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Recurrent Carcinoid Valve Disease: Dual Transcatheter Valve Replacements in a Single Procedure

R. Allen Ligon, MD; Todd Roth, MD; Larry A. Latson, MD

Key Words: percutaneous valve therapy, pulmonary valve disease, tricuspid valve disease, percutaneous intervention, structural heart disease intervention

Abstract

We describe transcatheter treatment of a 67-year-old woman with severe right heart failure secondary to dysfunction of bioprosthetic tricuspid and pulmonary valves previously replaced for carcinoid-associated valve sclerosis. This case highlights considerations for serial, same procedure, percutaneous transcatheter valve-in-valve tricuspid and pulmonary valve replacements in a carcinoid heart disease patient with pacemaker-dependent atrioventricular block.

Introduction

Carcinoid tumors are neuroendocrine neoplasms that may secrete myriad vasoactive substances including serotonin, tachykinins, and prostaglandins. Some of these substances appear to cause endothelial injury of cardiac valves with subsequent plaque deposition and sclerosis of the downstream sides of affected valves and subvalvular supporting tissues. Because many of these substances are metabolized/inactivated in the liver and lungs, cardiac valvular involvement is seen primarily on the right side of the heart unless there is a pathway, such as a patent foramen ovale, for some degree of right-to-left shunting.[1] Cardiac involvement is associated with poor long-term prognosis with an estimated 3-year survival rate of approximately 31%.[2,3] Surgical replacement of valves with severe carcinoid valvular disease is generally required to alleviate severe symptoms.[4,5] Successful surgery can increase median survival times to 6-11 years.[2,6] However, bioprosthetic valves may be subject to accelerated (with poor tumor control) or natural deterioration, and surgical re–replacement is significantly more technically difficult and associated with increased morbidity and mortality.[4,7] Percutaneous, transcatheter, valve–in-valve replacement of the pulmonary valve, and, more recently, tricuspid valve, have been shown to be effective in the short to medium time frame with significantly lower morbidity and mortality than re-do surgical valve replacement for conventional causes of bioprosthetic valve dysfunction.[8,9] We report successful same–procedure, serial, transcatheter, pulmonary and tricuspid valve-in-valve replacements in a 67-year-old carcinoid patient with concomitant pacemaker-dependent atrioventricular block, and discuss some of the technical considerations.

Case Series

A 67-year-old female developed severe carcinoid heart disease related to a pulmonary neuroendocrine neoplasm. She underwent resection of several tumors, including a left lower lung segment for the original tumor. In 1999, she required surgical replacement of the mitral valve with a 29 Carpentier-Edwards Perimount valve (Edwards Lifesciences, Irvine, CA, USA), the tricuspid valve with a 31 Carpentier-Edwards Perimount valve, and the pulmonary valve with a 25 Carpentier-Edwards Perimount valve. She developed postoperative complete heart block and was pacemaker-dependent with a ventricular lead extending through the bioprosthetic tricuspid valve. Due to recurrent atrial fibrillation episodes, she underwent multiple ablations and placement of a Watchman (Boston Scientific, Marlborough, MA,

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USA) left atrial appendage occluder. She had hyperlipidemia with mild two-vessel coronary artery disease treated medically. She presented to our clinic with a one-year history of significantly worsening exercise tolerance with limitations to activities of daily living (NYHA Class 3-4). She did not have evidence of increased serotonin or other vasoactive carcinoid-related substances.

Transthoracic echocardiography **(Figures 1 & 2)** demonstrated severe tricuspid valve regurgitation with mild stenosis, severe pulmonary valve stenosis with moderate regurgitation, and an estimated right ventricular pressure of approximately 70mmHg (~2/3 systemic). Her bioprosthetic mitral valve and native aortic valve were functioning well with no stenosis or regurgitation. Cardiac magnetic resonance imaging confirmed pulmonary stenosis, severe tricuspid and pulmonary insufficiency with a right ventricular indexed volume of 165 mL/m2 and a right ventricular ejection fraction of 38%.

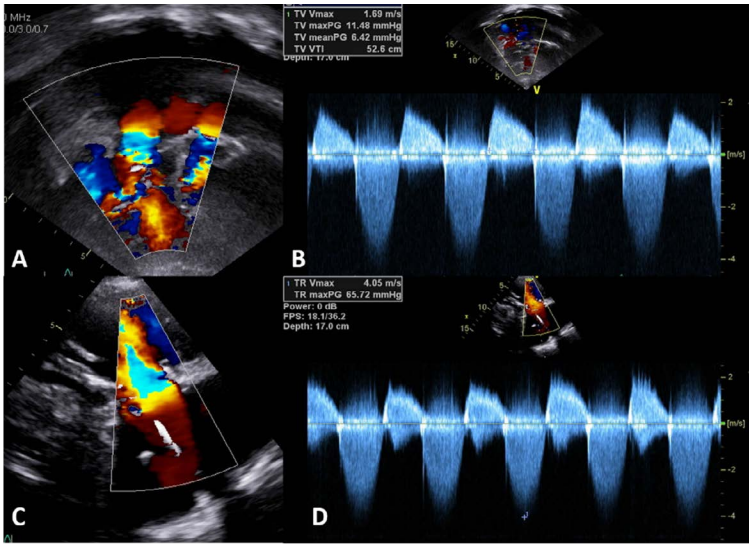

FIGURE 1 Pre-intervention Tricuspid Valve Disease
*Present was tricuspid valve stenosis with a mean gradient of 6mmHg **(A&B)** and severe tricuspid valve regurgitation with a regurgitation peak velocity of 4.05 meters/second **(C&D)**.*

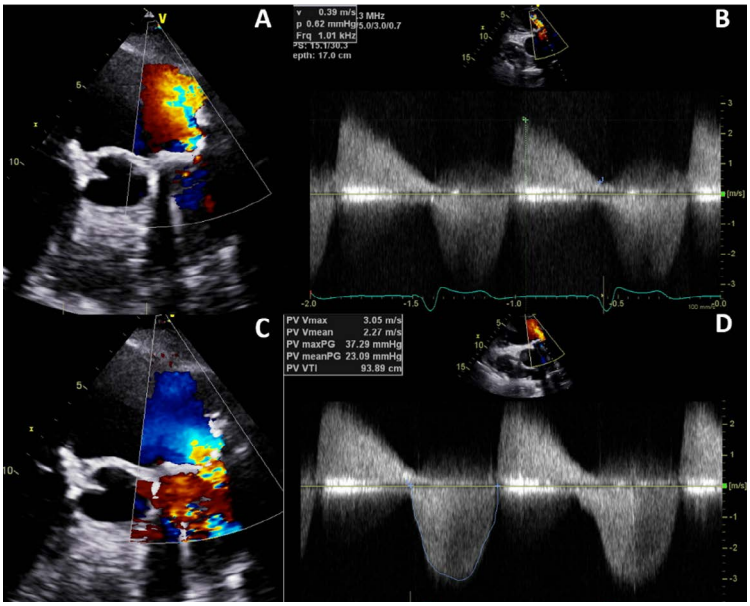

FIGURE 2 Pre-intervention Pulmonary Valve Disease
*Present was severe pulmonary valve regurgitation **(A&B)** and pulmonary valve stenosis with a peak gradient of 37mmHg **(C&D).***

The consensus recommendation of our Multidisciplinary Adult Congenital Heart Disease Conference was to proceed with transcatheter pulmonary and tricuspid valve replacements. Sequential pulmonary and tricuspid valve replacement during the same catheterization was planned. Due to the possibility of damage to the pacing lead within the tricuspid surgical valve frame by the transcatheter valve, preparations were made for urgent transvenous lead/pacemaker replacement if necessary.

Cardiac catheterization demonstrated moderately elevated diastolic pressures throughout. There was a 35mmHg systolic gradient across the pulmonary valve prosthesis with a cardiac index by the Fick method of 2.5 L/min/m2. An aortogram demonstrated that the coronary arteries were well away from both the pulmonary and tricuspid prosthetic valves. The pulmonary valve was a 25 Carpentier-Edwards Perimount valve, which has a native orifice diameter of 23mm. It was felt that a 22mm Melody valve (Medtronic, Minneapolis, MN, USA – outer diameter 24mm and lowest profile of available transcatheter valves) would provide an adequate orifice for this adult female patient. The valve was delivered using standard techniques with concomitant right ventricular pacing **(Figure 3)**. The tricuspid valve was a 31 Carpentier-Edwards Perimount valve with a native orifice diameter of 28.5mm. It was felt that a 29mm Sapien S3 transcatheter valve (Edwards Lifesciences, Irvine, CA, USA) was the best alternative for valve-in-valve tricuspid valve replacement. A non-trans-tricuspid lead for ventricular pacing was indicated for rapid pacing during deployment of the relatively short Sapien valve, and to ensure stable temporary pacing if the permanent transvenous pacemaker lead function was disrupted. We, therefore, utilized temporary coronary guidewire pacing.[10] A 0.014" coronary wire was advanced slightly into the lumen of the left main coronary artery through a 5 French left coronary guide catheter. Pacing was performed by attaching the generator to the guidewire and to a subcutaneous needle. The Sapien S3 valve delivery was performed over the same guidewire utilized for Melody placement **(Figure 4)**. A waist remained in the valve stent after inflation with nominal balloon volume using the Edwards Commander delivery system. Post-dilation was, therefore, performed with a 26mm ultra high-pressure balloon with elimination of the waist (with apparent fracture of the surgical valve ring) at 16 atm. The entrapped transvenous pacemaker lead continued to function normally. Both valves were in excellent position with excellent function by transesophageal echocardiography. There was only trivial central tricuspid insufficiency.

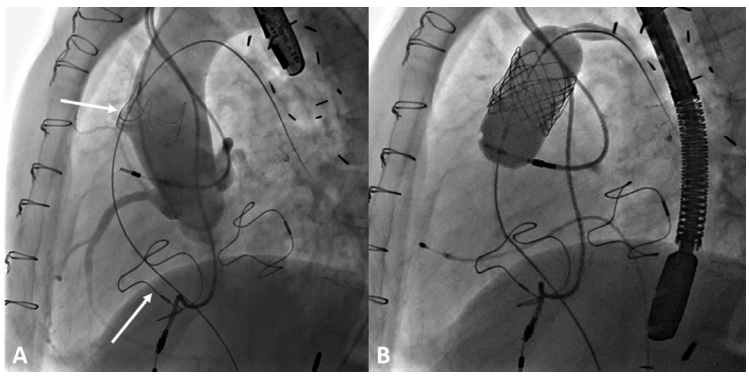

FIGURE 3 Transcatheter Pulmonary Valve Replacement
***A)** An aortogram demonstrates that the coronary arteries are indeed well away from the prosthetic pulmonary (cephalad white arrow) and tricuspid (caudal white arrow) valves. **B)** Valve-in-valve transcatheter pulmonary valve replacement from the transfemoral approach.*

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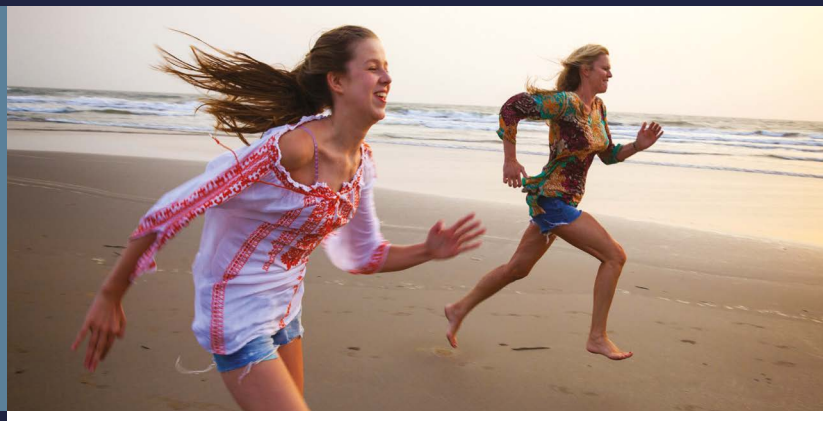

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- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.
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- 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. 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.

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- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
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*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.

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

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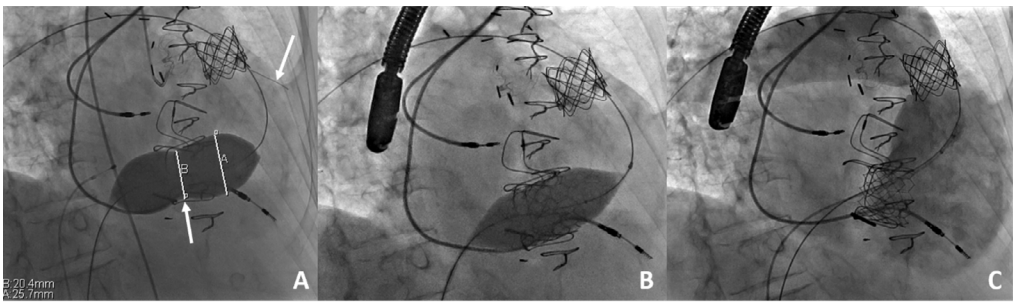

FIGURE 4 Transcatheter Tricuspid Valve Replacement
A) *Following pulmonary valve replacement, balloon sizing of the tricuspid bioprosthetic demonstrated a landing zone measuring 20.4mm at its narrowest portion (caudal white arrow). Pacing for intervention was performed via a coronary wire in the proximal left main coronary artery (cephalad white arrow).* ***B)*** *Valve-in-valve transcatheter tricuspid valve replacement from the transfemoral approach.* ***C)*** *Right ventriculogram in the anteroposterior view following dual-transcatheter valve replacement. Both valves were found to be well-positioned by angiography and functioning well by transesophageal echocardiogram.*

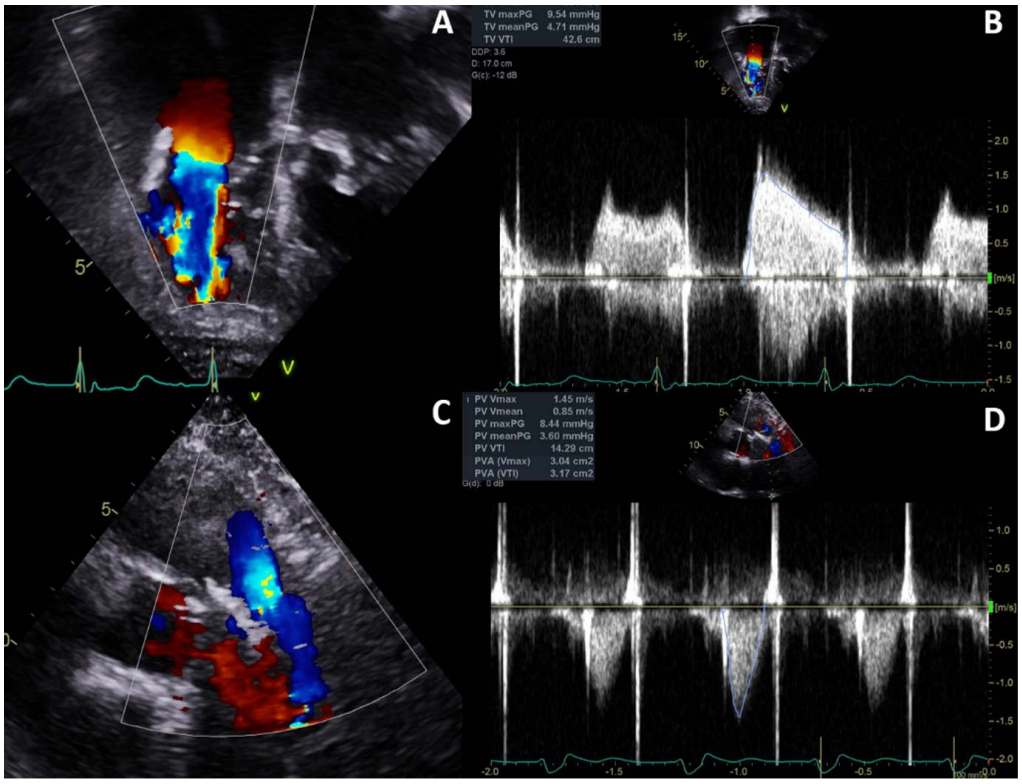

FIGURE 5 Post-intervention Outpatient Echocardiogram
A&B) *On outpatient follow up six months post-procedure, the patient reported no clinical symptomatology and transthoracic echocardiography demonstrated a mean gradient of 4.7mmHg across the tricuspid valve without any insufficiency.* ***C&D)*** *The pulmonary valve demonstrated no significant stenosis nor insufficiency.*

The patient had considerable improvement in clinical status with improved exercise tolerance and ability to perform all activities of daily living without marked fatigue (NYHA Class 1). Six months post-procedure, the outpatient echocardiogram demonstrated a mean gradient of 4.7mmHg across the tricuspid valve, with no evidence of insufficiency and no significant stenosis nor insufficiency of the pulmonary valve **(Figure 5).** Her dual chamber pacemaker continued to function well, without significant change in ventricular lead parameters.

Discussion

Carcinoid-associated cardiac valve disease can be particularly difficult to manage for multiple reasons. Circulating vasoactive substances may lead to abnormalities on multiple valves - primarily on the right side of the heart, but also on the left side if there is a pathway which bypasses the inactivating mechanisms of the liver and lung. Even after surgical replacement of affected valves, bioprostheses remain at risk for eventual deterioration, and the incidence of complete heart block is high.[11,12] Our demonstration of the feasibility of replacement of two valves in a single procedure using transcatheter techniques may offer new hope for better long-term function and survival in some patients. Especially because additional valve-in-valve replacements may be necessary in this population, it is essential to have a full understanding of the available transcatheter valve characteristics. The ideal valve has the lowest profile so that the valve orifice is reduced by the minimal possible amount with each added valve. The valve however, must be designed to expand to a large enough diameter to fit within the target surgical valve ring. "Cracking" of the surgical valve ring with ultra-high-pressure balloons has been accomplished in some patients to allow for placement of slightly larger than anticipated transcatheter valves.[13,14] The limits of expansion that can be achieved with different surgical valves, and differences in these limits for valves in different positions are still under investigation. Transvenous pacer leads are at risk for becoming nonfunctional when trapped between the surgical valve frame and a transcatheter valve stent during tricuspid valve-in-valve replacement. Alternative pacing techniques, such as coronary guidewire pacing, may enhance the safety of these procedures in pacemaker-dependent patients.

Our report uniquely represents an example of two transcatheter valve technologies working in concert to provide percutaneous transfemoral valve replacement of the pulmonary and tricuspid valves (within the same procedure) for carcinoid-dependent bioprosthetic failure. For the pulmonary position, the Medtronic Melody system was utilized for its superior lumen-to-prosthesis sizing ratio within the nominally 25mm prosthetic valve housing. For the Tricuspid position, the larger, nominally 31mm, prosthetic valve housing supported the Edwards Sapien system. Long-term outcomes comparing the currently available transcatheter valve systems remain unreported at this time. Mid-term results from transcatheter therapies in the tricuspid and pulmonary position(s) have been outlined in the literature.[8,9] However, direct comparison of different technologies to understand their truly long-term benefits and/or disadvantages remains an area of active investigation.

Conclusion

The technology and techniques for transcatheter valve replacement continue to progress at a rapid pace. The inherent advantages to percutaneous therapies are especially relevant to populations known to be at high risk for repeated valve replacements, such as those with carcinoid-related valve disease. As transcatheter technologies continue to advance, we must aim to alter our approach to provide the safest experience for our patients – not only considering the index procedure but possible future encounters as well. We demonstrate the feasibility of performing double right-sided transcatheter valve-in-valve replacement in the same procedure in a patient at high risk for requiring additional valve interventions over time. For these types of cases, careful, individualized pre-procedural planning should include analysis of the actual surgical and transcatheter valve dimensions, valve landing zone characteristics, and considerations of the methods to deal with possible procedure-induced malfunction of an essential transvenous pacemaker lead. A wider understanding of this transcatheter option may allow intervention in some high-risk patients sooner in their expected course of functional deterioration.

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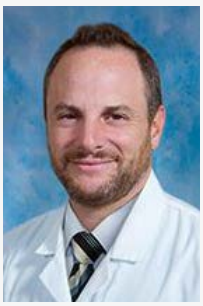

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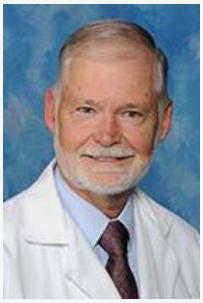

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Open-Heart Surgery, Without the Open-Heart Part

FDA Approves Harmony Transcatheter Pulmonary Valve

The U.S. Food and Drug Administration (FDA) today approved a first-of-its-kind heart valve that does something extraordinary. It takes the "open-heart" part out of certain open-heart surgeries. 20-year-old Jack Hurley couldn't be happier.

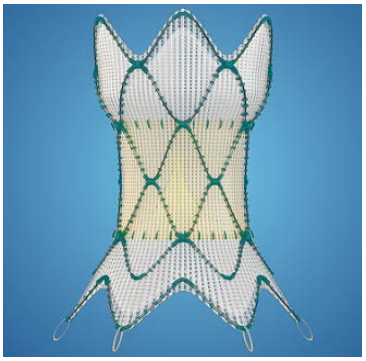
"One of the best things about the Harmony valve was not what it did for me, but for what I didn't have to do, like spend lots of time in the hospital with a long recovery time," he said.

"We are always looking for less invasive ways to treat our pediatric patients, and this new device will allow us to avoid open-heart surgery in many cases," said Matthew J. Gillespie, MD, attending interventional cardiologist, Director of the Cardiac Catheterization Laboratory, Co-Director of the Pediatric Valve Center at Children's Hospital of Philadelphia, and an investigator in the Harmony Pivotal Trial. Dr. Gillespie implanted Jack's Harmony valve. "For most patients, we are setting them up for a healthier life associated with their Congenital Heart Disease."

Jack's 20th birthday. With sisters Clare (left) and Nora (right).

The **Medtronic Harmony™ Transcatheter Pulmonary Valve (TPV)** is the first pulmonary heart valve in the world to be approved for patients with a specific type of congenital heart disease without requiring open-heart surgery. Rather than cut open a patient's chest to repair the heart, surgeons implant Harmony TPV through a much less invasive approach. They load the valve onto a catheter, make a small incision in the femoral vein or neck and deliver the valve directly inside the heart. Jack went home the next day and felt like he was back to normal within a week.

Jack was among an estimated 40,000 babies born every year in the US with congenital heart disease (CHD).[1] Jack's pulmonary heart valve, which allows blood to leave the heart and get oxygen from the lungs, didn't work properly. Surgeons repaired it when Jack was just three months old. But his family always knew the fix was temporary. The time would come, probably in Jack's late teens or 20's, that he would need open-heart surgery again.



Medtronic Harmony™ Transcatheter Pulmonary Valve (TPV)

"The idea that he needed another open-heart surgery at 18 years old was just devastating to me," said Jack's mom, Colleen. "It was such a relief for us to have a minimally-invasive option. And to see him back to living a normal life so quickly. It's just amazing."

Babies like Jack, born with chronic heart disease, face the possibility of multiple open-heart surgeries over the course of their lives. It can take patients weeks to recover from open-heart surgery, and each subsequent surgical procedure carries more risk than the previous one. An estimated 1.6 million adults currently live with CHD.[2] Thousands of them may now benefit from Harmony TPV.

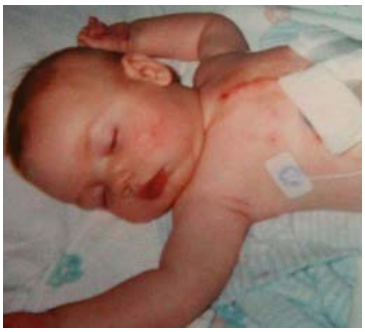
"It's our Mission to bring life-improving therapies to as many people as possible," said Nina Goodheart, president of the Structural Heart & Aortic operating unit at Medtronic. "Harmony does exactly that. Procedures are shorter and far less traumatic for patients. They spend less time in the hospital and recover faster. It's very gratifying for us to be able to provide this option to CHD patients and their families."

"Being able to offer this therapy will increase the options available to patients and families and decrease the amount of time patients spend in the hospital and in recovery," added Dr. Gillespie.

Harmony is among several Medtronic devices that received the FDA's Breakthrough Device Designation, a unique federal effort intended to speed up the approval process of certain life-saving technologies. Harmony is the third Medtronic device to receive the designation and then receive FDA approval.

"The strong collaboration among physicians, Medtronic and the FDA, from the earliest study phase all the way to approval, helped bring Harmony TPV to patients much faster than it might have otherwise," Goodheart said.

Jack and his family are grateful. He's active in sports, working part-time as a landscaper, and studying engineering in school.



Jack as a baby, after open-heart surgery

"Life is the best it could be for me right now," he said. "Whatever I do, I want to help people. I've been on the receiving end. I know how that feels. It would be great to be on the giving end someday."

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More Than 50,000 Children Screened for Congenital Heart Defects Using AI-Enabled Stethoscopes

Intelligent stethoscope with integrated ECG saved more than 36 lives and there are plans to expand screenings to 500,000 children worldwide

In recognition of World Congenital Heart Defects (CHD) Awareness Week, HD Medical Inc. announced it has screened over 50,000 children for CHDs using HD Steth, an ECG and artificial intelligence (AI)-enabled stethoscope, **https://hdmedicalgroup.com/shop/hd-steth/**. These screenings have been conducted at multiple locations in India, helping to save more than 36 lives to date. HD Medical, **https://hdmedicalgroup.com/**, said it plans to expand the screenings to over 500,000 children worldwide.

The children diagnosed with CHD were provided life-saving treatments and surgeries by the Sri Sathya Sai Sanjeevani Hospitals, **https://srisathyasaisanjeevani.org/**, in India.

CHDs are the most common types of birth defects. One out of 100 babies are born with CHD worldwide and nearly 40,000 infants in the U.S. are born each year with CHDs. In India, each year approximately 300,000 children are born with CHD and approximately 25% die before their first birthday. The absence of early screening and sophisticated pediatric care is causing over 250 deaths among children every day in India. Conventional stethoscopes used for screening have resulted in 28% false positives and 51% false negatives when used by non-specialists and health workers. While the ultrasound echocardiogram is a more accurate alternative, high equipment cost and low availability of trained medical professionals have limited its usage.

HD Medical's US FDA-cleared HD Steth addresses this problem, providing a cost-effective, easy-to-use solution for non-specialists and primary healthcare workers. HD Steth was tested and validated through a clinical study involving 1,200 children, with 91% sensitivity and 99% specificity for detecting heart murmurs caused by CHDs compared to ultrasound echocardiograms as a gold standard at the Sri Sathya Sai Sanjeevani Hospital at Raipur, Chhattisgarh State in Central India.

Based on this study, HD Steth was adopted in a large CHD screening program at their group hospitals and medical screening programs at multiple locations in India as follows:

- Sai Sanjeevani Hospital at Palwal, Haryana: 12,974
- Sai Sanjeevani Hospital at Kharghar, Maharashtra: 8,020
- Sai Sanjeevani Hospital at Raipur, Chhattisgarh: 2,000
- Sai Sanjeevani - Niraamaya Bastar initiative: 1,000
- Sai Sarla Memorial Hospital, Chickaballapur, Karnataka: 19,650
- Sai Arogya Vahini Trust Mobile Medical Clinics, Kolkata, West Bengal: 8,450
- Total number of Children Screened: 52,094
- Total number of Children Screened and Confirmed with CHDs: 90+
- Total number of Children Saved with Heart Surgeries: 36+

The Sri Sathya Sai Sanjeevani hospitals in Maharashtra, Chhattisgarh and Haryana are India's largest providers of totally free pediatric heart procedures, performing nearly 14,000 surgeries and catheter interventions

since 2012. "The centers stand committed to the investment in child health initiatives for a healthier nation in the future by offering quality healthcare provided totally free of cost," said C. Sreenivas, Chairman of Sai Sanjeevani hospitals, **https://srisathyasaisanjeevani.org/about-us/**. "The HD Steth device from HD Medical is very helpful for screening children with CHD at an early stage so that a timely surgical intervention can be possible to save their lives. We have recently signed an MOU between the Chhattisgarh State Government and HD Medical to screen 77,000 children in Bastar, a remote tribal region. HD Steth makes it possible for healthcare workers to screen children for CHD and refer them for follow-up care at our hospitals."

"HD Steth is very easy to use by non-specialists with minimal training requirements for cardiac auscultation and as a screening tool. We started a program to screen over 100,000 children in Chickaballapur District in Karnataka State during October 2020 and so far have screened close to 20,000 children despite COVID-19" said Satish Babu, MD, a leading endocrinologist trained at Cambridge University Hospital, King's College Hospital and Cardiff University Hospital in UK and currently practicing at Sri Sathya Sai Sarla Memorial Hospital, Muddenahalli near Bengaluru, Karnataka.

"We have also expanded the HD Steth screening program to countries such as Fiji, Sri Lanka, Nigeria, Malaysia, and the US," said Arvind Thiagarajan, founder and CEO of HD Medical. "These screenings will target 500,000 children within a year, demonstrating HD Medical's commitment to the cause of saving children through early CHD screening with better technology."

HD Medical Inc. is a Silicon Valley-based innovator of digital health solutions for AI-enabled detection and management of cardiovascular disease (CVD). HD Steth has been awarded FDA clearance (K201299).

For more information: **www.hdmedicalgroup.com**

Dr. Dipti Itchhaporia is New American College of Cardiology President

Itchhaporia looks to further digital transformation and health equity in cardiology during one-year term

Dipti Itchhaporia, MD, FACC, today begins her term as President of the American College of Cardiology. During her one-year presidency, she will lead the over 54,000-member global organization in its mission to transform cardiovascular care and improve heart health.

"From the moment I became a Fellow of the ACC, I've been excited about being a part of this community and contributing to advancing the field of cardiology and the patients we serve," Itchhaporia said. "I'm looking forward to connecting the cardiovascular community over the next year, as we emerge from a mostly virtual world, to make strides in our strategic priorities and improve the lives of heart disease patients. We must be prepared as a profession to embrace and move to center stage our solutions and vision of digital transformation and health equity."

Itchhaporia is an interventional cardiologist who is the Eric and Sheila Samson Endowed Chair in Cardiovascular Health, Director of Disease Management for Hoag's Jeffrey M. Carlton Heart and Vascular Institute in Newport Beach, California, and Associate Professor of Medicine at the University of California, Irvine. She has been a leader in the College for over 20 years, previously holding positions both nationally and in the ACC California Chapter.

Most recently, Itchhaporia held the position of ACC Vice President. She previously served as a member of the ACC's Board of Trustees and the Board of Governors, Secretary of the ACC as Chair of the Board of Governors, and President of the ACC California Chapter. She has also served on multiple ACC committees and helped to advance the College's education, science and innovation efforts, including as a member of the ACC Lifelong Learning Oversight Committee, Science and Quality Committee, Governance Committee, Practice Administrator Workgroup and as an advisor for the ACC's Innovation Program.

Itchhaporia's professional interests include quality measurement and improvement in cardiovascular disease, focusing on emerging risk factors and medical and lifestyle interventions to prevent coronary heart disease. She is also extensively involved in advancing technology and innovations that will advance the digital transformation of cardiovascular medicine to ultimately improve the lives of patients and clinicians, while helping to achieve health equity.

Itchhaporia's professional passions have led to leadership roles in advancing the ACC's strategic priorities, including serving as Chair of the ACC Board of Trustees Health Equity Task Force, which addresses issues of health disparities, the social determinants of health and improving access to care for underserved patients. Further work toward health equity will be at the forefront of her presidential year.

"Health equity has been a priority for the College for a long time and for the first time we are feeling like this could be actualized," Itchhaporia said. "In cardiology we need to have the mindset to prioritize health equity issues, and I'm excited that this is in our reach."

She received her medical degree from St. Louis University School of Medicine and completed her residency in internal medicine at Stanford University Medical Center. She then joined the general medicine faculty at the University of California, San Francisco (UCSF), ultimately pursuing a cardiology fellowship at Georgetown University and an interventional cardiology fellowship at Stanford University.

Other ACC officers for 2021-2022 are Vice President Edward T. A. Fry, MD, FACC; Board of Governors Chair Joseph Marine, MD, FACC; and Treasurer Christopher M. Kramer, MD, FACC.

ACC Launches NCDR EP Device Implant Registry

Formerly the ICD Registry, the new name reflects expanded offerings and aligns with other quality programs

Effective immediately, the American College of Cardiology is offering the EP Device Implant Registry, which will include data on ICD and CRT-D procedures previously captured in the NCDR ICD Registry as well as provide the flexibility to capture novel pacemaker procedures. The registry is aligned with the ACC's Electrophysiology Accreditation program, fully supporting the program's data requirements.

AMERICAN COLLEGE of CARDIOLOGY

"The expanded scope of the EP Device Implant Registry will allow hospitals to track new and existing procedures, giving them the ability to optimize patient care and outcomes," said NCDR Management Board Chair Frederick A. Masoudi, MD, MSPH, FACC. "The registry is well-positioned to support continuous quality assessment and improvement in the growing EP procedure service line."

In addition, the EP Device Implant Registry now allows participants to capture data on shared decision-making, a compliance requirement for the CMS National Coverage Determination for ICD/CRT-D primary prevention device implants.

Since its inception in 2005, the ICD Registry has been the national standard for understanding patient selection, care and outcomes in patients receiving ICD therapy. The new EP Device Implant Registry will continue to empower the patient care team in their decision making by providing nationally benchmarked data on patient care and outcomes for broader range of devices. Over 800 U.S. based hospitals currently participate in the EP Device Implant Registry. For a complete list of participating facilities, visit Find Your Heart a Home, **https://www.cardiosmart.org/find-your-heart-a-home**.

NCDR is the ACC's suite of cardiovascular data registries helping hospitals and private practices measure and improve the quality of the care they provide. The EP Device Implant Registry is one of 10 NCDR hospital and outpatient registries.

For more information about the EP Device Implant Registry, visit **ACC.org/EPDeviceRegistry**.

'Heart in a Box' Expands Transplant Opportunities

The Smidt Heart Institute, Home of the Nation's No. 1 Adult Heart Transplant Program, Uses Transmedics Organ Care System (OCS) to Grow Geographic Area of Service, Enabling More Lifesaving Organ Transplants

Dominic Emerson, MD, and Pedro Catarino, MD, both transplant surgeons with the Smidt Heart Institute, know how to be spontaneous. At any given moment, they can get the call that a donor heart or lungs are available, requiring them to quickly board a private aircraft to procure the vital organs.

Until recently, those flights were quick jaunts lasting no more than four hours-the time a donor heart can survive on ice. Now that is all changing, thanks to a medical device called the OCS Heart, or "Heart in a Box," which enables transplant surgeons to travel to much farther destinations to procure lifesaving organs by acting as a miniature intensive care unit that keeps the heart alive.

"Cedars-Sinai has the biggest adult heart transplant program in the world and takes on some of the most complex surgical cases," said Emerson, Associate Surgical Director of Heart Transplant and Mechanical Circulatory Support and Surgical Co-Director of the Cardiac Surgery Intensive Care Unit at Cedars-Sinai. "The Heart in a Box technology is helping break down a major barrier of transplantation, ultimately offering many patients a second chance at life."

How it Works

The OCS Heart is the only such device currently under review with the Food and Drug Administration and is being used as part of a clinical trial at Cedars-Sinai. Fardad Esmailian, MD, surgical director of heart transplant and mechanical circulatory support at Cedars-Sinai, says the device has already gained approval in Europe and Australia and has been tested in the U.S. for more than five years.

"Cedars-Sinai was one of the largest enrolling clinical trial sites for the Organ Care System's Proceed II clinical trial and remains active in enrolling patients in its current EXPAND and DCD clinical trials," said Esmailian, who has served as principal investigator for all the trials. "We are eager to continue witnessing the improved access this system has brought to our patients."

Once a donor heart is removed from the body, instead of being placed on ice in a cooler, the heart is connected to a portable device that keeps it at a human-like, metabolically active state--allowing transplant surgeons to travel farther distances to retrieve donor hearts.

"Our hope is to increase the transplantation rate by about 20% or 30% using this kind of a device," said Joanna Chikwe, MD, the Irina and George Schaeffer Distinguished Chair in Cardiac Surgery in honor of Alfredo Trento, MD, Professor and Chair of the Department of Cardiac Surgery in the Smidt Heart Institute. "In doing so, our institute can heal the hearts of even more patients who otherwise have nowhere to turn."

A Heart and Lungs Travel from Hawaii

Recently, Emerson and Catarino flew to Hawaii-a state with limited heart transplant availability-to procure a heart and lungs from a donor. The heart spent more than seven hours outside of a human body being oxygenated and maintained in a beating state with the OCS Heart device.

"We spent the long flight home monitoring and caring for the heart," said Catarino, a recognized leader in the field of heart and lung transplantation and aortic surgery. "The whole travel team was eager to land, knowing two lives would be saved that very night."

Once the surgeons, heart and lungs arrived at Cedars-Sinai, Emerson headed straight into surgery to perform the heart transplant. His colleague, Dominick Megna, MD, Surgical Director of the Lung Transplant Program, performed the lung transplant.

Donald Stivers, 74, who had been battling ischemic cardiomyopathy, received the heart as part of an ongoing clinical trial evaluating the system as a way to use hearts that would otherwise not be available.

"There are so many mixed emotions, but I am so fortunate-the joy is truly overwhelming," said Stivers, who lives in Three Rivers, California, and who is eager to resume his once-active lifestyle of hiking in the mountains surrounding his home.

Stivers opted into the OCS Heart clinical trial because of his age and height of 6 feet, 4 inches-two qualifiers that could make it extremely difficult to find a donor match.

"I was told I had six to 12 months left to live if a heart didn't become available," recalled Stivers.

But when he and his wife got the call late one night in early March, his feelings of desperation turned to hope, knowing he could now be given more moments in the mountains and time spent with his children, grandchildren and great-grandchildren.

"There is hope out there," said Stivers. "And I found mine through this donor and the team at Cedars-Sinai."

For Emerson and his fellow transplant surgeons, Stivers' journey makes the long flights, middle-of-the-night surgeries and often-complex cases more than worthwhile.

"Our jobs are predictably unpredictable," said Emerson. "At the same time, it's extremely rewarding. At the end of the day, people like Don are so desperately sick, yet you can give them high-quality, memory-building time back to enjoy life."

JUNE

04-09

ATC 2021 American Transplant Congress
Virtual
https://www.atcmeeting.org/

JULY

16-17

CITI 2021
14th Annual Conference: A Case Based Workshop
Chicago, IL, USA
https://cictsymposium.com/

17-18

8th Congress of the Asia-Pacific Pediatric Cardiac Society
Taipei, Taiwan
http://www.appcs2020.org/

AUGUST

27-28

ESC Congress 2021 – The Digital Experience
Virtual
https://www.escardio.org/Congresses-&-Events/ESC-Congress

30-31

Frist Annual PICS Fellows & Early Career Course
Las Vegas, NV, USA
Kimberly_ray@chdinterventions.org

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