International Edition Vol. 18 - Issue 3

March 2020

## **Content**

1 Balloon Atrial Septostomy Can Be Safely Performed At Bedside Using Z-5 Atrioseptostomy Catheter

> Gurumurthy Hiremath, MD John L Bass, MD Katy Soule, PA-C Kari Erickson, DNP, APRN Jim Berry, RDCS Varun Aggarwal, MD

10 Compelling Presentations Mark Third Heart Summit At Herma Heart Institute

Jeanne James, MD

### 14 Medical News

- Texas Children's Names
   Adult Congenital Heart
   Disease Program Leadership
   Team
- Practice Builders Announces New Automated Patient Acquisition Solution
- Congenital Heart Disease More Deadly In Low-Income Countries

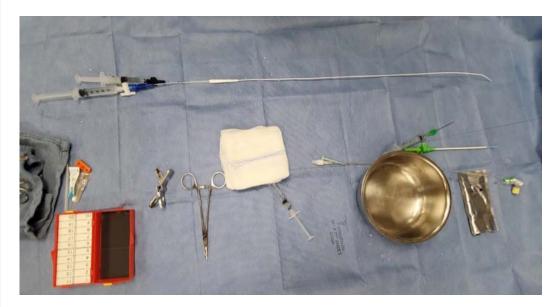
# **Balloon Atrial Septostomy Can Be Safely Performed At Bedside Using Z-5 Atrioseptostomy Catheter**

Gurumurthy Hiremath, MD; John L Bass, MD; Katy Soule, PA-C; Kari Erickson, DNP, APRN; Jim Berry, RDCS; Varun Aggarwal, MD

Conflicts of Interest: None Funding Source: None

### Introduction

Since the first description of balloon atrial septostomy (BAS) by Rashkind and Miller in 1966 for Transposition of Great Arteries (TGA), it has continued to be a life-saving procedure for many children born with Complex Congenital Heart Diseases by improving atrial level mixing before a definitive surgical correction can be performed<sup>1,2</sup>. Until recently, there were two commercially available balloon catheters in the US used for this procedure; the Miller balloon atrioseptostomy balloon catheter (Edwards Lifesciences, Santa Ana, CA) and the Z-5 atrioseptostomy catheter (Numed, Inc. Hopkinton, NY). Among the two available options, the most commonly used balloon catheter for performing bedside atrial septostomy procedure in the US (under echocardiographic guidance without use of fluoroscopy) was the Miller balloon atrioseptostomy catheter. However, due to reports of difficulty in balloon deflation, balloon fragmentation or detachment upon attempted retrieval, Edwards Lifesciences did a recall on the Miller Balloon Atrioseptostomy catheter.



**FIGURE 1** Bedside table with access needle, 6 Fr sheath and 13.5 mm Z-5 balloon septostomy catheter prepared with negative pressure.

International Edition

Vol. 18 - Issue 3

### **TABLE OF CONTENTS**

### Balloon Atrial Septostomy Can Be Safely Performed At Bedside Using Z-5 Atrioseptostomy Catheter

Gurumurthy Hiremath, MD; John L Bass, MD; Katy Soule, PA-C; Kari Erickson, DNP, APRN; Jim Berry, RDCS; Varun Aggarwal, MD

### 10 Compelling Presentations Mark Third Heart Summit At Herma Heart Institute

Jeanne James, MD

### 14 Medical News

- Texas Children's Names Adult Congenital Heart Disease Program Leadership Team
- Practice Builders Announces New Automated Patient Acquisition Solution
- Congenital Heart Disease More Deadly In Low-Income Countries





www.digisonics.com
Visit us at ACC 2020:
Booth #9026

Vendor neutral solution with seamless intgration to hemodynamics systems, imaging modalities, PACS & EMR

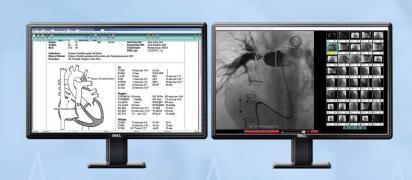
Extensive library of modifiable Mullins diagrams with 300+ exclusive to Digisonics

Trend plots with pediatric and fetal z-scores

Quick report capability for bringing forward data from previous reports

Robust data mining and business analytics package

Interoperability with QLAB, EchoPAC & TomTec



Enterprise Pediatric
Reporting & Imaging Solutions
for Cath, Echo and MR



The FDA classified this recall as Class 1, implying that the use of device may cause serious injury or death, https://www.fda.gov/ medical-devices/medical-device-recalls/edwards-lifesciencesrecalls-miller-and-fogarty-atrioseptostomy-dilation-cathetersdue-balloon.

With the Miller balloon unavailable in the US, there has been concern about performing BAS at the bedside under echocardiographic guidance alone, using the Z-5 atrioseptostomy balloon catheter. Here, we aim to describe both the catheters and some tips and tricks for performing the bedside septostomy using the Z-5 atrioseptostomy catheter using a patient example.

### Miller Balloon Atrioseptostomy Catheter Edwards Lifesciences, Santa Ana, CA

The Miller atrioseptostomy catheter has been a commonly used catheter for performing atrial septostomy bedside under echocardiographic guidance. This is a single lumen wire-wound balloon catheter with a 35 degree "hockey stick" angled tip to facilitate crossing the preexisting patent foramen ovale (PFO). The catheter has no end hole and takes a maximum volume of 4 cc, which results in a maximum balloon diameter of 19 mm. The advantages of this catheter are its soft and smooth tip, and relative ease of crossing the PFO without need for fluoroscopy. These properties make it extremely user-friendly especially for bedside procedures. The most frequent complications encountered with this catheter include failure of deflation, balloon rupture, fragmentation, detachment and embolization. Due to these concerns, the balloon was recalled from the market on March 28, 2019, https://www.fda.gov/medical-devices/medicaldevice-recalls/edwards-lifesciences-recalls-miller-and-fogartyatrioseptostomy-dilation-catheters-due-balloon.

### **Z-5 Balloon Atrioseptostomy Catheter** NuMED, Inc., Hopkinton, NY

The Z-5 Atrioseptostomy Catheter (Figure 5B) is a balloon catheter specifically designed for the neonate with Congenital Heart Disease requiring septostomy. It is a dual lumen balloon catheter (one lumen for a wire and the other lumen for the balloon inflation) and comes in two balloon sizes; 9.5 mm ± 0.5 mm non-compliant latex-free balloon, at 1.0 cc volume and a 13.5 mm ± 0.5 mm non-compliant latex-free balloon, at 2.0 cc volume.

The 9.5 mm catheter is primarily designed for infants under 2 kilograms. It can pass through a 5 Fr sheath and features an end hole that accommodates a 0.014" guidewire. The 13.5 mm catheter requires a 6 Fr sheath and features an end hole that accommodates up to a 0.021" guidewire. The inflated geometry of the balloon is a sphere. There is a radio-opaque band under the balloon for improved fluoroscopic visualization (Figure 2). The catheter tip is angled at 35° to facilitate passage through the PFO to the left atrium. To inflate the balloon of the 9.5 mm catheter to its maximum diameter, 1.0 cc of saline or diluted contrast (if using fluoroscopy) is injected into the balloon after purging. To inflate the balloon of the 13.5 mm catheter to its maximum diameter. 2.0 cc of saline or diluted contrast is injected into the balloon after purging. Catheters are supplied with a one-way stopcock for locking the balloon in inflated position while performing septostomy.

The advantages of this catheter include its low-profile balloon (5 and 6 Fr sheath compatibility for the two sizes respectively) and the presence of an end hole, which helps in advancing the catheter over a wire and also provides the ability to measure pressures and perform angiography to confirm position.



FIGURE 2 Panel A: Z-5 septostomy balloon with angled tip and deflated balloon. Panel B: After full inflation. Panel C: deflation, the balloon tends to fold and develop wrinkles.



# **Septostomy At Bedside vs. In the Cardiac Catheterization Laboratory**

Balloon atrial septostomy can be performed safely either at bedside under transthoracic echocardiographic guidance or in the cardiac catheterization laboratory using echocardiographic and fluoroscopic guidance.

The proponents of bedside atrial septostomy cite the advantages of speed, lack of radiation exposure, and avoiding risks of patient transfer from the ICU to the cardiac catheterization laboratory<sup>3,4</sup>. Advantages of performing the procedure in the catheterization laboratory include access to fluoroscopy to help guide catheters, especially with difficult anatomies such as juxtaposed atrial appendages. In large studies comparing outcomes of septostomy at bedside vs. the cardiac catheterization laboratory, the outcomes and efficacy were similar<sup>5,6</sup>.

Most interventional cardiologists who prefer bedside septostomy used the Miller atrioseptostomy catheter instead of the Z-5 catheter. There are reports in the pediatric interventional cardiology community of cardiologists moving away from bedside septostomy to the catheterization laboratory after the recall of the Miller septostomy balloon (personal communication). Concerns about use of the Z-5 atrioseptostomy balloon at bedside included the relatively stiff and blunt tip of the balloon catheter that may prove difficult to advance across the PFO without fluoroscopic guidance.

At our institution, BAS was routinely performed bedside using echocardiographic guidance with the Miller atrial septostomy balloon. After switching to the Z-5 atrial septostomy balloons, we found that bedside atrial septostomy can be performed with equal ease using this catheter.

### **Case Example**

An urgent septostomy was necessary in a 3.2 kg newborn male born at 37w5d with D-Transposition of the Great Arteries and a restrictive atrial septal communication of approximately 2mm in size (Figure 3A). The procedure was performed at bedside with transthoracic echocardiographic guidance. The patient was intubated and on a conventional ventilator. Intravenous sedation and monitoring during the procedure were provided by neonatology staff. The right groin was prepared and draped in the usual manner. A bedside table was prepared with all the equipment necessary (Figure 1). Vascular access was obtained using the modified Seldinger technique using a micropuncture needle under ultrasound guidance. A 6 Fr sheath was placed in the right femoral vein over a 0.035 inch J wire that was visualized in the right atrium (Figure 5). A 13.5 mm Z-5 atrial septostomy balloon was inserted through the 6 Fr sheath and advanced to the atrial septum and across the ASD using echocardiographic guidance (Figure 4A and 4B). The balloon course was continuously visualized as it was advanced from the sheath using subcostal sagittal echocardiography (Figure 4B). Balloon position in the left atrium was confirmed. The balloon was inflated with 2 ml of saline, and withdrawn sharply to the right atrium and deflated (Figure 4C and 4D). This was repeated three times. Echocardiography confirmed an unrestrictive 5mm atrial communication (Figure 3B). The atrial septostomy catheter was removed safely and was intact. The entire procedure lasted less than 30 minutes.

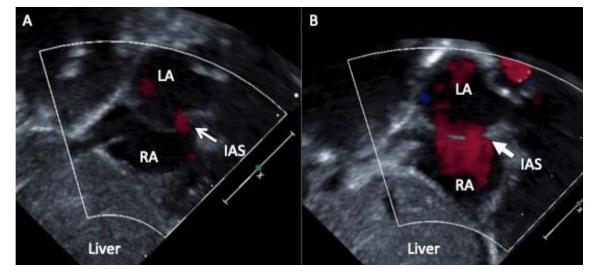


FIGURE 3

Panel A: Subcostal sagittal echocardiographic images show a restrictive inter-atrial communication at baseline.

Panel B: shows a large unrestrictive atrial communication following successful atrial septostomy. (IAS: Inter-atrial septum; RA: Right atrium; LA: Left atrium)

# RIGHT DATA.



Melody™ Transcatheter Pulmonary Valve (TPV) System



Proven to Delay Conduit Replacement

**88.8**%

freedom from reoperation\*
\*U.S. IDE Study.

Proven Valve Competence

98.1%
of subjects with ≤ mild PR\*

# Designed Specifically for Pulmonary Valve Replacement

The Melody valve is the longest studied transcatheter pulmonary valve at eight years post-implant.

The Melody TPV System first received CE mark in September 2006.
The Melody TPV System received

The Melody TPV System received Health Canada approval in December 2006 and U.S. approval under an HDE on January 25, 2010 (H080002). PMA approval received January 27,

2015 (P140017). ©2020 Medtronic. All rights reserved. UC201900307a EN 01/2020 Medtronic Further, Together

### Melody<sup>™</sup> Transcatheter Pulmonary Valve, Ensemble<sup>™</sup> II Transcatheter Valve Delivery System

#### Important Labeling Information for the United States

Indications: The Melody TPV is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has  $\geq$  moderate regurgitation, and/or a mean RVOT gradient  $\geq$  35 mm Hq.

Contraindications: None known.

#### Warnings/Precautions/Side Effects:

- DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.
- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.
- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

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

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

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

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

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

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

Important Labeling Information for Geographies Outside of the United States

- 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.

### medtronic.com

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



### Tips And Tricks For Bedside Septostomy With Z-5 **Septostomy Catheter**

A 0.035 inch J wire is preferred for sheath introduction as the tip is easily visible and atraumatic (Figure 5). We use the 21 G micropuncture needle for vascular access and then use the 4 Fr micropuncture dilator to exchange the 0.018" micropuncture wire for the 0.035" J wire. As the dilator and sheath reach the tip of the wire, the J straightens out, demonstrating the location of the dilator tip and avoiding injury to the heart. The sheath tip should be positioned in the IVC below the liver to avoid contact with the inflated balloon during the septostomy pull, which may result in inadvertent damage to the balloon.

Continuous echocardiographic guidance starting immediately after vascular access is extremely helpful. Subcostal imaging to show the IVC in long axis is helpful in guiding sheath placement, and to guide the septostomy catheter across the atrial septum in real time (Figure 4). If resistance is felt while advancing the catheter, the catheter could be entering side branches or hepatic veins. Special care should be paid with the 9.5 mm Z-5 balloon as it can inadvertently track into these small vessels relatively easily. Advancing a guidewire ahead of the septostomy balloon can prevent this from occurring. The catheter can also be pulled back and re-advanced slowly under real-time echocardiographic visualization with gentle rotation. The 35 degree tip angle helps to guide the tip across the atrial septum.

When taken out of the packaging, the tip of the balloon catheter is formed by the catheter shaft and deflated balloon that extends all the way to the tip, resulting in a blunt and non-tapered appearance (Figure 2A). After inflation and deflation, the balloon tends to fold and develop wrinkles (Figure 2B, 2C). Inflating and deflating the balloon outside the body can create an uneven balloon catheter tip that may make crossing the atrial septum difficult. The author's personal preference is to prepare the Z-5 septostomy balloon with negative pressure prior to use without inflating the balloon.

The balloon must be well-visualized in the left atrium before the septostomy (Figure 4C). Special care and time should be spent on visualizing, so that the balloon is not inside a pulmonary vein or across the mitral valve. The balloon inflation volume should not exceed 1.0 cc for the 9.5 mm catheter, or 2.0 cc for the 13.5 mm catheter. Over-inflation could cause balloon rupture. The balloon is pulled into the right atrium with a fast, snapping motion. This pulling maneuver must be stopped at the inferior vena cava-right atrial junction (Figure 4D), and the balloon rapidly advanced back into the right atrium (since balloon is non-compliant, it does not conform to the shape of the IVC and may injure the vessel). Immediately deflate the balloon by applying negative pressure to the inflation device (a 3.0 cc syringe is recommended unless faster deflation is needed, then up to a 10.0 cc syringe may be used).

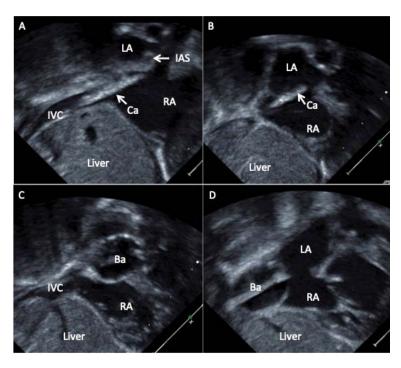
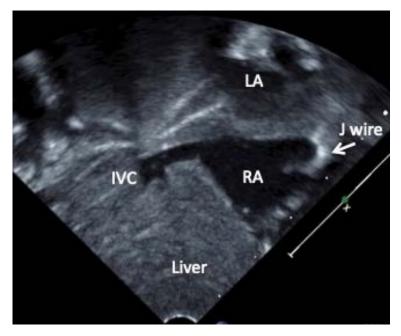


FIGURE 4 Subcostal sagittal echocardiographic images to guide the septostomy procedure. Panel A: The Z-5 atrioseptostomy catheter is advanced under echocardiographic guidance and real time visualization from the IVC to the right atrium. Panel B: The 35 degree angle catheter tip is turned to the atrial septum and guided into the LA. Panel C: The balloon is inflated in the LA and position is confirmed with echocardiography. Panel D: In one swift motion, the balloon is pulled across the atrial septum to the IVC-RA junction to create an atrial septal defect. (IVC: Inferior vena cava; RA: Right atrium; LA: Left atrium; Ba: Balloon; IAS: Interatrial septum)



**FIGURE 5** 0.035 inch J wire advanced from the right femoral vein through the IVC with the tip in the right atrium. (IVC: Inferior venacava; RA: Right atrium; LA: Left atrium)



### Summary

In our experience, bedside atrial septostomy with the Z-5 balloon atrioseptostomy catheter is feasible, safe, and can be performed with relative ease with proper technique and echocardiographic guidance. Concerns about the need to take all children to the catheterization laboratory for a septostomy with Z-5 balloon catheter may not be warranted.

### References

- Rashkind WJ, Miller WW. Creation of an atrial septal defect without thoracotomy. A Palliative Approach to Complete Transposition of the Great Arteries. JAMA. 1966;196:991–2.
- 2. Rashkind, W.J. and Miller, W.W. Transposition of the Great Arteries: Results of Palliation by Balloon Atrioseptostomy in Thirty-one Infants. Circulation, 38:453-462, 1968.
- 3. Baker EJ, Allan LD, Tynan M, et al. Balloon atrial septostomy in the neonatal intensive care unit. Br Heart J 1984; 51: 377-8.
- Bullaboy CA, Jennings RB, Jr, Johnson DH. Bedside balloon atrial septostomy using echocardiographic monitoring. Am J Cardiol 1984; 53: 971-2.
- Zellers TM, Dixon K, Moake L, Wright J, Ramaciotti C. Bedside balloon atrial septostomy is safe, efficious, and cost-effective compared with septostomy performed in the cardiac catheterization laboratory. A J Cardiol. 2002;89:613–5.
- Savorgnan F, Zaban NB, Elhoff JJ, Ross MM, Breinholt JP. No difference found in safety or efficacy of balloon atrial septostomy performed at the bedside versus the catheterisation laboratory. Cardiol Young. 2018 Dec;28(12):1421-1425. doi: 10.1017/S1047951118001439. Epub 2018 Aug 28.





GURUMURTHY HIREMATH, MD Corresponding Author Director of Pediatric Catheterization Laboratory,

Division of Pediatric Cardiology Department of Pediatrics, University of Minnesota Masonic Children's Hospital 2450 Riverside Ave, Minneapolis, MN, USA hiremath@umn.edu or 612.626.2755



KATY SOULE, PA-C

Manager of Clinical Operations, Pediatric Cardiology Division of Pediatric Cardiology, Department of Pediatrics University of Minnesota Masonic Children's Hospital Minneapolis, MN, USA



JIM BERRY, RDCS

Senior Cardiac Sonographer
Division of Pediatric Cardiology,
Department of Pediatrics
University of Minnesota
Masonic Children's Hospital
Minneapolis, MN, USA



JOHN L BASS, MD

Professor, Pediatric Cardiology Division of Pediatric Cardiology, Department of Pediatrics University of Minnesota Masonic Children's Hospital Minneapolis, MN, USA



KARI ERICKSON, DNP, APRN

Nurse Practitioner
Division of Pediatric Cardiology,
Department of Pediatrics
University of Minnesota
Masonic Children's Hospital
Minneapolis, MN, USA



**VARUN AGGARWAL, MD** 

Assistant Professor,
Pediatric Interventional Cardiologist
Division of Pediatric Cardiology,
Department of Pediatrics
University of Minnesota
Masonic Children's Hospital
Minneapolis, MN, USA



**KEYNOTE SPEAKER** 

# **Dr. Sanjay Gupta**

Dr. Sanjay Gupta is the multiple Emmy award winning Chief Medical Correspondent for CNN.

# 2020 Scientific Atlanta Sessions

### The Intersection of Innovation & Practice

SCAI 2020 Scientific Sessions is a comprehensive multi-day conference dedicated to interventional cardiology and endovascular medicine. This year's program, presented by world-renowned experts offers didactic, algorithm- and case-based learning, hands-on training, and networking with more than 2,000 interventional cardiologists, physicians, industry partners, hospital administrators, and cardiovascular professionals.

### **Program Highlights Include:**

- Clinical Focuses: Congenital, Coronary, Peripheral Vascular, and Structural Heart Disease
- Case Competitions and Exchanges
- Cath Lab Leadership and Cardiovascular Professional Sessions
- Featured Research: Abstracts, Case Reports, and Late Breaking Clinical Science

- ◆ Fellows Summit for Complex Cases
- ♦ Global Summit and Case Exchange
- ◆ Innovations and Technology Summit
- Live Cases
- ◆ TAVR Academy
- ◆ Transseptal Workshop
- Women in Innovations (SCAI-WIN)
   Sessions

Registration is open.

For more information, visit www.scai.org/SCAI2020





# **Compelling Presentations Mark Third Heart Summit At Herma Heart Institute**

Jeanne James, MD

In October 2019, the Herma Heart Institute at Children's Wisconsin held its third annual *Heart Summit*, welcoming pediatric cardiologists and cardiothoracic surgeons from across the United States and around the world for a unique learning event. This year's summit focused on "Management of the Failing Fontan: A Look Into the Future," offering real-time surgical and cardiac catheterization demonstrations, as well as lectures on the unique yet disparate morphologies of single ventricle physiology associated with isomerism and heterotaxy syndrome.

#### **Cornerstone Presentation**

The *Heart Summit* has become known for the innovative use of 3D intraoperative video presentations broadcast in real time to attendees in the auditorium. This year did not disappoint. Noted surgeon **Viktor Hraska, MD, PhD**, Medical Director of Cardiothoracic Surgery and Surgical Director of the Herma Heart Institute, performed a Fontan completion in a 10-year-old girl. The patient was a unique case: In addition to her univentricular heart, she had only one functioning lung. The Fontan operation generally is performed between 18 months and three years, but was contraindicated for this patient at the typical age for Fontan completion due to elevated Glenn pressure, pulmonary venous obstruction and evidence that her left lung was not participating in significant oxygen exchange.



The catheterization lab during the 2019 Heart Summit



Dr. Viktor Hraska and the surgical team performing open heart surgery with 3D cameras broadcasting live to Heart Summit attendees in the auditorium

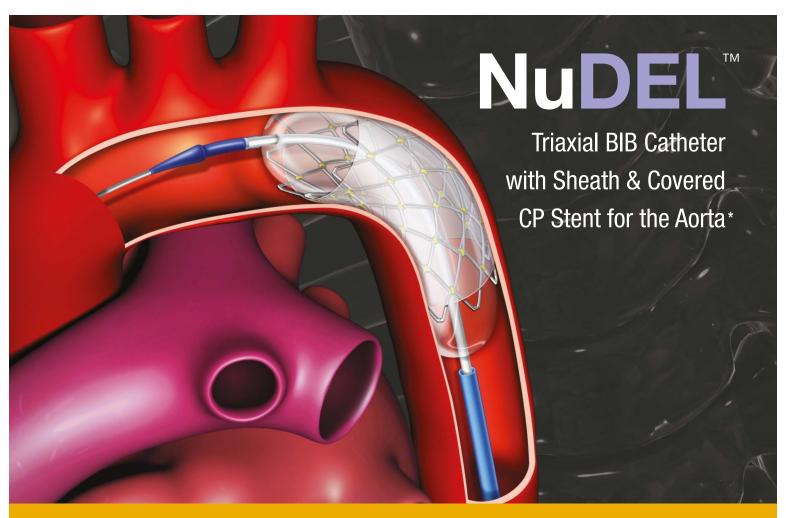
During the surgery, Dr. Hraska performed not only the Fontan anastomosis, but also a novel procedure — turndown of the innominate vein to the right atrium, an innovative technique intended to lessen lymphatic congestion by providing a "pop-off" for potentially elevated Glenn and Fontan pressures. Dr. Hraska is well-acquainted with the turndown procedure, having performed it eight times while practicing in Europe.

Summit attendees were able to see the procedure in phenomenal detail via the live broadcast, and they enjoyed the opportunity to ask Dr. Hraska questions in real-time during the procedure. One of the expert panelists shared that watching the intraoperative 3D video gave him chills. Despite having more than 30 years of experience working in the field, he explained, he had never been able to visualize what happens in the operating room with such clarity.

### **More Learning Opportunities**

In addition to the live, interactive broadcast of the Fontan procedure and innominate vein turndown, conference attendees participated in multiple sessions over the course of the three-day *Heart Summit*.

There were two real-time demonstrations of patients undergoing catheterization in preparation for Fontan completion surgery



# The All-In-One Aortic Stent System

The NuDEL<sup>™</sup> Stent Delivery System is designed for the efficient and effective treatment of Coarctation of the Aorta.

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

The NuDEL System is available for immediate purchase in the EU. Contact us or your local distributor to place an order.



World Leader in Pediatric Cardiology

**( E** 0120



and a breakout poster session where trainees and junior faculty presented their latest findings in Congenital Heart Disease research and quality improvement initiatives. Presentations from geneticists and pulmonologists expanded on recent work in their fields; notably, the findings from Herma Heart Institute physicians that challenge previous dogma about exercise for Fontan patients, who should indeed exercise more, not less. Lively discussions among attendees and presenters were a common and welcome feature at each session.

Lectures during the third day of the *Heart Summit* focused on isomerism and Heterotaxy Syndrome, which sometimes occurs in patients with complex congenital heart defects. **Robert Anderson, MD, PhD**, of the Institute of Child Health at University College London and keynote speaker at the opening of the summit, presented a lecture on isomerism and Heterotaxy Syndrome, complete with high-definition displays of four affected hearts on loan from the Farouk Idriss Archives at the Anne and Robert H. Lurie Children's Hospital in Chicago. Patients who present with heterotaxy are among the most high-risk of single-ventricle patients and, to date, have the lowest long-term survival rates. Understanding the anatomy of these patients is an important step to removing obstacles for treatment, preparing them to be the best possible surgical candidates and preventing postoperative complications.



The 3D glasses used throughout the Heart Summit give an element of depth that is otherwise often unseen

In this third occurrence of the *Heart Summit*, pediatric cardiologists, surgeons and advanced practice providers enjoyed an innovative and unique learning opportunity that combined different modalities — not only standard lectures but video, live 3D surgery, broadcasts from the catheterization laboratory, and virtual reality teaching — all enhanced by a highly interactive format.

### Coming in 2020

The next *Heart Summit* is slated for **October 28<sup>th</sup>-30<sup>th</sup>**, **2020**, in Milwaukee, Wisconsin, where our topic will be "**Decision Points in Conotruncal Malformation.**" Drs. Shakeel Qureshi, John Cheatham and Robert Anderson will be among our speakers. Earlier that week, Dr. Anderson will host a pre-Summit anatomy fellowship lecture series that is open to all interested cardiac trainees.

We hope that you will join us for the **2020 Heart Summit**. Find the agenda and registration information at <a href="http://childrenswi.org/heartsummit">http://childrenswi.org/heartsummit</a>.





**JEANNE JAMES, MD** 

Medical Director of Pediatric Cardiology Herma Heart Institute Children's Wisconsin Milwaukee, WI, USA



The congenital heart professionals network exists to facilitate communications between congenital heart professionals locally, regionally, and globally.

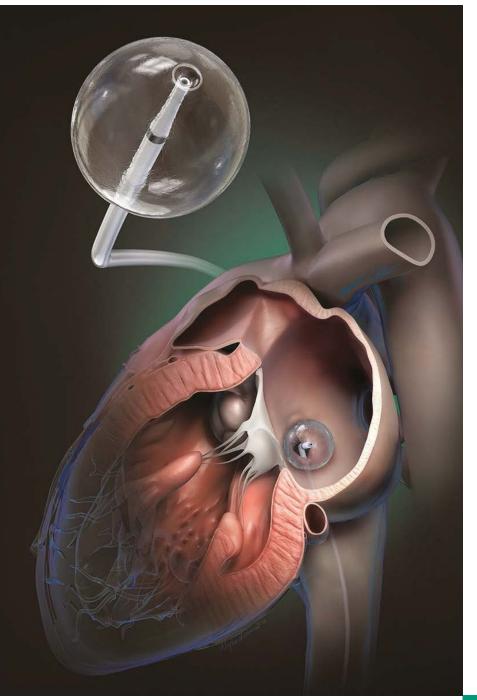
**JOIN TODAY** 

www.chip-network.org



Funded by Cincinnati Children's Heart Institute





**Z-5**Atrioseptostomy
Catheter

- Inner catheter lumen for utilization of a guidewire
- Exceptionally low profile for compatibility with 5F and 6F Introducers
- 35 degree tip angulation facilitates passage into the left atrium
- Non-compliant, latex-free balloon maintains its shape during pullback

# **OPENING DOORS TO THE FUTURE**

Distributed by:

B. Braun Interventional Systems Inc. | Part of the B. Braun Group of Companies
Bethlehem, PA | USA | 877-836-2228 | www.bisusa.org



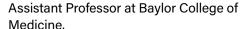
# Texas Children's Names Adult Congenital Heart Disease Program Leadership Team

### **Esteemed Cardiologist and Cardiovascular Surgeon to Guide Largest Program in Texas**

Texas Children's Hospital is proud to announce two new leaders of the Adult Congenital Heart Disease (ACHD) Program at Texas Children's Heart Center®. Dr. Peter Ermis serves as Medical Director of the ACHD Program and Dr. Edward Hickey began serving as Surgical Director of the ACHD Program in October, 2019. Together, the esteemed cardiologist and cardiovascular surgeon will guide the largest ACHD program in the state. Texas Children's is ranked #1 in the nation for cardiology and heart surgery by U.S. News & World Report.

Texas Children's ACHD Program allows patients with Congenital Heart Disease to receive seamless continuity of care from birth throughout adulthood. As pediatric patients with congenital heart defects transition into adulthood, the program's multidisciplinary team of experienced Congenital Heart Disease specialists advises them on health and lifestyle choices for their adult needs, including physical challenges, exercise options and family planning. The program offers comprehensive medical and surgical care in collaboration with colleagues at Texas Children's Pavilion for Women® and Texas Children's Fetal Center®. The hospital's ACHD Program is accredited by the Adult Congenital Heart Association (ACHA) and is one of only three programs accredited in Texas.

**Dr. Ermis,** a native Houstonian and dedicated member of Texas Children's ACHD Program team since 2014, also serves as





"I'm honored to take on a leadership role in the program where I began my cardiology career," said Dr. Ermis. "As this population of patients grows, it is even more important they are cared for by Congenital Heart Disease specialists

who recognize their specific needs as they transition to and live through adulthood. Our team is revolutionizing the way we care for these patients and I look forward to continuing to do so in partnership with Dr. Hickey."

Dr. Ermis received his undergraduate degree at Rice University. He earned his medical degree from the University of Texas Health Science Center at San Antonio and went on to complete his residency and pediatric and adult cardiology fellowship at Baylor. He is board certified in Pediatric Cardiology, Adult Cardiology

and Adult Congenital Heart Disease. Dr. Ermis is a fellow in the American College of Cardiology and member of the American Academy of Pediatrics, Texas Heart Institute Cardiac Society and the International Society on Adult Congenital Heart Disease.

Dr. Hickey, a recognized leader in cardiovascular surgery, most recently served as Associate Professor of Cardiac Surgery at the University of Toronto and Cardiac Surgeon and Chief of the ACHD Program at The Hospital for Sick Children. In addition to his leadership role, he will also perform congenital heart surgeries and serve as Associate Professor of Surgery at Baylor.

"I'm thrilled to join Texas Children's and lead the ACHD Program alongside Dr. Ermis," said Hickey. "Treating these unique patients requires dedication from an entire team and it is evident Texas Children's is paving the way in this field. I'm looking forward to joining this innovative and collaborative group as we continue to develop tailored approaches for our patients."

**Dr. Hickey** received a Bachelor of Medicine degree from the University of Southampton in the UK, where he also completed



his general surgery residency. He went on to complete higher surgical training in cardiothoracic surgery and simultaneously earned his Doctor of Medicine Research thesis from Oregon Health & Science University and the University of Southampton, respectively. Dr. Hickey then received the John Kirklin Fellowship from the Congenital Heart

Surgeons' Society, University of Toronto and spent two years at The Hospital for Sick Children. He also completed residency training in cardiovascular surgery at the University of Toronto followed by a clinical fellowship in congenital heart surgery.

To learn more about Texas Children's ACHD Program, visit <a href="https://www.texaschildrens.org/achd">https://www.texaschildrens.org/achd</a>.





# **Practice Builders Announces New Automated Patient Acquisition Solution**

## The Online Physician Reputation Builder Launches the myPracticeReputation™ Platform

For more than 40 years, Practice Builders, has been an industry leader helping physicians and medical practices attract new patients. The company recently announced the launch of the myPracticeReputationTM (myPR) platform, an automated patient acquisition solution to enhance the online reputations of physicians and medical practices.

The myPR platform is an easy-to-use reputation management solution designed to enable users to showcase the practice as well as their physicians' standard of quality care. The platform helps decrease staff workload and ultimately helps them achieve desired objectives of increasing patient volume and additional revenue for the practice. It does so in the following ways:

- Uses automated practice marketing, which strengthens clients' reputations with automated reviews, improving the average rating by 1.3 stars.
- Increases visibility by placing clients at the top of search results with optimized Google My Business (GMB) listings.
- Helps grow revenue with targeted ads that leverage listings strategically placed and aimed at specific patient populations, increasing patient volume and profitable market share.
- Leverages automation and integration, seamlessly integrating with more than 60 practice management and electronic medical records systems.

"Our focus continues to be on supporting physicians," said Sharon Mason-Parker, CEO of Practice Builders. "myPR enhances our ability to help practices thrive; it gives practices the power to take charge of their online reputation and to attract, connect, convert and retain patient populations."

Practice Builders provides clients with important practicemanagement marketing solutions that meet specific needs and objectives. Until now, services and products have included:

- One-stop marketing solution partner and resource offering competitive pricing,
- Customized client-owned website that fits the needs of the practice,
- Specialized healthcare marketing expertise,
- Multiple marketing products, services and custom solutions such as SEO, social media, video and content marketing, and
- On-demand services, training and much more.

The platform launched in December 2019. For more information, email info@practicebuilders.com, call 855.898.2710 or visit https://www.practicebuilders.com.



Neonatology Today is interested in publishing manuscripts from Neonatologists, Fellows, NNPs and those involved in caring for neonates on case studies, research results, hospital news, meeting announcements, and other pertinent topics.

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com



# **Congenital Heart Disease More Deadly In Low-Income Countries**

Despite tremendous advances in the treatment of CHD, the first comprehensive estimate of prevalence and mortality finds major differences between high-income and low-income countries

### **Children's National Hospital**

Even though mortality from Congenital Heart Disease (CHD) has declined over the last three decades as diagnosis and treatments have advanced, the chances for a child to survive a CHD diagnosis significantly differs based on the country where he or she is born.

This eye-opening finding is drawn from the first comprehensive study of Congenital Heart Disease across 195 countries, prepared using data from the *Global Burden of Diseases, Injuries and Risk Factors* Study 2017 (GBD), and recently published in *The Lancet*. <a href="https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(19)30402-X/fulltext">https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(19)30402-X/fulltext</a>

"Previous congenital heart estimates came from few data sources, were geographically narrow and did not evaluate CHD throughout the life course," write the authors, known collectively as the 2017 GBD Congenital Heart Disease Collaborators. Co-lead author Meghan D. Zimmerman, MD, worked on the study while completing her Pediatric Cardiology and *American Heart Association Global Health* Fellowships at Children's National Hospital, and two pediatric cardiologists from Children's National, Cardiology Associate Chief Craig Sable, MD, and Gerard Martin, MD, Medical Director of Global Services, provided leadership and oversight of this paper. The remaining collaborators are from more than 45 institutions around the world, spanning cardiology, public health and schools of medicine on every continent.

This is the first time the GBD study data was used along with all available data sources and previous publications--making it the most comprehensive study on Congenital Heart Disease burden to date. Key differences between this study and prior estimates include:

- Anatomic groupings of CHD by type, rather than simply categorized as moderate, severe or critical.
- Inclusion of new data sources, including data from screening programs, congenital registries, administrative data and data sources in mortality and survival.
- A control mechanism to account for cases of CHD that remit on their own to reduce the risk of overestimating prevalence.
- Inclusion of all cases of Congenital Heart Disease, including those with chromosomal or genetic anomalies such as Trisomy 21 that often co-occur.

This more comprehensive data set led to findings that showed lower predicted long-term survival, higher remission, and lower prevalence

than previous studies that extrapolated evidence from studies of high-income countries. However, it also means these new estimates are a more accurate representation of the current global state of affairs. Overall, the study found:

- A 34.5% decline in deaths from Congenital Heart Disease between 1990 to 2017.
- Nearly 70% of deaths caused by CHD in 2017 (180,624) were in infants less than one year old.
- Most CHD deaths occurred in countries within the low and low-middle socio-demographic index (SDI) quintiles.
- Mortality rates get lower as a country's SDI rises.
- Birth prevalence of CHD was not related to a country's sociodemographic status, but overall prevalence was much lower in the poorest countries of the world. This is because children in these countries do not have access to life saving surgical services.
- Nearly 12 million people are currently living with CHD globally, 18.7% more than in 1990.
- The burden of CHD is not fully realized by just looking at prevalence and mortality. The measure "Years of Life Lost" provides deeper insight into the staggering burden of CHD, taking into account both absolute mortality and age at death.

"In high income countries like the United States, we diagnose some heart conditions prenatally during the 20-week ultrasound," says Dr. Martin, a Pediatric Cardiologist at Children's National Hospital who contributed to the study. "We catch others right after birth with a pulse oximetry screening for critical Congenital Heart Disease. We can operate to correct a critical issue within the first week of life. And now our CHD kids are growing and thriving through adulthood and having families of their own."

"For children born in middle- and low-income countries, these data draw stark attention to what we as cardiologists already knew from our own work in these countries--the lack of diagnostic and treatment tools leads to lower survival rates for children born with CHD," adds Dr. Sable. "This is one of the most significant publications I have been a part of as it highlights the substantial loss of life to CHD in infancy around the globe."

The authors write, "The UN has prioritized reduction of premature deaths from heart disease, but to meet the target of 'ending preventable deaths of newborns and children under five years of age,' health policy makers will need to develop specific accountability measures that address barriers and improve access to care and treatment."

The study also includes a 400-page appendix breaking down each area by type of congenital anomaly, world region and country.





### **APRIL**

16-18

### **EPIC-SEC**

Atlant, GA, USA

https://www.epicsec.org/

### **17-18**

17TH ANNUAL CHICAGO SONOGRAPHER **UPDATE-ECHOCARDIOGRAPHIC ASSESSMENT** OF COMMON CONGENITAL HEART DISEASE AND CORONARY ARTERY IMAGING

Chicago, IL, USA

https://www.luriechildrens.org/sonographer

### 24-25

### **BEYOND PRETTY PICTURES -**3D ECHOCARDIOGRAPHY IN **CONGENITAL HEART DISEASE**

Edmonton, Alberta, Canada

http://www.pedsecho.ca/beyond-pretty-pictures-2020/

### **MAY**

02

### **ACHA MICHIGAN REGIONAL CONFERENCE**

Grand Rapids, MI, USA

https://www.achaheart.org/get-involved/events/?c=1655

### 07-10

### **FELLOWS 2020 INTERVENTIONAL CARDIOLOGY FELLOWS COURSE**

Orlando, FL, USA

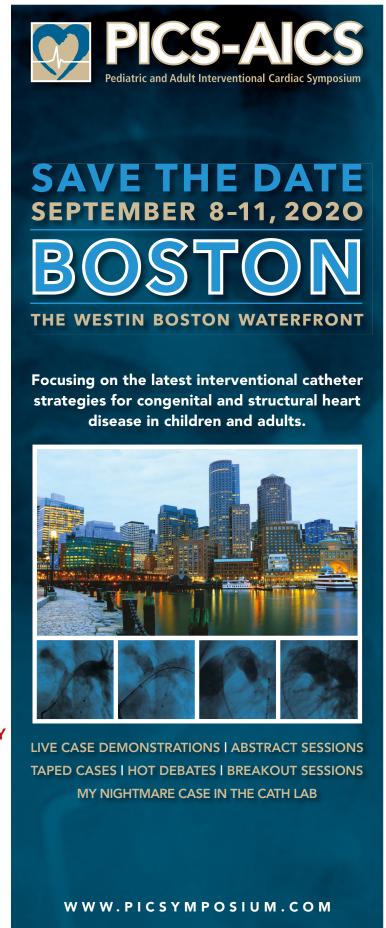
https://www.crf.org/fellows

### 13-16

### **SCAI 2020 SCIENTIFIC SESSIONS**

Atlanta, GA, USA

http://www.scai.org/SCAI2020







### CORPORATE OFFICE

11500 Elk Horn Drive Clarksburg, MD 20871 USA

### CORPORATE TEAM

FOUNDER & SENIOR EDITOR

Tony Carlson Tony@cct.bz CO-FOUNDER &
MEDICAL EDITOR
John W. Moore, MD, MPH
Dr.John@cct.bz

EDITOR-IN-CHIEF Kate Baldwin Kate@cct.bz STAFF EDITOR Loraine Watts

EDITOR-IN-CHIEF EMERITUS Richard Koulbanis

STAFF EDITOR & WRITER
Virginia Dematatis

### **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

Shakeel A. Qureshi, MD
P. Syamasundar Rao, 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

# 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.

© 2020 by Congenital Cardiology Today ISSN 1554-7787 print. ISSN 1554-0499 electronic. Published monthly. All rights reserved.