearly ideal group of controls. "In essence, they have the same genetic makeup, except theoretically, the LQTS-causing mutation," says Auerbach.

To ensure that the seizures reported in the registry were not merely misdiagnosed cardiac arrhythmias, Auerbach investigated the effect of beta blockers, drugs often prescribed to LQTS patients to prevent cardiac arrhythmias. While the drugs effectively reduced patients' arrhythmias, they had no effect on seizures, minimizing the chance that the seizures were simply misdiagnosed cardiac side effects.

Looking at the patients' genetic information, Auerbach and his colleagues found that patients with the three different types of LQTS (LQTS1-3) showed similar heart rhythm symptoms, but vastly different prevalence of seizures. LQTS1 and LQTS2 patients had much higher prevalence of seizures than LQTS3 or no mutation - with LQTS2 at the greatest risk.

Further investigation of the LQTS-causing mutation showed that the specific location of the mutation greatly affected the risk of cardiac arrhythmias and seizures. In one location on the gene, the mutation protected against these symptoms, but in another location on the same gene, the mutation increased the risk of those symptoms. Understanding what each of these mutations does may shed new light on a basic mechanism of seizures and may provide viable therapeutic targets to treat LQTS.

Auerbach says there is still a lot more work to do, but believes, "you could begin applying these findings to patients today by telling physicians treating LQTS patients to look outside the heart."

# University of Miami Pediatric Cardiology Reunion February 6th, 2016

*By Bradley W. Robinson, MD*

On Saturday evening February 6th, 2016, the Super Bowl came a day early as 52 former and current pediatric cardiology fellows (1975-to present), faculty and staff from the University of Miami gathered at the Miami Shores Country Club in Miami, Florida, for a fellowship reunion, and to pay tribute to their mentors. The program was organized by Drs. Ming-Lon Young (1984) and Jay Chandar (1987).

The program started with a CME program on "Global Pediatric Cardiology," sponsored by Joe DiMaggio Children's Hospital. Speakers were:

- Anne Fournier, MD, FRPCC, FACC, FHRS (Electrophysiology Fellow 1985), "Kawasaki Disease: The Myocardial Perspective."
- Makram Ebeid, MD, FAAP, FAAC, (1993) discussed: "The State of the Art in Interventional Pediatric Cardiology."
- Ming-Lon Young, MD, MPH, FAAP, FACC, FHRS, CCDS, "From University of Miami to the World with Panelists Discussion."
- Dr. Vikas Kohli (1997), "Pediatric Cardiology in India,"
- Dr. Serge Geffrard's (2005), "Pediatric Cardiology in Haiti."

The Master of Ceremonies was Dr. Jocelyn Garcia de Viera, Class of 2003.

Dr. Arthur Pickoff, FAAP, FACC, (1979) gave the keynote speech thanking mentors (Henry) Gelband, Peter Ferrer, Dolores Tamer, Grace Wolff, and Otto Garcia for giving us "our careers." Dr. Pickoff shared stories and memories of each faculty member. He spoke about the joys of research and the lineage of the program while reminding us that patient care was our number one priority.

Dr. Henry (Heinz) Gelband, former Chief of Cardiology (1975-1996), spoke next highlighting his 21 years as Chief. Dr. Gelband attributed much of his success to always surrounding himself with individuals who were as bright or brighter than him and those who worked as hard as he did. This in turn led to a successful program with smart, hardworking individuals. He mentioned some of the firsts in the field of Pediatric Cardiology that were initiated by his fellows and faculty. He shared touching stories on how it was more than a fellowship (but a family), and how faculty/staff/fellows went the extra mile to help each other and patients in times of need.

Dr. Dolores Tamer gave us a brief history of Pediatric Cardiology in South Florida. She reminded us to donate to the Dr. Francisco Hernandez lectureship (see instructions below).

Dr. Peter Ferrer, spoke about each of the original faculty, and gave personal tributes to each. He noted the faculty has accomplished the mission of passing the torch to future generations of pediatric cardiologists. "The seeds we (faculty) have planted have become strong trees full of leaves and flowers of life."

Dr. Jay Chandar gave thanks to Dr. Arthur Pickoff as being one of our mentors on the faculty.

Representing two faculty members who had passed on were: Mr. Armando Perez (husband of Grace Wolff) and Dr. Eloina Garcia (wife of Otto Garcia). Two fellows who are no longer with us were remembered: Robert Pierce (1992) and Sharanjeet Singh (1982).

Dr. Irma Pacheco (1985), Dr. Leonor Zies (1977) and Dr. Sharon Kaminer (1990) presented awards to Drs. Ferrer, Gelband and Tamer respectively.. Photographs were largely sponsored by Dr. Jack Bendel (Class of 1998).

A music and slide presentation of the fellows and faculty was prepared by Dr. Ming Young with the help of Dr. Kak-Chen Chan

(Joe DiMaggio Children's Hospital). The link to photographs and videos are:

- https://youtu.be/xWx9teziYWQ (Retirement Party).
- https://youtu.be/VGJ0nNHX14c (Arthur Pickoff).
- https://youtu.be/L-WQNtqhBn0 (Heinz Gelband).
- https://youtu.be/NDmO7Wco9t4 (Dolores Tamer).
- https://youtu.be/RpT3XwRrgjw (Pedro Ferrer).

**Donations for The FA Hernandez Lectureship and Project Haiti Heart**

FA Hernandez Lectureship: Dr. Hernandez is the Father of Pediatric Cardiology in Florida. He is well-known for his work on ECG findings in Ebstein's Anomaly. He came to Miami from Cuba in 1945, and established the Rheumatic Fever Convalescent Home, which became the first Cardiac Hospital in Florida (National Children's Cardiac Hospital). Dr. Gerold Schiebler started the FAH Lectureship to honor Dr. Hernandez with plans to invite renown pediatric cardiologists to mentor young cardiologists at University of Florida and University of Miami on alternating years. The Lectureship is not yet self-sustaining, but your donations may make it that way.

Please send your donations to:

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Gainesville, FL 32610

Checks should be made payable to UF Foundation Inc. In the memo space put, "FA Hernandez Lectureship, Fund #F017171."

Project "Haiti Heart"

In 2004, Dr. Serge Geffrard, a native of Haiti (Class of 2005) and Dr. Ming Young (Class of 1984) co-founded Project Haiti Heart. Project Haiti Heart is a nonprofit 501(c)(3) organization, whose mission is to provide medical, humanitarian, and spiritual aid for the people of Haiti. In 2008, construction stage 1 was completed on the Obstetrics wing of the hospital. Today, the Obstetrics Center is staffed by 3 physicians and 2 midwives, and delivers 1000 babies/year. The plan is to expand medical facilities by building a 12,000 square foot, two-story building to include: an emergency room, outpatient center, medical intensive care unit, surgical intensive care unit, medical ward, pediatric ward, CT scan room, operating room, and cardiac catheterization lab. The expansion project will allow us to provide primary and tertiary care to over 300,000 Haitians, and will help to further rebuild the nation's infrastructure. Please visit http://projecthaitiheart.org to make your donations.

Thanks goes to Drs. Chandar and Young for their assistance in this article.

**Biographical Sketch**

Dr. Bradley Robinson is a graduate of the University of Miami Pediatric Cardiology program in 1992. He currently is at The Nemours Cardiac Center at the Alfred I. duPont Hospital for Children in Wilmington, DE. He is currently Associate Professor of Pediatrics at the Sidney Kimmel Medical College at Thomas Jefferson University in Philadelphia, PA. His current interests are: exercise physiology, fetal cardiology, and medical education of students and residents and fellows in Pediatric Cardiology.

*Bradley W. Robinson, MD*
*U Miami Pediatric Cardiology*
*Class of 1992*

*The Nemours Cardiac Center*
*Alfred I. duPont Hospital for Children*
*1600 Rockland Rd.*
*Wilmington, DE 19803 USA*

*Bradley.Robinson@nemours.org*

# The Congenital Heart Collaborative - Two Academic Children's Hospitals Working as One

*By Timothy F. Feltes, MD*

In June 2016, The Congenital Heart Collaborative celebrated its' first anniversary in, what will be a multi-year agreement between Nationwide Children's Hospital in Columbus, Ohio, and University Hospitals Rainbow Babies & Children's Hospital in Cleveland, Ohio, to form a co-managed cardiac service. These two hospitals have faculty on both campuses actively engaged in parallel missions to provide value-based clinical care excellence and innovation, education, and research. In all aspects of the collaborative, from the governance structure to the sharing of recruitment and case management duties, the overarching premise has been one of mutual respect between institutions, physicians, nurses, administrators, and support personnel leading to a culture of one program on two campuses.

**The Congenital Heart Collaborative Organizational Structure**

In 2014, senior representatives of both institutions engaged in discussions to formulate a common congenital heart program with the goal of expanding patient access to high quality quaternary Pediatric Cardiac and Cardiothoracic Surgery services in their respective communities. In addition, the "Collaborative," as it became known, would support the academic mission of their respective organizations to: preserve the highest quality medical education, grow clinical research activities, recruit and retain talented qualified physicians, trainees. An agreement for a pediatric heart services program was drafted and signed by both organizations.

Nationwide Children's Hospital in Columbus, Ohio


University Hospitals Rainbow Babies & Children's Hospital in Cleveland, Ohio

**TCHC Service-Line Organizational Structure**

The collaborative administrative infrastructure has been modeled after the Heart Center service line at Nationwide Children's Hospital. This service line is overseen by a medical and surgical physician leader (Co-Directors) with a senior program administrator (Vice President level) and local program director. The collaborative's senior leadership is further supported by a local business manager, nursing director, quality manager and clinical area managers. The collaborative senior administration has solid-line accountability to the executive committee of the collaborative. All nursing, medical, surgical, allied health and support personnel have a straight-line matrix to the Co-Directors and service line administrator. Dual (dotted line) matrices to traditional administrative accountability still apply for hospital employees of the collaborative.

An in-depth and thorough programmatic assessment of the cardiac services was conducted prior to the execution of the master affiliation agreement in order to generate the short-, medium-range, and long-term operational goals (Milestones) for the collaborative. Short-term goals focused on such things as: the cohorting of cardiac patients either in the cardiac intensive care or step-down units, defining and recruiting for physicians and cardiac nursing, and immediate capital needs. Longer-term milestones included: business planning for the expansion of medical and surgical services, design of a new cardiac catheterization and intervention suite, and dedicated cardiac intensive care and step-down units. With all milestones, members of the collaborative from both campuses were and will continue to be engaged in the process.

**Provision of Clinical Services**

In the very early phase of the collaborative, as we were developing the service line at UH Rainbow Babies & Children's Hospital, we engaged in extensive education and preparation of the in-patient services. Medical services at Rainbow Babies and

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Children's Hospital were never interrupted. Temporarily, high acuity complex surgical and interventional procedures were performed at Nationwide Children's Hospital, but surgical and interventional services were likewise provided on-campus in Cleveland. Despite the recruitment of surgical and interventional personnel to UH Rainbow Babies & Children's Hospital, the plan has all along been to continue to work as a common team with specialty services credentialed on both campuses.

**Provision of Administrative Services**

The physician and administrative leadership of the collaborative were committed to a continued presence on both campuses. Regularly scheduled face-to-face meetings supplemented by teleconferences were put into place to keep pace with our ambitious milestones and to address all clinical and non-clinical aspects on an ongoing basis. This commitment continues today and will remain long-term.

**Building One Team**

From the very beginning, our goal was to develop one team that worked in a collaborative spirit with mutual respect. This involved a significant level of nursing and physician interactions and sharing of knowledge. A variety of venues were utilized to achieve this goal. Regular site visits between campuses were conducted that included credentialing of nursing staff on both campuses in order to give hands-on experience to the bedside practitioner.

Communication was and continues to be pivotal in the success of the collaborative. We utilize regular town hall meetings to remind employees of the collaborative's mission, goals and progress, including quality committee and financial reports, as well as ongoing strategic planning. The culture of these meetings is one of transparency and the staff is encouraged to ask or submit (anonymously) questions or concerns and to share positive feedback. The town hall meetings are attended by the collaborative medical and administrative leadership.

Case Management Conferences occur twice weekly. In these secure teleconferences, teams from both campuses present cases for surgical or interventional consideration, along with dialogue related to medical management and quality care.

**Speculation**

Health care delivery in the United States is evolving. Redundancies of high-cost medical and surgical care such as that seen in the management of patients with Congenital Heart Disease increases inefficiencies and negatively impacts societal costs. The Pediatric Cardiology Quality Improvement Collaborative and National Cardiovascular Data Registry IMPACT™ (IMproving Pediatric and Adult Congenital Treatments) are just two examples of cooperative efforts in our field focused on improving patient outcome. Although the collaborative between the heart programs at UH Rainbow Babies & Children's Hospital and Nationwide Children's Hospital is just in its' infancy and proof-of-cost containment has yet to be validated, the potential for such seems apparent. Likewise, the collaboration between centers focused on common missions of expanding medical knowledge and innovation, delivery of high-quality cost-effective care, and education of the future medical workforce is a refreshing change to the competitive climate that exists in our medical community.

**CCT**

*Timothy F. Feltes, MD, FACC, FAHA*
*Co-Director of The Congenital Heart Collaborative*
*Chief of Pediatric Cardiology and Co-Director of The Heart Center at Nationwide Children's Hospital*
*Professor and Senior Vice Chair of Pediatrics at The Ohio State University*
*Columbus, OH USA*

*Timothy.feltes@nationwidechildrens.org*

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Company offices:
11502 Elk Horn Dr.
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Editorial offices:
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**Publishing Management:**
- Tony Carlson, Founder, President & Sr. Editor - *TCarlsonmd@gmail.com*
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