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Hybrid Pulmonary Outflow Tract Stenting in a Small Child with Complex Heart Disease

Niall Linnane, MD; Jonathan McGuinness, MD; Philip Roberts, MD; Brian Grant, MD; Damien Kenny, MD

Introduction

Non-surgical interventions on the pulmonary outflow tract have evolved in the last number of years to include more complex procedures in increasingly smaller children. This has led to challenges with regard to access. Large sheaths and stiff wires in small hearts lead to haemodynamic instability[1] and thus an alternative per-ventricular access route has been described.[2,3] We describe such a case outlining how collaboration between cardiology and cardiothoracic surgical colleagues facilitated a successful resolution of a serious hemodynamic issue in a patient with complex Congenital Heart Disease.

Case

We present a case of a 30-month-old infant weighing 14kg with a background history of dextrocardia with situs inversus, atrio-ventricular discordance with a ventricular septal defect and pulmonary atresia with an anterior aorta and non-confluent branch pulmonary arteries supplied by bilateral patent ductus arteriosus (PDA). He was initially palliated with bilateral PDA stent placement and subsequently underwent a hemi-Mustard, pulmonary artery reconstruction and bidirectional Glenn, and a Rastelli with a 18mm Contegra conduit (Medtronic, Galway, Ireland) at 10 months of age. He had a difficult post-operative course which was complicated by mediastinitis and sepsis with a resistant gram-negative organism. He developed a retrosternal collection requiring sternal rewiring twice and placement of calcium containing antibiotic beads around the conduit in the mediastinum to resolve the infection.

He was admitted to his local hospital with low saturations 20 months after his surgery. His echocardiogram showed reduced right ventricular function with severe tricuspid regurgitation suggesting significantly elevated right ventricular systolic pressures. Furthermore, the echocardiogram did not demonstrate flow in the right ventricle to pulmonary artery (RV-PA) conduit. He had a CT angiogram which confirmed occlusion of the (RV-PA) conduit.

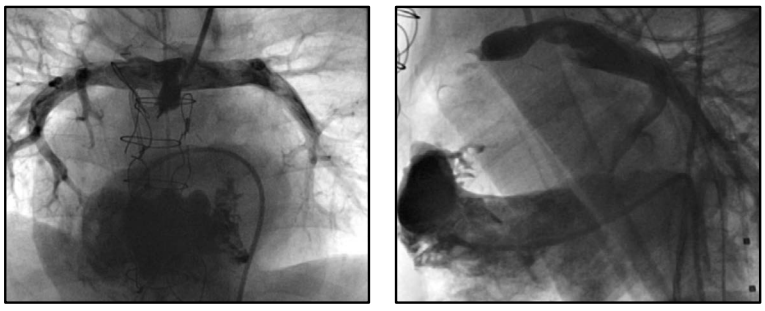

FIGURE 1
Anteroposterior (AP) and lateral (lat) projection of initial simultaneous RV and PA angiogram demonstrating no flow in right ventricle to pulmonary artery conduit

His case was discussed at the joint cardiac and cardiothoracic conference and due to the history of mediastinitis and his complex anatomy, a plan was made for an initial percutaneous cardiac

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catheterisation to evaluate if there was any residual flow through the conduit with subsequent progression to a hybrid per-ventricular re-canalisation of the thrombosed RV - PA conduit.

The procedure was performed under general anaesthetic. Vascular access was obtained through the right femoral artery and vein and left internal jugular vein (IJV). Angiograms in the RV after crossing the Hemi-Mustard pathway and left SVC/Glenn demonstrated conduit occlusion with no flow from RV to main PA and thus confirmed CT findings **(Figure 1)**. The RV and PA ends of the conduit were separated by a 2.5cm gap. Initially, the mean Glenn pressure was 15mmHg and the RV systolic pressure was supra-systemic. On probing, there was no lumen found in the conduit.

The decision was made to proceed with re-canalisation. A subxiphoid approach was utilised by the cardiothoracic surgery team to expose the lower anterior surface of the RV and a 9Fr sheath was placed through purse-string sutures into the RV. The sheath was angled towards the RV to PA conduit and a Chiba needle (Cook Medical, Limerick, Ireland) which was manually curved to simulate the posterior trajectory towards the pulmonary arteries, was advanced through the thrombosed conduit towards the MPA. Once cannulation of the PA was confirmed with an angiogram, an 0.014" Granslam coronary wire (Asahi Intecc, Aichi, Japan) was advanced into the LPA and was snared from the left IJV creating a loop from the RV through the Glenn shunt. A 4Fr sheath was advanced to the MPA from the RV, through the pre-existing sheath in the RV and the conduit was ballooned with a 5x20mm coronary balloon (Boston Scientific, Galway, Ireland) followed by a 8x30mm Sterling balloon (Boston Scientific, Galway, Ireland). Subsequent RV angiography confirmed a passage facilitating flow antegradely from the RV to the PA.

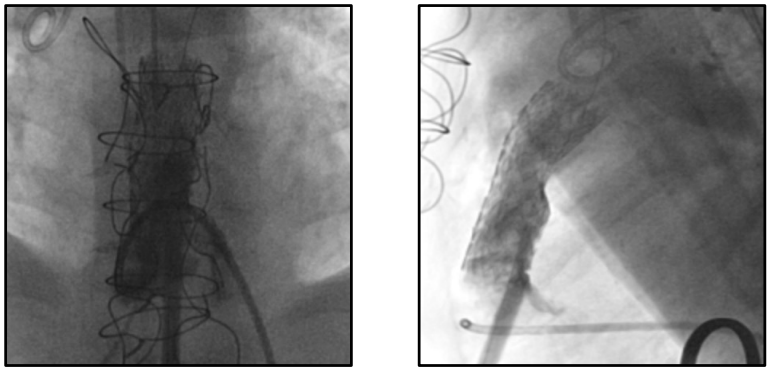

FIGURE 2

AP and lateral projections following 1st stent placement

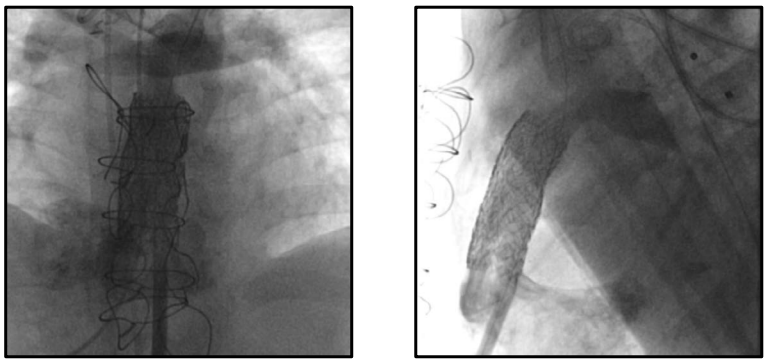

FIGURE 3

AP and lateral projections following 2nd stent placement

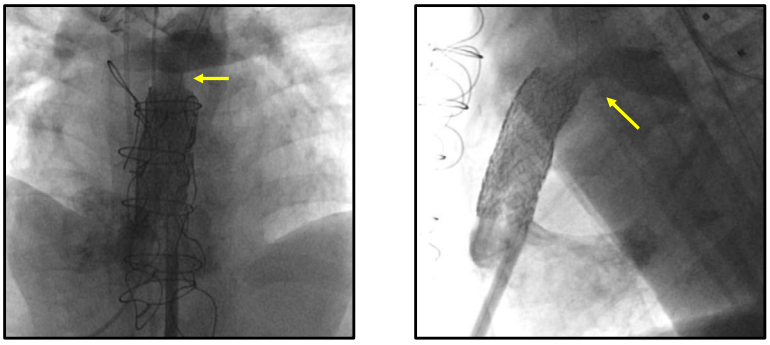

FIGURE 4

AP and lateral projections demonstrating residual narrowing (arrow) distal to the stents

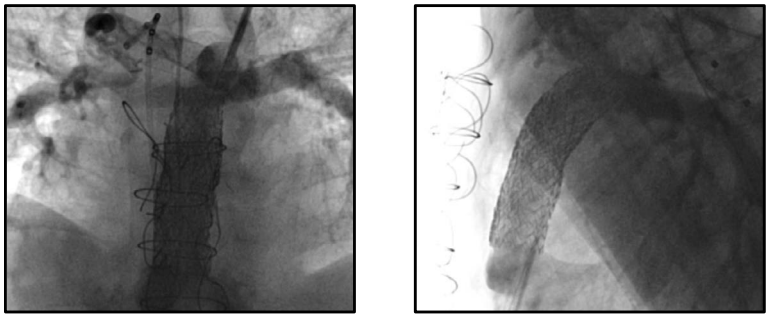

FIGURE 5

AP and lateral projections of final angiogram after 3rd stent insertion

This manoeuvre facilitated passage of a 10Fr sheath into the RV-PA conduit. A 36mm Intrastent Max LD (Medtronic, Galway Ireland) was placed within the conduit on a 12mm x 4cm Powerflex balloon (Cordis, Florida, USA). This was post dilated with a 14 x 30mm Altosa balloon (Andratec, Koblenz, Germany). A further 36mm Intrastent Max LD on a 12mm x 4cm Powerflex balloon was placed proximal to the initial stent to ensure full coverage of the conduit and was post dilated with a 14 x 30mm Altosa balloon **(Figure 2 and 3).**

At this stage the RV pressure had dropped to 65% of systemic pressure. The mean Glenn pressure had increased to 22mmHg. Angiogram demonstrated attenuation of the pulmonary end of the conduit. Thus, a further 26mm Intrastent Max LD mounted on an 14 x 30mm Altosa balloon was placed **(Figure 4 and 5).** Subsequent RV pressure was less than 50% systemic systolic pressure and the Glenn pressure remained at 22mmHg. The final angiogram showed good stent position with no extravasation of contrast. All sheaths were removed with good haemostasis. A mini-vac drain was inserted into the inferior pericardium. The patient made a good recovery and was transferred back to his local hospital 10 days post procedure.

Discussion

Since 1966 when Rashkind et al described the first balloon atrial septostomy, the field of interventional cardiac catheterisation in children has evolved at a rapid pace.[4] With the evolution of equipment, the patient cohort has

expanded, and now interventional therapies can be offered to not only smaller patients, but also to patients with more complex anatomy who may have traditionally been treated surgically.

Part of this evolution has involved development of hybrid therapies to provide more direct "surgical" access to treat complex pathologies in smaller patients. A recent retrospective review has demonstrated a high success rate when using the per-ventricular subxiphoid technique in small children requiring a variety of interventional therapies.[5]

Perforation of atretic pulmonary valves has evolved to become a common procedure performed by interventional cardiologists and there have been multiple methods described for the perforation. Latson et al reported originally in 1991 with perforation of an atretic valve with a coronary wire.[6] Around the same time Qureshi et al[7] and Parsons et al[8] reported on the use of laser valvotomy to perforate the atretic valve. With the passage of time newer equipment bred newer techniques; firstly with radiofrequency perforations being described[9] and, subsequently, with the use of more advanced coronary wires used for chronic total occlusion procedures.[10]

Valve perforation has been previously described via a hybrid approach although direct puncture with a needle through the ventricle is only rarely reported.[3,11-13] While these percutaneous and hybrid techniques were initially developed for atretic pulmonary valves, they have been modified to be used for chronically occluded vessels.[14]

There is little published on the re-cannalisation of thrombosed conduits, largely due to conduit thrombosis being rare with a reported incidence of <1% in a large series.[15] Our patient was able to maintain pulmonary blood flow due to the Glenn shunt performed as part of the Hemi-Mustard approach to his atrio-ventricular discordance which is well-described.[16] The history of mediastinitis led to some reticence at approaching conduit rehabilitation/replacement via a surgical route particularly in the context of the right ventricular pressure load which had led to some RV dysfunction.

The puncture site on the RV needs to be carefully considered in such cases to optimise trajectory towards the targeted site of intervention. Manipulation of the sheath can help direct the catheter; however, in smaller infants, ventricular cavity size is limited and the lack of specifically designed "hybrid" sheaths may lead to instability in sheath position.

In our case, we describe the use of a Chiba biopsy needle (Cook Medical, Limerick, Ireland) to perforate the thrombosed conduit to form a tract between the right ventricle and pulmonary artery to allow serial dilatations and stent insertion. The use of a Chiba needle has been well-described for transhepatic access in children[17-19] and has been reported in a small infant for right ventricular outflow tract stent insertion.[11]

The use of the Chiba needle is advantageous as it allows the stylet to be removed and an 0.014" wire to be advanced through the lumen. In this case, the trajectory of the anterior conduit to the malposed pulmonary arteries posteriorly required manipulation of the Chiba needle with a curve from anterior to posterior to ensure a suitable trajectory into the MPA. The angles created by the complex anatomy would have made the procedure technically very challenging percutaneously. Using the hybrid approach not only allowed a curve to be place on the Chiba needle to account for the angles, but also allowed a larger sheath to be used to facilitate the placement on larger stents.

While the hybrid approach removes the limitations of percutaneous access, wire placement and stability can still be an issue. The use of an arteriovenous wire loop is well described[20] and in this case we used the patient's complex anatomy to form a ventriculo-venous loop and provide wire stability despite using a soft coronary wire initially. While the needle and wire crossed into the MPA, there are often concerns that the tract will not be large enough to allow passage of the balloon, thus a 4Fr sheath was place initially across the conduit into the MPA to ensure the coronary balloon would pass into position.

Deciding on how aggressive to be with the dilation of the 18mm Contegra was challenging due to the balance of minimizing acute elevation of the Glenn pressure with establishing a large enough egress from the RV to maintain stented conduit patency. The Max LD stent, which is an open cell stent, has the advantage of being more flexible, allowing access to side branches and foreshortening less when stretched.[21] Furthermore, Cools et al have demonstrated the strength of this stent when they mechanically tested it in comparison to three other stents used in the right ventricular outflow tract prior to pulmonary valve implantation.[22] While their work demonstrated the superior strength of the Cheatham Platinum (CP) stent (Numed, Hopkinton, NY),[22] the closed-cell design of this stent makes it less flexible and may reduce the patency result in a thrombosed conduit.

Finally, we decided against placement of a transcatheter pulmonary valve. Certainly the history of serious mediastinal infection influenced our decision with established concerns regarding endocarditis following transcatheter pulmonary valve replacement in younger patients in particular.[23] Also determining the lifetime impact of early valve replacement in younger patients is uncertain with the likelihood of needing multiple valve replacements being measured against how well patients tolerate pulmonary valve regurgitation in the medium term.

Conclusion

Complex patients often lead to complex decisions which lead to complex interventions. The advent of hybrid techniques and inter disciplinary collaboration allow for these patients to get the optimum care. Understanding the intricacies of this patient's anatomy allowed the correct access point to be chosen and for available equipment to be manipulated to ensure procedure success. Furthermore, understanding the material properties of the available stents and outcomes from their use makes sure the correct decisions are made and the best outcome for the patient is achieved.

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SCAI 2022 Scientific Sessions Coverage

First Intermediate to Long-Term Study of the Harmony Transcatheter Pulmonary Valve System Validates Safety and Efficacy

New Analysis of the Largest Harmony TPV Recipients Cohort Show Echoes Initial Acute Findings

A study of one-year outcomes in the largest cohort to date of Harmony transcatheter pulmonary valve (TPV) patients with congenital heart disease (CHD) and severe pulmonary regurgitation (PR) was presented today as late-breaking clinical research at the *Society for Cardiovascular Angiography & Interventions* (SCAI) 2022 Scientific Sessions. The findings show Harmony TPV patients had favorable clinical and hemodynamic outcomes, confirming earlier results and demonstrating continued device safety and effectiveness across studies and valve types at one year.

Approximately one in five CHD patients have an abnormality of their right ventricular outflow tract (RVOT) (NLM). Prior to TPV technology, CHD patients were treated with invasive procedures such as open-heart surgery or opted for surgical valve replacement later in life. The Harmony TPV is designed to be a non-invasive, non-surgical treatment option for many of these adolescent and adult CHD patients not previously able to be treated with TPVs.

Data was pooled from the Harmony Native Outflow Tract Early Feasbility Study, Harmony TPV Pivotal Trial, and Continued Access Study. Eligible patients had severe PR by echocardiography or PR fraction ≥30% by cardiac magnetic resonance imaging and a clinical indication for pulmonary valve replacement. Forty-two patients received the TPV22 device and 45 received the modified TPV25 device. Additionally, 19 patients received an early iteration of the 25-mm valve (clinical TPV25) that was later found to have less predictable deployment and discontinued. The primary safety endpoint was freedom from procedure- or device-related mortality at 30 days. Efficacy was assessed as freedom from PR, stenosis, and interventions (≥ moderate PR, mean RVOT gradient > 40 mmHg, device-related RVOT reoperation, and catheter reintervention) through one year. Adverse events were adjudicated by a Clinical Events Committee.

A total of 108 patients were catheterized, 106 underwent TPV implants, and 104 remained implanted for >24 hours. The two patients who had surgical explantation within 24 hours had received a clinical TPV25 valve. Mean (SD) patient age at baseline was 29.0 (12.7) years; 62.0% were male and 86.1% had an original diagnosis of Tetralogy of Fallot. At one year, there were no deaths, and 95.1% of TPV22 and 89.7% of mTPV25 patients were free from PR, stenosis, and interventions. Eighty-five percent of patients, or greater, had none/trace PR and ≥90% had none/trace paravalvular leak at all follow-up visits.

"We knew that Harmony TPV patients were doing well acutely, but this data now validates these findings in the intermediate term" said Daniel S. Levi, MD, FSCAI, Mattel Children's Hospital at UCLA, Los Angeles, CA. "Even a year after implant, the valve is continuing to function well without significant interventions, obstruction or regurgitation. This gives us confidence that we are going down the right treatment path with this pulmonary valve."

Researchers will continue to follow this patient cohort and to further demonstrate that Harmony TPV remain safe and effective in the long run.

Helping Little Hearts Lifetime Service Award

The SCAI Lifetime Service award recognizes the work of interventional cardiologists, specializing in the treatment of pediatric congenital heart disease, who work tirelessly to develop less invasive solutions and optimize outcomes for their young patients.

Prof. Hijazi who has nearly 30 years of experience in congenital cardiology, has pioneered several ground-breaking interventional procedures in the field. He is an internationally recognized leader in the nonsurgical repair of congenital and structural heart defects in children and adults and in the development of novel trans-catheter devices.

Drs. Tom Jones, Frank Ing, Ziyad M. Hijazi, Damien Kenny and Howaida El-Said

In addition to his role as the chief medical officer at Sidra Medicine, Prof. Hijazi established the hospital's Department of Pediatrics and world-class Heart Center; staffed by some of the top pediatric specialists and healthcare professionals from across the globe. The Heart Center provides treatment (medical, interventional, electrical and surgical) for patients with congenital or acquired heart disease.

Speaking about his receipt of the SCAI award, Prof. Hijazi said: "I am honored and humbled to be awarded by the Society of Cardiovascular, Angiography and Interventions in recognition of my work in treating patients with congenital heart disease. This has been my lifetime goal, and I am proud to be able to continue this mission here at Sidra Medicine, where we have changed the lives of hundreds of patients with CHD at our heart center. We are also preparing the next generation of students to carry the baton of pioneering and quality based interventional care for patients in Qatar."

Digital Twin Technology Set to Takeover Cardiology Devices Industry in India, says GlobalData

Digital (virtual) twin technology has been progressing so that it now allows for tailored and predictive health treatment in India. The technology develops a virtual prototype for a real-life product that can monitor, evaluate, and enhance its performance in the cardiology market by bridging the real and virtual world, and it will not be long until digital twin technology takes over the existing cardiology devices industry in India, says GlobalData, a leading data and analytics company.

GlobalData's research reveals that the Indian cardiology market, which accounted for 23% of the Asia-Pacific market in 2021, is expected to grow at a compound annual growth rate of 5% through 2030.

Ayshi Ganguly, Medical Devices Associate Analyst at GlobalData, comments: "By combining the virtual and real worlds, several startups are expected to leverage the twin technology in India by creating digital twins of organs and modify the medical devices using 3D printing. Twin-tech is expected to not only improve the shelf-life and performance of the cardiological devices, but also reduce animal testing over time, thereby helping to speed up the design of medical equipment."

Modeling, labor, machineries, materials, methods, and measurement may all be validated digitally, thereby decreasing waste, and increasing energy efficiency. Cardiological sectors are expected to use this method to integrate sustainability into the heart of their operations, bringing strategy, design, and manufacturing together under one roof.

Twin technology has not only stepped into life sciences, but has also taken into consideration human body modelling. Indian startups plan to build a platform for cardiovascular research by customizing affordable devices like implants and stents for heart patients in India.

The startups also want to incorporate 3D printing into an automated process for creating patient-specific implants and single-use surgical equipment. This will ensure the quality check of each patient, thereby boosting treatment quality.

Ganguly concludes: "Digital twin technology is expected to aid medical startups in India to better understand customers' demands, develop changes to existing products, operations, and services, and even drive innovation and revenue."

Catherine Krawczeski, MD, Named Chief of the Department of Pediatrics at Nationwide Children's Hospital

Dr. Krawczeski Will Also Serve as Chair of Pediatrics at The Ohio State University College of Medicine

Catherine Dent Krawczeski, MD, has been named Physician-in-Chief and Chief of the Department of Pediatrics at Nationwide Children's Hospital. Dr. Krawczeski will also serve as Chair of Pediatrics at The Ohio State University College of Medicine, pending approval from The Ohio State University Board of Trustees. Dr. Krawczeski will begin this new role in Summer 2022.

Dr. Krawczeski has served as division Chief of Cardiology and Co-Director of The Heart Center at Nationwide Children's since 2018, and she also holds the Dunlap Endowed Chair in Cardiology. At The Ohio State University College of Medicine, she has been professor with tenure of pediatrics with co-appointments in Cardiology and Critical Care, and senior vice chair of the Department of Pediatrics.

"I have the highest regard for Nationwide Children's Hospital, hospital leadership and the One Team culture that provides a strong foundation for and influence on this organization," said Dr. Krawczeski." Our commitment to child health and wellness, to improving outcomes for all children and the support of the community we serve is truly unsurpassed."

"We could not be happier about Dr. Krawczeski stepping into this role as an innovative leader who is also a preeminent clinician and researcher," said Tim Robinson, chief executive officer of Nationwide Children's." Executive positions such as this are among the most vital at our hospital, as they help drive the advancement of clinical care, and guide the education and training of the next generation of pediatric physicians."

During her tenure as division Chief of Cardiology and Co-Director of The Heart Center, Dr. Krawczeski has prioritized the expansion of the division to facilitate academic success, align clinical needs and improve team dynamics, including the implementation of a Safety II intervention focused on multidisciplinary team decision making in the management of high-risk patients. She has been the principal investigator or co-investigator for seven National Institutes of Health grants; author of more than 200 peer-reviewed publications, book chapters and abstracts; and presenter at dozens of national and international conferences.

"Dr. Krawzeski's impressive skill set ideally positions her for this critical role at the college," said Carol Bradford, MD, MS, FACS, Dean of the Ohio State College of Medicine and Vice President for health sciences at The Ohio State University Wexner Medical Center." In academic medicine, Dr. Krawzeski is known as a 'triple threat' — an expert researcher, educator and physician. Her rich knowledge and experience will help propel our already outstanding Department of Pediatrics forward to realize our ambition of transforming the health of our communities through inclusive and innovative education, discovery and care."

Among her many awards and honors, Dr. Krawczeski was most recently chosen as a 2020 fellow in the Executive Leadership in Academic Medicine at Drexel University, designed for senior women health care faculty who are most likely to become executive leaders. She received her medical degree from the University of Missouri-Kansas City. She is a fellow of the American Academy of Pediatrics, the American College of Cardiology and the American Heart Association.

Dr. Krawczeski resides in New Albany, Ohio with her husband, Rick.

About Nationwide Children's Hospital

Named to the Top 10 Honor Roll on U.S. News & World Report's 2021-22 list of "Best Children's Hospitals," Nationwide Children's Hospital is one of America's largest not-for-profit free-standing pediatric health care systems providing unique expertise in pediatric population health, behavioral health, genomics and health equity as the next frontiers in pediatric medicine, leading to best outcomes for the health of the whole child. Integrated clinical and research programs, as well as prioritizing quality and safety, are part of what allows Nationwide Children's to advance its unique model of care. Nationwide Children's has a staff of more than 13,000 that provides state-of-the-art wellness, preventive and rehabilitative care and diagnostic treatment during more than 1.6 million patient visits annually. As home to the Department of Pediatrics of The Ohio State University College of Medicine, Nationwide Children's physicians train the next generation of pediatricians and pediatric specialists. The Abigail Wexner Research Institute at Nationwide Children's Hospital is one of the Top 10 National Institutes of Health-funded free-standing pediatric research facilities. More information is available at NationwideChildrens.org.

The Adult Congenital Heart Association Elects New Board Leadership

ACHA Announces the Appointment of Five New Members to its Board of Directors, as well as the Creation of a Patient and Family Advisory Board

The Adult Congenital Heart Association (ACHA) – whose mission is to empower the Congenital Heart Disease community by advancing access to resources and specialized care that improve patient-centered outcomes – has announced five new members to its Board of Directors:

- Binta Baudy, MPH, Assistant Vice President, Texas Children's Hospital
- Mindy Beyer, RN, Quality Improvement Specialist, Maine Medical Partners-MaineHealth Cardiology and Congenital Heart
- William Causey, Retired Attorney
- Neema Khatri, Branch Chief, Recovery Support Function Coordination, Federal Emergency Management Agency
- Kristi Ryan, RN, CPNP-AC, Nurse Practitioner, Adult Congenital Heart Program, OSF HealthCare Children's Hospital of Illinois

CHD, the most common birth defect diagnosed in one in 100 births, is a chronic illness that ranges among simple, moderate, and complex heart defects, and needs to be monitored over the course of a patient's life. Through education, outreach, advocacy, and research, ACHA serves and supports the nearly two million adults with congenital heart disease, their families, and the medical community.

As members of the Board of Directors, Beyer and Khatri will co-chair the organization's newly formed Patient & Family Advisory Board, which will provide advice on current and proposed ACHA initiatives, receive, and respond to diverse consumer perspectives, and help execute new initiatives in local communities.

"I look forward to working with these accomplished professionals," said Jeff Ishida, Chair of ACHA. "They bring diverse backgrounds that will help further our mission and strengthen ACHA's presence and impact in communities all across the nation."

Through education, outreach, advocacy, and research, ACHA serves and supports the nearly two million adults with congenital heart disease, their families, and the medical community.

"We are very excited to welcome these industry leaders, who will serve alongside an already impressive list of nationally recognized board members," said, Mark Roeder, ACHA President and CEO. "Their talents, connections and specialized skill sets will bring great value to our committees, staff members, and other volunteers, strengthening the mission of our organization."

Edwards Mitris Resilia Valve Receives FDA Approval for Mitral Replacement Surgeries

PRNewswire/ -- Edwards Lifesciences (NYSE: EW) today announced it received approval from the U.S. Food and Drug Administration (FDA) for the MITRIS RESILIA valve, a tissue valve replacement specifically designed for the heart's mitral position.

The MITRIS RESILIA valve has a saddle-shaped sewing cuff that mimics the asymmetric shape of the native mitral valve. It also features a low-profile frame that helps avoid obstruction of the left ventricular outflow tract by stent posts and is visible under fluoroscopy, to facilitate potential future transcatheter interventions for patients. This therapy is the company's latest innovation offering advanced RESILIA tissue with an anti-calcification technology that also allows devices to be stored under dry packaging conditions, facilitating ease of use.

RESILIA tissue is bovine pericardial tissue and serves as the platform for Edwards' new class of valves. RESILIA tissue has been studied in two robust pre-market clinical trials, as follows: (i) the COMMENCE trial comprised of 694 patients enrolled in an aortic arm who were followed for five years, some of whom will be followed for 10 years, and 83 patients enrolled in a mitral arm who were followed for five years, some of whom will be followed for 10 years, and (ii) the EU Feasibility trial comprised of 133 patients enrolled who were followed for five years. These studies together represent outcomes on 904 patients and more than 3,800 patient years of follow-up.

"For patients who need mitral valve replacement, the advanced MITRIS RESILIA valve is based on a trusted pericardial valve platform, designed to mimic the native valve and incorporating tissue with integrity-preservation technology that will potentially allow the valve to last longer," said Kevin Accola, MD, Cardiovascular Surgeon, AdventHealth Orlando.

"Mitral valve disease is prevalent, and the patients impacted experience the disease in variable ways," said Daveen Chopra, Edwards' Corporate Vice President, Surgical Structural Heart. "It was important to design the MITRIS RESILIA valve to perform like the native mitral valve, handling the highest pressures in the heart and offering sustained hemodynamic performance, so that surgeons and patients can have confidence in this new therapy option."

Edwards is dedicated to partnering with clinicians to develop patient-centric innovations for complex surgical structural heart procedures that improve long-term care and outcomes for patients. The introduction of the MITRIS RESILIA valve completes the portfolio of surgical heart valve innovations incorporating the advanced RESILIA tissue, including an aortic valve, an aortic valved conduit and now a mitral valve. Edwards continues to invest in innovations in the surgical structural heart field.

The MITRIS RESILIA valve is built on the trusted Carpentier-Edwards PERIMOUNT platform, which in 2021, celebrated 40 years of innovative valve replacements for patients. In addition to FDA approval, the MITRIS RESILIA valve has also received regulatory approval in Japan, Canada, and other countries globally.

Dr. Accola is a consultant to Edwards Lifesciences.

About Edwards Lifesciences

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

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

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

AUGUST

03-06

NeoHeart: Cardiovascular Management of the Neonate
Anaheim, California, USA
https://web.cvent.com/event/f5efadb3-8886-4c5b-9944-c41980940049/summary

05-06

International PDA Symposium 2022
Anaheim, California, USA
https://pdasymposium.com/

21-26

Pediatric & Adult Congenital Cardiology Review
Huntington Beach, California, USA
https://ce.mayo.edu/cardiovascular-diseases/content/2022-pediatric-and-adult-congenital-cardiology-review-course

30-09/03

Cardiology 2022: 25th Annual Update on Pediatric and Congenital Cardiovascular Disease
Huntington Beach, California, USA
https://chop.cloud-cme.com/course/courseoverview?P=5&EID=2646

SEPTEMBER

05-06

2nd Annual PICS Fellows & Early Career Course
Chicago, Illinois, USA
kimberly_ray@chdinterventions.org

07-10

PICS Symposium
Chicago, Illinois, USA
https://www.picsymposium.com/

Hospital Directory 2022-2023

Currently Updating

Published Mid-August

- Send updates to Kate Baldwin, Kate.f.Baldwin@gmail.com
- Updates due by 7.29.22
- Hospitals that Offer Open Heart Surgery for Children in North America
- Contact information at each hospital for Chief of Pediatric Cardiology & Fellowship Director
- Lists each hospital's Pediatric Cardiologists & Cardiothoracic Surgeons
- Lists Pediatric Cardiology Fellowships
- Distributed to Division Chiefs by mail
- Hard copies are available at CCT's booth at PICS 2022
- Electronic version available on CCT's website: CongenitalCardiologyToday.com

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