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Reactive Ductus Arteriosus in a Nineteen Month Old Patient

By Maria C. Yates, MD; Nischal K. Gautam, MD; P. Syamasundar Rao, MD

Introduction

A hemodynamically significant Patent Ductus Arteriosus (PDA) may be seen in up to 8 per 1000 live births of preterm infants.[1] Increased survival of preterm infants has resulted in the need for transcatheter closure for PDA, reviewed elsewhere.[2-7] Ductal spasm during cardiac catheterization and angiographic study may lead to inappropriate device selection and the potential for device embolization and procedure failure. Here we present a case of a reactive ductus in a 19-month-old female which resulted in device embolization.

Case Report

A 19 month old female was referred to us for consideration of transcatheter occlusion of PDA. She was born prematurely at approximately 32 weeks of gestation. She was discharged home from the Neonatal Intensive Care Unit (NICU) at 2 months of age. She was followed by her primary pediatric cardiologist with a diagnosis of a moderate-sized PDA with left-to-right shunt. Parents reported no cardiac symptomatology and she was on no cardiac medications. At a routine follow-up visit with her primary pediatric cardiologist at 17 months of age, she was found to have mild left atrial and left ventricular enlargement on echocardiogram resulting in referral for transcatheter occlusion. Our evaluation revealed: a grade III/VI continuous machinery murmur typical for PDA; no signs of heart failure, mild enlargement of left atrium and left ventricle; and a moderate-sized ductus (Figure 1A & B) on echocardiographic study. We agreed with primary cardiologist's diagnosis of PDA and the recommendation for transcatheter occlusion.

At age 19 months, cardiac catheterization and selective cineangiography were performed with intent to transcatheter occlude the ductus. On the morning of the procedure, a grade III/VI continuous murmur of PDA was heard on auscultation. The parents informed us that the patient may have a latex allergy. Therefore, diphenhydramine 10 mg (1.2mg/kg) was administered intravenously immediately prior to the procedure. Other medications used during the general endotracheal anesthesia included: fentanyl, and rocuronium, and inhaled sevoflurane. Right and left heart catheterization was performed percutaneously, hemodynamic data recorded and an aortic arch cineangiogram was obtained. Hemodynamic data revealed right heart pressures at the upper limits of normal and a significant left to right shunt with a Qp:Qs of 1.5:1 (Table). However, angiography revealed a very small ductus, measuring less than 1mm in diameter (Figure 2). Based on the angiographic appearance, a 5-mm loop, 6-cm long Gianturco coil was selected for occlusion of the PDA. The coil was deployed across the PDA in a manner described in our previous publications.[3,7-9] However, the coil embolized into a small distal branch of the left pulmonary artery, requiring

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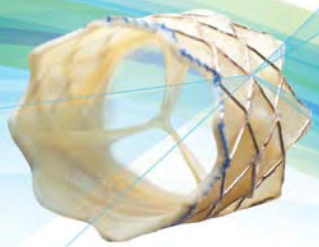

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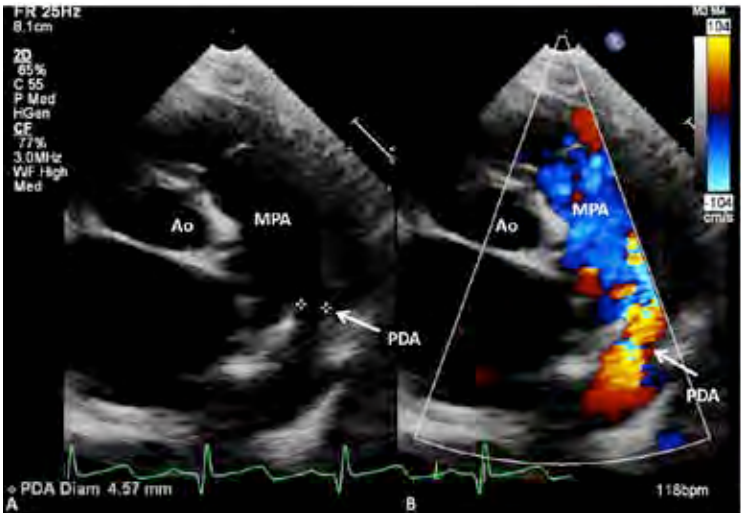

Figure 1. Selected video frames from precordial short axis views demonstrating a patent ductus arteriosus (PDA); 2D measurement of the minimal ductal diameter (A) with left to right shunt by color Doppler (B) are shown. AO, aorta; MPA, main pulmonary artery.

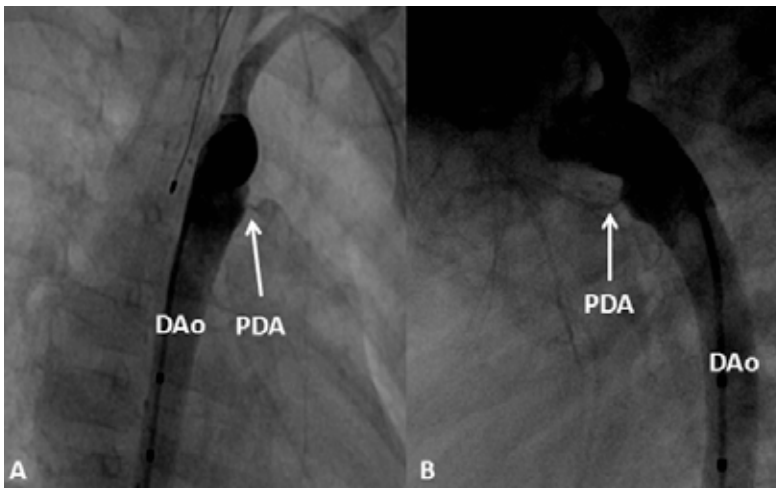

Figure 2. Selected aortic arch cineangiographic frames in right anterior oblique (A) and straight lateral (B) views demonstrating an extremely small (arrows in A and B) patent ductus arteriosus (PDA). DAo, descending aorta.

Table. Hemodynamic Data (All data were obtained while the patient was on room air)

Site	Prior to Ductal Occlusion		After Ductal Occlusion	
	Pressures mmHg	O_2 Saturation (%)	Pressures mmHg	O_2 Saturation (%)
Superior Vena Cava		72		
Right Atrium	m = 6	72	m = 5	
Right Ventricle	30/7	72	29/6	76
Main Pulmonary Artery	29/19, m=24	86	29/11, m = 20	76
Right Pulmonary Artery	25/13, m=17	78		
Left Pulmonary Artery	25/13, m=17	82		
Left Ventricle	90/6	96		
Ascending Aorta	90/55, m=75	96	88/50, m = 70	96
Descending Aorta	90/55, m=75	96	87/50, m = 70	
m = mean; O_2, = oxygen				

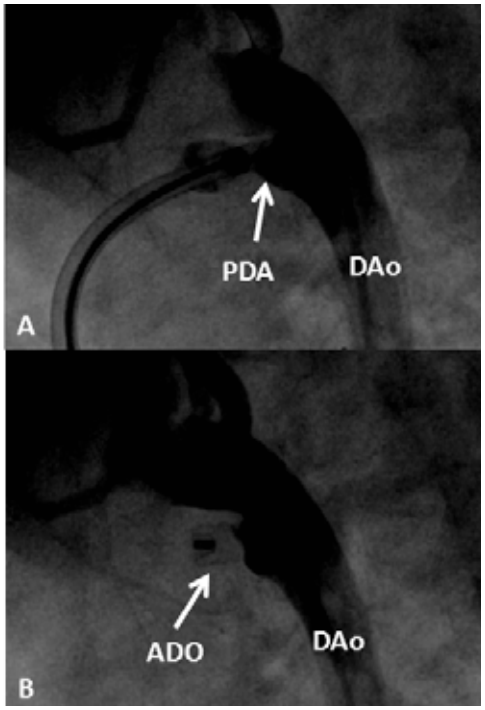

Figure 3. Selected aortic arch cineangiographic frames in straight lateral view demonstrating a moderate-sized patent ductus arteriosus (PDA) in A prior to occlusion of the PDA and complete closure without residual shunt (B) following Amplatzer Duct Occluder (ADO) device closure. DAo, descending aorta.

transcatheter retrieval. The PDA was then successfully closed with a 6/4 Amplatzer Duct Occluder (Figure 3A & B). Post device implantation angiography (Figure 3B) and O_2 saturation data (Table) revealed no residual shunt. Echocardiography the next morning revealed no residual shunting across the ductus arteriosus (Figure 4).

Discussion

Here we present a case of a hemodynamically significant ductus arteriosus based on echocardiographic findings (Figure 1) and oxygen saturation data (Table) which, on angiography, was a very narrow ductus (Figure 2). The ampulla, however, was of good size. The data are indicative of intra-procedural ductal spasm, although the ductus was not crossed prior to angiography. However, inadvertent stimulation of ductus while catheterizing right and left branch pulmonary arteries cannot be excluded. Because of the extremely small size of the ductus, we elected to use a Gianturco coil for occlusion of PDA, which spontaneously dislodged, requiring transcatheter retrieval. Subsequently, successful occlusion with an Amplatzer Duct Occluder was performed (Figures 3 & 4). It is not clear whether the ductal constriction that spontaneously occurred was secondary to inadvertent catheter stimulation or related to drugs administered immediately prior to or during the procedure.

Literature Review and Potential Causes

Prior reports suggesting reactive ducti with spasm of the ductal musculature have invoked: relative calmness (reopened by excitement),[10] ductal constriction in a formerly premature infant,[11] kinking of the ductus in upright position,[12] and former prematurity[13,14] as contributory factors. Presence of a large proximal shunt[15] has also been suggested as a reason for non-opacification of a ductus on angiography. Prematurity appears to be the predominant associated abnormality in the vast majority of the cases reported thus far,[10,11,13,14] including the present case.

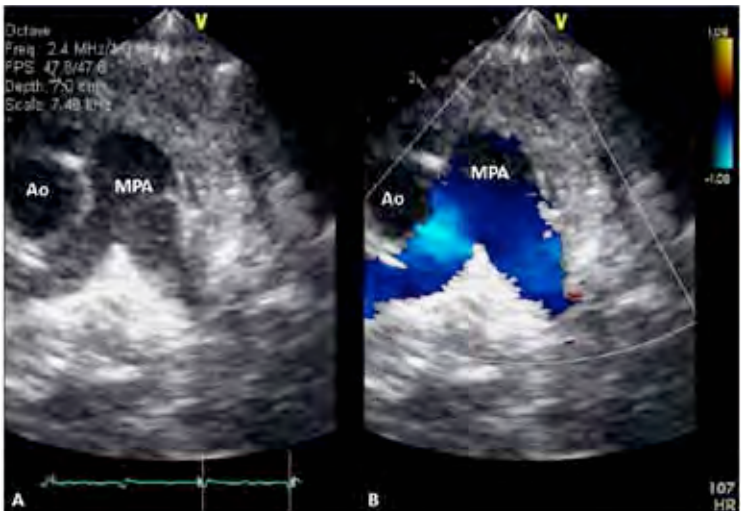

Figure 4. Selected video frames from precordial short axis views of an echocardiogram performed on the day following ductal closure demonstrating no residual shunt. AO, aorta; MPA, main pulmonary artery.

Prematurity. Normal postnatal closure of the ductus arteriosus occurs in two phases: functional and anatomical closure.[1,16-18] Functional closure typically occurs within hours of birth in full-term infants, and is characterized in part by cellular migration of the medial smooth muscle within the ductus, which results in the intima protruding into the lumen of the ductus. Anatomic closure is completed within 2-3 weeks and consists of necrosis of the ductal tissue and connective tissue formation to form the ligamentum arteriosum.[1,16-19] Disruption of this process can be caused by prematurity, lung disease, sepsis, hypoxia, or other stress-induced factors. In the premature infant the effect of the factors that lead to ductal occlusion may be blunted.[20,21] The mechanism by which such altered ductal muscle constriction takes place may be related to persistence of biochemical profiles of fetal ductal smooth muscle cells in the premature infant[21,22] and of vaosmotion.[23,24] However, it is not established that such abnormalities persist into late infancy. The ductal reactivity demonstrated in our case, as well those of Shapiro,[10] DuBrow,[11] Lozier[13] and Batlivala[14] and their colleagues, would indicate the presence of ductal muscular reactivity way beyond the neonatal period, into late and even past infancy.

Drugs and pharmacologic agents producing ductal constriction. The ductus is known to be reactive in response to multiple medications, including prostaglandins, oxygen, catecholamines, bradykinin, acetylcholine and other kinins.[25] Nonsteroidal anti-inflammatory drugs such as indomethacin and ibuprofen have been administered for both prophylactic and therapeutic management of PDA; however, these are effective after 14 days of life. Cotton and colleagues showed that cimetidine, a selective H2 blocker, had vasoactive properties on the ductus arteriosus.[26] Their studies indicated that histamine may have both vasodilatory and vasoconstrictive effects upon the ductus arteriosus; however, in their study the patients were receiving long-term cimetidine,

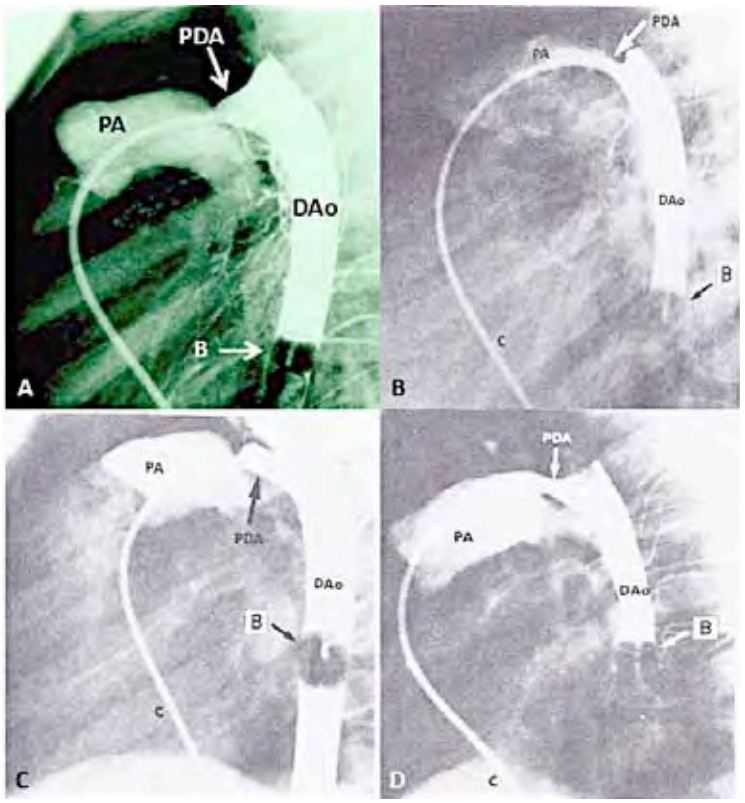

Figure 5. Balloon (B) occlusion aortography demonstrates good opacification of patent ductus arteriosus (PDA) in four different patients. C, catheter; DAo, descending aorta; PA, pulmonary artery.

but more importantly, the observation in their study was ductal patency, not ductal constriction. The proposed mechanism for the observed association between cimetidine and PDA in preterm infants is via a cytochrome P450 (CYP) mechanism. Multiple CYPs were expressed within the ductus arteriosus; however, the study was limited to specimens from mice. Diphenhydramine is metabolized via CYP pathways, but it is unknown if this mechanism would be involved in ductal vasoreactivity or if a single intravenous dose of diphenhydramine in the setting of general anesthesia would have any significant vasoactive effect. We were unable to identify any cases in the literature reporting ductal constriction secondary to diphenhydramine.

Prevalence

The prevalence of clinically identified reactive ductus appears low. This is the only case the senior author has witnessed among nearly 330 consecutive cases of transcatheter closure of PDAs (50 button device closures,[27,28] 80 published[29] and unpublished Gianturco coil occlusions and 200 published[30] and unpublished Amplatzer Duct Occluder device deployments) that the senior author was involved with, giving a prevalence of 0.3%. However, Batlivala and his associates[14] found seven cases out of 331, giving a prevalence of 2.1%, much greater than that seen in our experience. The true incidence is probably somewhere in

between these two figures. However, there are no data on what percentage of formerly premature babies will have reactive PDAs.

Therapeutic Implications

Medium- and large-sized PDAs are closed to prevent further volume overloading of the left heart and to treat congestive heart failure and small PDAs are closed for eliminating the risk of bacterial endocarditis. Successful ligation of PDA was first performed by Gross and Hubbard in 1939.[31] Since that time, surgery was the mainstay in the management of PDA until transcatheter methods were developed. The first transcatheter method was developed by Porstman and his associates in 1967;[32,33] this is followed by that described by Rashkind and his collegues.[34,35] A number of other devices have since been designed and tried in animal models followed by use in human subjects; and these were reviewed elsewhere.[2-7]

At the present time, Gianturco coils, Amplatzer Duct Occluder I and II, Gianturco-Grifka Vascular Occlusion Device and Duct-Occlud pfm are the only devices approved by FDA for transcatheter occlusion; of these, Gianturco coils and Amplatzer Duct Occluder-I are most commonly used. The criteria for section of the type and size of the device are based on minimal ductal diameter and shape of the ductus.[6,7] Both these require assessment of PDA on angiography. The case presented in this report and the previous publications by DuBrow,[11] Lozier[13] and Batlivala[14] and their associates suggest that ductal constriction may occur in infants who were premature and the embolization of the device may occur with consequent failure of the procedure. This is largely related to misjudgment of the size of the ductus. Several suggestions to avoid the problem will be offered:

1. If the patient is formerly a premature infant, the potential for development of ductal constriction should be kept in mind during the process of transcatheter closure of PDA.
2. Because the ductus is known to constrict by increased arterial oxygen tension, supplemental oxygen should be avoided until after aortic arch cineangiography is performed.
3. A catheter positioned in the ductal ampulla via an anterogradely positioned catheter (Figure 3A) or balloon occlusion aortography[35] as illustrated in Figure 5, may help complete opacification of the ductus.

We suggest that in the event a patient requires intraprocedural diphenhydramine for latex sensitivity or other allergy, extreme care should be taken to evaluate physical findings and echocardiographic data in the assessment of the degree of left to right shunting. However, it seems most likely that the ductal spasm observed in our case occurred as a result of the procedure itself and the patient's former prematurity. In such cases it may be prudent to obtain angiography prior to any hemodynamic measurements in an attempt to minimize any chance of ductal spasm.

Summary and Conclusions

We present a 19-month-old infant who developed spontaneous ductal constriction which resulted in selection of Gianturco coil for occluding the ductus which embolized. Immediately thereafter successful occlusion of the PDA with an Amplatzer device was undertaken. Extensive review of the literature resulted in identification of only a few cases of reactive ductus beyond the neonatal period. Prevalence of ductal constriction is very low (less than 2%) and it would appear that the reactive ductus causing ductal constriction is related to the patient's premature birth. Preservation of fetal ductal muscular characteristics may be responsible for this problem. When transcatheter occlusion of PDA is planned in a formerly premature infant, appropriate precaution should be undertaken to avoid inappropriate selection of closure device and its size to prevent embolization.

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"When transcatheter occlusion of PDA is planned in a formerly premature infant, appropriate precaution should be undertaken to avoid inappropriate selection of closure device and its size to prevent embolization."

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Life Cycle of a Pediatric Cardiovascular Device: The Nit-Occlud® PDA Coil Enters Clinical Practice in the United States

By John W. Moore, MD

Figure 1. Nit-Occlud® by pfm medical.

The Premier Issue of *Congenital Cardiology Today* (CCT) reported that the Nit-Occlud Device had entered an FDA clinical trial with the goal to achieve FDA Clearance to market the device for closure of Patent Ductus Arteriosus (PDA).[1] The Issue "hit the street" during the *PICS Symposium* in September 2003. The CCT report predicted that FDA clearance would be achieved, perhaps as early as in 2006. The prediction was correct, but the timing was much too optimistic. FDA Clearance was finally granted to to market the Nit-Occlud® Coil Device was finally granted in August, 2013.[2]

Per its FDA labeling, the Nit-Occlud® PDA Coil is indicated for occlusion of small to moderate PDA (minimum angiographic diameter less than 4 mm) in pediatric patients. In addition, there are certain exclusions such as patients with pulmonary hypertension.

The Nit-Occlud® PDA Coil became available for unrestricted use in the United States early in 2014. The coil can be obtained through BBraun Interventional Systems, Inc. (Bethlehem, PA), its United States Distributor. At the present time, some centers such as The Kaiser Permanente Medical Center in Los Angeles are implanting it frequently. This Center is participating in the Coil's FDA Post-Approval Study. Other centers are just becoming aware of the Coil's availability and advantages.

The Nit-Occlud® is manufactured in Cologne, Germany by pfm medical. As illustrated in Figure 1, it is a nitinol coil with a tight cone/reverse cone configuration and numerous coil loops. The six available sizes accommodate most PDA encountered in practice. Occlusion is achieved by blockage of flow, distortion of the PDA, and ultimately by device and PDA thrombosis. The device is typically implanted from a venous approach using the 4 or 5 French end-hole catheter provided as part of the delivery system. It has a controlled release mechanism that allows the operator to accurately position the coil with all but one of the coil loops on the aortic side of the PDA's narrowest portion. It also allows the operator to remove and reposition it if required.

JACC Interventions reported the combined results of the FDA Pivotal and Continuing Access Studies late in 2014.[3] Three hundred-fifty-seven patients were enrolled in the studies. Fifteen centers participated and patients were enrolled in the study until late in 2007. Four centers (Mattel Children's Hospital at UCLA, Children's Hospital of Central California, Nationwide Children's Hospital, and Advocate Children's Hospital) each enrolled more than fifty patients. Ninety-seven percent of the patients had an audible PDA murmur. The median patient age was about 3 years and median weight was about 14 kilograms (smallest 4.7 kilograms). Angiographic evaluations demonstrated that median minimum PDA diameter was 1.9 mm with largest minimum diameter of 3.9 mm. Seventy-five percent of the patients were classified as Krichenko Type A (conical), 14% were Type E (elongated) and 5% were Type D (complex), 5% were Type B (short) and only 1% were Type C (tubular). Three hundred-forty-seven (97.2%) had successful device implantation as in Figure 2. Among these

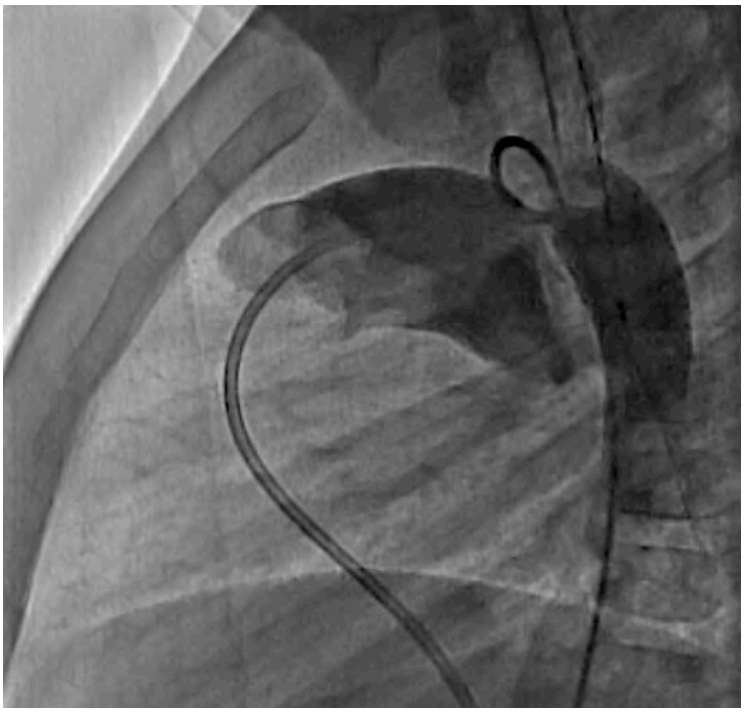

Figure 2A. "PDA with minimum diameter 2.8 mm.

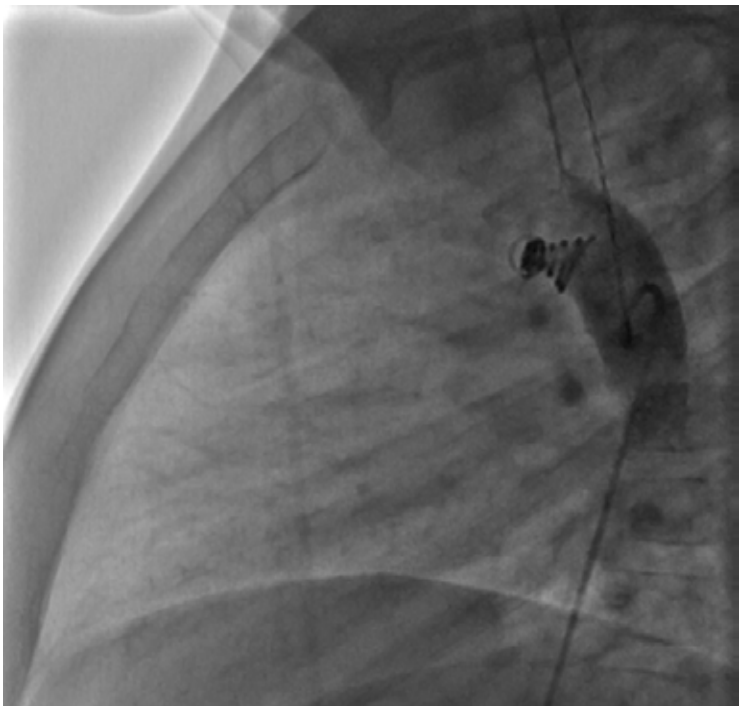

Figure 2B. PDA closed status post implant of 9 x 6 Nit-Occlud® Coil.

patients, 308 had echocardiograms a mean of 14.3 months after implantation. Two hundred-ninety-nine had complete closure by Color Flow Doppler evaluations (96.8%).

The studies' safety outcomes were also noteworthy. (As in other cardiovascular device studies, the FDA required that adverse events (AE) be tracked beginning from the implant procedure until the last clinical follow-up.) There were no mortalities and no Serious AEs (life-threatening, requiring surgery, prolonging hospitalization, resulting in permanent injury or disability) noted up to a mean of 14 months follow-up. There were 9 device related AEs, the most significant of which were three device embolizations, each of which was retrieved in the catheterization laboratory. There were also 6 procedure related AEs, none of which were consequential. The total AE rate was 4.7% up to 14 months post-implant.

The Efficacy and Safety outcomes summarized above were comfortably within the "Performance Criteria" metrics adapted by the FDA for these studies. These Criteria had been set forth in 2000 by a Multi-Organizational Advisory Panel to the FDA and were derived from historical data and expert consensus related to coil and device closures of PDA.[4] Notably, the procedural outcomes and safety data from the Nit-Occlud® Studies are also quite competitive with current practice data as set forth in the IMPACT and other contemporary Registries.[5]

Finally, from the perspective of a practicing congenital interventional cardiologist, I personally find the Nit-Occlud® PDA Coil to be an excellent option for occlusion of most incidences of PDA. I especially like the small catheter delivery system (rather than sheath) and the excellent control system, which provides the capability to position the device optimally, and also, the ability to reposition it if necessary.

I am also very confident that occlusion procedures will be successful, and thus feel comfortable offering this device to patients and families.

About the Author

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CHOC Children's in Affiliation with UCI School of Medicine Hosts the 3rd Biennial Sports Cardiology & Sudden Cardiac Arrest in the Young Conference – January 23rd-24th, 2015, Anaheim, California

By Anjan S. Batra, MD, FHRS; Mary Hickcox, CME Program Coordinator

On January 23rd-24th, 2015 CHOC Children's hosted the *3rd Biennial Sports Cardiology & Sudden Cardiac Arrest in the Young Conference* at Disney's Grand Californian Hotel & Resort in Anaheim, CA.

More than 152 participants and faculty from all over the United States: Alaska, Arizona, Alabama, California, Colorado, Florida, Georgia, Iowa, Illinois, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, North Carolina, Nevada, New York, Ohio, Oregon, South Carolina, Texas, Utah and West Virginia attended. Additionally, an international presence was represented from Australia, Canada and Puerto Rico.

In affiliation with UC Irvine, Dr. Anjan S. Batra, Medical Director of Electrophysiology, CHOC Children's, Division Chief and Vice Chair of Pediatrics, UC Irvine School of Medicine, was the program chair and along with Linda Glenn, DNP(c), MN, RNC-NIC, NE-BC, Director of Planning and Business Development for the Heart, Cancer and Neonatal Service Lines, CHOC Children's hosted this conference.

Dr. Michael Ackerman, Professor of Medicine, Pediatrics, and Pharmacology at the Mayo Clinic College of Medicine, Director of the Long QT Syndrome/Inherited Arrhythmia Clinic and the Sudden Death Genomics Laboratory at the Mayo Clinic, was keynote speaker and participated in several salient discussions, as well as moderated one session during the conference.

Expert Conference Faculty (Back, Left-to-Right): S. Berger, MD; M. Silka, MD; J. Perry, MD; C. Davis, MD; M. Cohen, MD; K. Shannon, MD, M. Ackerman, C. Erickson, MD; A. Chang, MD. (Front, Left-to-Right): J. Moore, MD; I. Law, MD; A. Batra, MD; J. Salerno, MD; T. Saarel, MD, and, C. Koutures, MD.

PACES

Of special note, the Pediatric & Congenital Electrophysiology Society (PACES), a nonprofit organization, endorsed, advertised and hosted a special committee who attended this conference. PACES www.pediatricepsociety.org) is an international group of physicians and allied professionals dedicated to improving the care of children and young adults with cardiac rhythm disturbances. The group's primary mission is to foster high-quality collaborative research and exchange of ideas on arrhythmia topics that are particularly relevant to infants and children, or patients of any age with congenital heart disease. An ad hoc committee, chaired by Ian Law, MD, Clinical Professor of Pediatrics, Director of Clinical Cardiology, Division of Pediatric Cardiology, Director, Pediatric Electrophysiology, University of Iowa Children's Hospital, University of Iowa Carver College of Medicine, met several times during the conference to review guidelines and submit a proposal for a national registry of young children and athletes with sudden cardiac death.

Day 1, Session 1

Day 1 of the conference began on Friday, January 23rd, 2015. This educational conference was divided into nine topic sessions, starting off with "Interpretation of the ECG in the Young Athlete." Conference participants heard Michael Silka, MD, present on "New ECG Criteria for the Young Athlete – The New Normal." Ronald Kanter, MD, discussed the "Impact of New ECG Criteria on Screening." Program Chair, Anjan S. Batra, MD, FHRS finished Session I with "Findings You Don't Want to Miss on Routine ECGs." The audience had time to ask questions and listen to the panel discuss their practice experience in this area. As a result, participants were able to evaluate the Seattle Criteria for interpretation of EKGs in athletes and determine when to use the Seattle Criteria in the evaluation of athletes in their own practice.

Panelists from Session 5

Front, Left-to-Right: Drs. Ackerman, Shannon, Batra and Chang

Session 3 Debate Panelists

Session 2

Session 2 discussed "Genetic Testing and the Risks of Sudden Cardiac Arrest." The conference Keynote Speaker, Michael Ackerman, MD, PhD, FAAC, discussed the "Role of Genetic Testing in the Evaluation of a Patient with Possible Channelopathy." "Management of the Genotype Positive, Phenotype Negative Patient" was a cased-based presentation presented by Kevin Shannon, MD. Dr. Batra presented "Channelopathies, Exercise and Sudden Cardiac Death." Lastly, Anthony Chang, MD, MBA, MPH, discussed "Current Limitations and Future Potential of Genomics in Predicting Sudden Cardiac Arrest in the Young." Outcomes of this session gave participants the data to consider incorporating genetic testing into their practice; how to interpret and use genetic testing results to better manage an athlete's sports participation; and, when results indicate, test family members to prevent Sudden Cardiac Death.

Session 3

In the afternoon, Session 3 was a series of three debates on "Risk Stratification of Sudden Cardiac Arrest." The first debate, Ronald Kanter, MD, (protagonist) and Mitchell I. Cohen, MD, FACC, FHRS, (antagonist) presented their viewpoints regarding "Asymptomatic Patients with WPW: They Deserve a Non-invasive Workup for Risk Stratification and Should be Allowed to Play Competitive Sports." The second debate was on "Asymptomatic Patients with HCM: They Deserve a Non-invasive Workup for Risk Stratification and Should be Allowed to Play Low-Moderate Intensity Level Sports" with Shubhayan Sanatani, MD, FRCPC, (protagonist) and Stuart Berger, MD, (antagonist). Finishing Session 3, Kevin Shannon, MD, (protagonist) and Ian Law, MD, (antagonist) debated "A Patient With an ICD Should be Allowed to Play Competitive Sports." A panel discussion with audience questions followed. The debates allowed the audience to review the evidence on hypertrophic cardiomyopathy and risk stratification, with a specific focus on sports participation. Additionally, they were able to evaluate the pros/cons of sports participation for a patient with an ICD.

Session 4

Shubhayan Sanatani, MD, FRCPC, presented in Session 4: "Catecholaminergic Polymorphic Ventricular Tachycardia: Persistent Challenges and New Insights." Conference attendees were able to glean insights from Dr. Sanatani's experience and apply to their practice.

Session 5

Session 5 ended the first day of the conference with a panel discussion:

The Disney Grand Californian Hotel: Sequoia Ballroom

"What Steps Need to be Taken to Prevent SCA in the Young Athlete?" Ian Law, MD, moderated the session. The goal of this session was for conference attendees to apply insights gained from review of cases presented to improve the prevention, diagnosis and treatment of patients in their practice. Panelists for this session were: Michael Ackerman, MD, PhD. FAAC; Christopher C. Erickson, MD; Jack Salerno, MD; and, Tess V. Saarel, MD.

PACES Task Force for Prevention of Sudden Death in the Young

Prior to the start of the second day, the "PACES Task Force for Prevention of Sudden Death in the Young" met for the first time during the Conference at breakfast. Those attending were: Santiago Valdes, MD, Shu Sanatani, MD, Steve Fishberger, MD, Ron Kanter, MD, Lynn Batten, MD, Tony McCanta, MD, Ernesto Rivera, MD, Monica Goble, MD, Kathie Parks, MD, Alice Lara, MD, Jim Christiansen, MD, Richard Lamphier, MD, Mike Ackerman, MD, Mitchell Cohen, MD, Ian Law, MD, Jim Perry, MD, Stu Berger, MD, Salim Idriss, MD, AJ Batra, MD, Tess Saarel, MD, Jack Salerno, MD, and Chris Erickson, MD.

Highlights from this inaugural Task Force identified gaps in literature on SCD and ways to develop studies to fill those gaps. It was agreed the focus of this task force needs to look at ways to detect the potential for sudden cardiac arrest in all children and young adults. Additionally, the statements/opinions from the Task Force need to reach primary care providers and athletic trainers. Recommendations from chairs Jack Salerno, MD and Chris Erickson, MD were: (1) The Task Force proceed with a position paper identifying issues or problems with identifying those at risk for SCA; and, (2) The Task Force needs to be an advocate in several key areas of SCA prevention including CPR/AED training.

Conference Details – Day 2

Day 2 of the Conference, Saturday, January 24th, 2015, was opened with a moving keynote address from Michael Ackerman, MD, PhD, FAAC, on "State of the Molecular Autopsy Following Sudden Cardiac Death." This presentation gave the audience the patient's family perspective on the importance of a molecular autopsy for sudden cardiac death patients and the healing closure it can bring.

Session 6

Session 6: "Distinguishing Normal from Pathologic Cardiovascular Changes" enabled participants to identify normal athletic heart versus physiologic hypotrophy and describe when there is a cause for concern. Mitchell I. Cohen, MD, FACC, FHRS, covered "Pathologic vs. Physciologic Hypertrophy." Kevin Shannon, MD, presented "The Dilated Aorta - Is There a Risk?" Jeremy Moore, MD, reviewed "ECGs, Cardiac Enzymes and MRI Findings in Endurance Athletes." Stuart Berger, MD, discussed "Congenital Coronary Anomalies: Major Player or Mere Spectator?"

Session 7

Just before lunch, Session 7 introduced the expanded theme of this year's conference by addressing "Sports Cardiology in Young Athletes." From the presentations in this session, participants were able to develop strategies for counseling patients, who are starting a fitness program, returning to sports and/or have CHD, on exercise recommendations appropriate to their fitness level. Dan Cooper, MD, presented his "Research in Sports and Exercise Cardiology: Challenges, Opportunities, Future Directions." Michael Silka, MD, examined "Physiologic Responses to Training in Children and Adolescents." Just before lunch, James Perry, MD, gave "Exercise Recommendations for the Patient with CHD."

Session 8

In the afternoon, Session 8 focused on "Basic Exercise Physiology and Sports Cardiology." This session described: the cardio pulmonary exercise test and, how to interpret results; the use of exercise testing to determine patients at risk for SCA; how to tell the difference between a patient with heart disease, lung disease or one who is de-conditioned; and how to diagnose and manage a patient with heat stroke. Dan Cooper, MD, began this session with "Basic Exercise Physiology and CPET." Christopher Davis, MD, PhD, reviewed "New Approaches to Using Exercise as Therapy or as Biomarker." Lastly, Chris Koutures, MD, FAAP, discussed "Heat Stroke: When it is and When it is Not."

Session 9

Closing the conference, Session 9 presented - "'Real World' Cases in Sports Cardiology." Michael Silka, MD, and Kevin Shannon, MD, were the moderators for the panel discussion. The audience was able to apply insights gained through the discussion of complex sports cardiology cases to improve the diagnosis and treatment of patients in their practice.

Save the Date!

This *3rd Biennial Conference* was adjourned with plans to return to Disney's Grand Californian Hotel in Anaheim, CA, at the end of January, 2017. Updated information will be posted: www.choc.org/scaconference.

In partnership with CHOC Children's, Miami Children's will host in alternate years, a symposium on Sudden Cardiac Arrest. The venue is Miami Marriott Biscayne Bay and scheduled dates are February 19th-20th, 2016. More details to follow.

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Medical News, Products & Information

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Heart Surgery Outcomes for Pediatric / Congenital Patients Online

Newswise – Continuing its commitment to increase public awareness and understanding of cardiothoracic surgical outcomes, The Society of Thoracic Surgeons (STS) has released the first publicly accessible national report of surgical outcomes from its Congenital Heart Surgery Database (CHSD). The CHSD is a component of the world-renowned STS National Database, which is widely considered the gold standard for a medical specialty clinical outcomes database. Public reporting results are available at www.sts.org/publicreporting.

"The public reporting of these results represents something entirely new, in that this is the first time ever that pediatric and congenital heart surgery outcomes in the United States have been made available to the public on a national level," said Jeffrey P. Jacobs, MD, Chair of the STS Public Reporting Task Force and Professor of Surgery at The Johns Hopkins University. "STS has always been a strong advocate of transparency within the specialty. We believe that our patients and their families have the right to know the outcomes of cardiothoracic surgery procedures so that they can make well-informed decisions."

The CHSD is the largest database in North America focused exclusively on pediatric and congenital cardiac malformations; more than 95% of hospitals in the United States that perform pediatric heart surgery submit surgical data.

For the first round of STS Public Reporting Online from the CHSD, 25 sites (22.7%) participated, which closely resembles the level of participation in the first round of public reporting from the STS Adult Cardiac Surgery Database (ACSD) that began 5 years ago. ACSD participation is now at 42.7% (453 sites).

For the CHSD participants who volunteered to publicly report, STS released 4-year observed, expected, and risk-adjusted center-level operative mortality rates for the aggregate of all patients, as well as for patients stratified on the basis of the five STAT Mortality Categories (surgical procedures grouped by complexity). Outcomes have been risk-adjusted to take into account procedural complexity and individual patient factors such as age, weight, non-cardiac abnormalities (including chromosomal abnormalities), previous surgeries, preoperative co-morbidities, and other medical conditions that could affect results.

"Reporting hospital surgical outcomes using risk-adjusted analysis is extremely important because it allows for a fair assessment, on a level playing field, of outcomes across hospitals that treat different populations of patients," said Marshall L. Jacobs, MD, Chair of the STS CHSD Task Force. "As pediatric and congenital cardiac surgeons, we perform operations on patients born with a wide variety of heart defects of varying complexity, and many patients have additional risk factors. Adjusting for these risk factors allows us to better understand reported mortality rates, especially for centers that operate on the most challenging patients."

Unlike ACSD public reporting, which includes a star-ratings system to report hospital outcomes, star ratings are not currently reported for the CHSD. Star ratings, based on a hospital's overall risk-adjusted observed-to-expected operative mortality ratio, will be added to the summer 2015 release.

"Public access to outcomes data for adult heart surgery and now pediatric and congenital heart surgery is at an unprecedented level and will continue to increase," said Dr. Jeffrey Jacobs. "Next year, we plan to add public reporting for STS General Thoracic Surgery Database participants, starting with outcomes for lobectomy in cancer patients."

To access the CHSD outcomes directly, visit www.sts.org/congenital-public-reporting-module-search.

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 6,900 cardiothoracic surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The Society's mission is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

Launched in late 2010, the STS Public Reporting initiative started with Adult Cardiac Surgery Database participants voluntarily reporting to the public their heart bypass surgery performance. Since that time, ACSD reporting has evolved to include coronary artery bypass grafting (CABG) surgery, aortic valve replacement (AVR), and AVR with CABG. Public reporting from the Congenital Heart Surgery Database was added in 2015, and the General Thoracic Database will begin in early 2016.

The STS National Database was established in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. There are three components to the STS National Database, each focusing on a different area of cardiothoracic surgery—Adult Cardiac, General Thoracic, and Congenital Heart Surgery, with the availability of Anesthesiology participation within the Adult Cardiac Surgery Database and the Congenital Heart Surgery Database.

The Adult Cardiac Surgery Database now contains more than 5.5 million cardiac surgery procedure records and currently has more than 3,300 participating physicians, including surgeons and anesthesiologists representing more than 90% of all adult cardiac surgery centers across the U.S. Launched in 2002, the Congenital Heart Surgery Database contains more than 330,000 congenital heart surgery procedure records and currently has more than 740 participating physicians, including surgeons and anesthesiologists.

Many People with Congenital Heart Disease Living Longer

Newswise — At one time, many children born with Congenital Heart Disease (CHD) suffered from issues that carried fatal prognoses. Thanks to technological advancements in the past 30 to 40 years, Dr. Elizabeth Adams of Penn State Hershey Children's Heart Group can predict that a child born today has a 90% chance of living to adulthood, even with severe CHD.

"Most children with CHD are now living to adulthood and historically that has not been the case," she says.

The Adult Congenital Heart Association (ACHA) now reports that there are an estimated 2 million adults living with CHD in the U.S., meaning that, for the first time ever, there are more adults than children with CHD.

Affecting about 1% of the population, CHD is a genetic condition and is present from birth.

"Most of what we're talking about are structural problems with the way the heart is formed – hearts that are missing chambers, hearts that have narrow or leaky valves, or structures that are not in the right place," Adams says.

CHD is usually detected prenatally via ultrasound during pregnancy followed by a cardiac ultrasound to confirm and identify a problem. Occasionally children are not diagnosed until after birth and most of those cases are identified within the first year of life. In some less serious cases, patients are not diagnosed until much later in life.

"Some conditions will produce symptoms very early on while others may not produce symptoms until well into adulthood," she says.

If a baby is not diagnosed prenatally, there are a number of warning signs suggestive of CHD. He or she may not feed properly, may have poor weight gain, may be pale or blue, and in more severe cases, could suffer cardiac collapse.

"At about a week of life, infants with some of the most severe types of Congenital Heart Disease may get very sick, very quickly," Adams says.

Early detection is possible today due to sophisticated ultrasound capabilities that are now commonly used and allow doctors to find the majority of the cases prenatally.

Less invasive procedures have also been developed that can spare patients open heart surgery.

"For example, if a baby is born today with a narrow pulmonary valve, that child will probably not need surgery," Adams said.

The child would undergo a cardiac catheter procedure where a balloon is inserted into the valve to open it without an operation. In some cases, adult valve replacement or repairing small holes can be done via catheter as well.

"Instead of a week in the hospital, it's one night plus a week of recovery time instead of a couple of months," Adams said.

The incidence of CHD is increasing slightly, probably related to better detection, and in some cases, genetic transmission of cases from parent to child.

Dr. Adams personally takes care of a half dozen parent-child combinations with heart defects.

Researchers are currently trying to understand the ways in which congenital heart defects are transmitted and why some are more likely to be passed on to offspring than others.

App Developed by Nationwide Aims to Help Make Homes Safer

Newswise — Nationwide Children's Hospital is joining Nationwide – one of the largest and strongest diversified insurance and financial services organizations in the U.S. – in their effort to prevent childhood injury. According to the Centers for Disease Control and Prevention (CDC), and many injuries occur in and around the home. Through this new Make Safe Happen initiative, Nationwide Children's researchers developed a new Make Safe Happen app to help prevent childhood injury. The app, now available for free on both iOS and Android, aims to help parents make their home safer. Parents can learn as they go with customized room-to-room safety checklists and links to safety products for the home.

"I have been an injury researcher for more than a decade, but it wasn't until I was pregnant with triplets that I realized the need to make safety easier for busy parents," said Dr. Lara McKenzie, a principal investigator with Nationwide Children's Hospital's Center for Injury Research and Policy (CIRP). "We created something that I needed as a mom, and that would give parents and caregivers the tools they needed to make their home safer for their family. You can create shopping lists, set reminders and track your progress towards making your home as safe as possible for your family. And you can do all of this on your smartphone."

Since the 1930s, Nationwide has played an active role in supporting this issue, including their engagement with CIRP, founded by Dr. Gary Smith, an internationally-recognized pediatrician and author of more than 150 child injury-related articles in peer-reviewed journals. Contributions made by the Nationwide Foundation to Nationwide Children's have supported important child safety research, and most recently the development of the Make Safe Happen app.

"Nationwide has always been committed to protecting what matters most to our members, and for parents, there's nothing more important than the safety of their children," said Matt Jauchius, Nationwide's CMO. "This is an issue we've been passionate about as a company for more than 60 years. We're dedicated to devoting resources to help prevent these tragedies from taking place through our new Make Safe Happen program."

"We are grateful to Nationwide for their long-standing support of our mission to conduct innovative research and make discoveries that will prevent injuries in children," said Dr. Smith, pediatrician and founder and director of CIRP. "We commend Nationwide for bringing the important issue of child injury to the forefront through Make Safe Happen and are grateful for the support of Nationwide and the Nationwide Foundation in bringing the Make Safe Happen app to life as an empowering tool for parents everywhere."

The Nationwide Foundation is an independent corporation funded by contributions from Nationwide companies. For more information on child home safety visit: MakeSafeHappen.com.

Landmark Study Asks, Are All Defibrillators Created Equal?

Newswise - The Valley Hospital was selected as the United States Coordinating Center for the PRAETORIAN Trial, an international trial designed to compare for the first time the traditional implantable cardioverter-defibrillator (ICD) with a newer model that

may reduce the risk of complications associated with these otherwise life-saving devices.

Although ICDs have been used for decades to safeguard patients deemed at high risk for sudden death due to a heart rhythm disorder (arrhythmia), the traditional model relies on a transvenous electrode or lead placed in the heart. A major drawback of these ICDs has been the lead, which can break, become infected, or injure the heart and surrounding blood vessels. The alternative is a newer form of ICD, called a subcutaneous or S-ICD that is implanted entirely under the skin without entering the heart or blood vessels. Valley was one of the first hospitals in New Jersey and one of only three hospitals in the tri-state area to have early experience with the S-ICD.

“Both types of ICDs have been shown to reduce the risk of sudden death,” says Suneet Mittal, MD, Director of Electrophysiology and the Principal Investigator at Valley for the Praetorian Trial. “The S-ICD, because it does not involve a lead within the heart, may significantly reduce the likelihood of lead-related complications. This trial is the first attempt to compare the two types of ICDs in a randomized trial.”

In the PRAETORIAN trial, which originated at the Academic Medical Center in Amsterdam, the Netherlands, patients are randomly selected to receive either a traditional ICD or an S-ICD. Mark W. Preminger, MD, Director, Implantable Arrhythmia Devices at Valley, enrolled the first patients in the United States into the study earlier this month.

“The S-ICD® is the world’s only subcutaneous ICD, and it represents a major step forward in the evolution of defibrillator technology,” Dr. Mittal says. “We are delighted to offer this advanced breakthrough in arrhythmia treatment to our Valley Hospital patients, and proud to be a leading participant in this important international trial.”

For more information please visit www.clinicaltrials.gov.

17-Month-Old Girl From Hawaii Receives New Heart Surgery

Newswise – San Diego – In the second pediatric heart transplant in Rady Children’s history, a team of surgeons successfully implanted a heart in 17-month-old Jahazie Faualo from Oahu, Hawaii on Jan. 31st, 2015. The surgery occurred less than three weeks after the Hospital’s first-ever heart transplant on Jan. 14th, in which 11-year-old San Diego resident Eric Montano, who suffered from a condition called restrictive cardiomyopathy, received a new heart. Both operations involved transporting the donor heart to Rady Children’s from another state and then, moments after the new heart arrived, removing the patient’s failing heart and replacing it with a healthy donor heart. Jahaziel suffered from a condition called dilated cardiomyopathy, a disease in which the heart becomes weakened and enlarged and cannot pump blood efficiently.

Rady Children’s cardiac transplant surgeon and surgical director Dr. Eric Devaney led the transplant surgery. He traveled by plane to the donor hospital to retrieve the heart, carefully transported it back to Rady Children’s, and then immediately joined cardiac transplant surgeon Dr. John Lamberti in the operating room. The surgeons then

removed Jahaziel's failing heart and sutured the new donor heart into place.

"I've performed many heart transplants over the years, but it's still a miraculous thing," said Dr. Devaney. "When you first provide blood flow to the new heart, and you see it start to beat, it's incredible."

Transplant cardiologist and Medical Director Dr. Rakesh Singh monitored Jahaziel before the surgery and will be responsible for overseeing her post-operative care.

"It takes a village to perform heart transplantation. There are at least 50 people behind the scenes that help make this possible," said Dr. Singh. "It's also important to think about the donor family and the sacrifice they had to make during a very difficult moment. It's because of their sacrifice that this actually occurred."

"When we got the call, it was scary and exciting at the same time," said Jahaziel's father, Mac Faualo. "Eventuallywe knew she would get a new heart; we just didn't expect it to be this soon."
"When we got the call at about 12:30 in the morning, I was asleep, but soon I was wide awake and crying tears of joy. I couldn't believe it was happening," said Jahaziel's mother, Jamey Sua. "We were so excited we couldn't sleep the rest of the night."

Recovering from a heart transplant typically requires a hospital stay of two weeks. Although heart transplant patients must remain on various medications for the rest of their lives, most are able to lead normal lives, return to school full time and participate in activities they were unable to do before transplantation.

3D Printing Makes Heart Surgery Safer for Children

Newswise — Three-dimensional printing technology can make surgery safer for children with Congenital Heart Disease (CHD) and reduce the duration as well as the number of invasive procedures required. Richard Kim, MD, a cardiac surgeon at Children's Hospital Los Angeles, recently used a 3D printed heart as a model to plan a life-saving procedure for his young patient, Esther Perez. The child was born with a rare, life-threatening cardiac defect.

Esther had a ventricular septal defect, a fairly common congenital anomaly. However, her particular defect was unusual and would require complex surgery to repair it. Her intra-cardiac anatomy required complex re-routing of the blood supply, a procedure only performed at a handful of other pediatric hospitals nationwide.

Typically, surgeons are not able to determine their approach until they open the chest, put the child on a heart bypass machine, survey the problem and then, make a quick decision on how to proceed with repair. Since the variation in normal anatomy is increased in hearts with congenital abnormalities, an exact replica – a three dimensional roadmap -- allows surgeons to strategize before entering the operating room.

"Instead of opening the chest and making a decision about how to proceed, I could immediately begin fixing the problem," said Kim, who is also an assistant professor at the Keck School of Medicine of the University of Southern California. "A 3D model allowed me to plan the surgery in advance, which meant Esther spent less time in surgery and received less anesthesia – making the procedure safer."

Three-dimensional printing technology can create an object of any shape by printing layer upon layer, employing plastics or other materials in place of ink, explained Jon Detterich, MD, a pediatric cardiologist who specializes in noninvasive cardiac imaging. He gathered both 2D and 3D MRI scans then translated the information into a format that could be read by a 3D printer. "As useful as scans are for visualizing structural defects, there's nothing like holding a life-sized, three-dimensional replica in your hands," said Detterich, who is also an Assistant Professor at the Keck School of Medicine of USC.

"So far, only a small number of 3D models have been used for heart surgery, so it's too soon to tell if they improve surgical outcomes," said Frank Ing, MD, Chief of Cardiology and co-director of the Heart Institute at CHLA. "But our experience suggests that using models saves time in the OR – which means increased safety and decreased costs." Ing is also a Professor at the Keck School of Medicine of USC.

Also, this knowledge will likely translate into a need for fewer surgeries, and allow children – like Esther Perez – to spend less time recuperating in intensive care. Esther, who would have required multiple surgeries during the first years of her life, made a rapid recovery and is expected to look forward to a life free of medical complications. For more information, visit CHLA.org.

Long-Term Use of VAD Induces Heart Muscle Regeneration

Newswise – Prolonged use of a Left Ventricular Assist Device (LVAD) by patients with heart failure may induce regeneration of heart muscle by preventing oxidative damage to a cell-regulator mechanism, UT Southwestern Medical Center investigators have found. This paper appeared online in the *Journal of the American College of Cardiology.*

LVADs are mechanical pumps that are sometimes implanted in patients who are awaiting heart transplants. LVADs substitute for the damaged heart by pumping blood throughout the body.

Dr. Hesham Sadek, Assistant Professor of Internal Medicine at UT Southwestern, is senior author of the study, which looked at pre- and post-LVAD samples of heart muscle in 10 patients with heart failure. The study authors examined the paired tissue samples for markers of DNA damage and cell proliferation.

Their study builds on earlier work with mice that demonstrated that newborn mammalian hearts are capable of a strong, regenerative response to injury by activating cell division. The earlier studies further showed that the ability to respond to injury is lost due to changes in circulation that occur after birth, which lead to a more oxygenated environment in the heart, ultimately causing oxidative damage to the cellular machinery that controls heart-muscle regeneration.

In the current study, the investigators reasoned that, by assisting the damaged heart, LVADs would alleviate oxidative damage that occurs within the heart-muscle cells.

“We looked at markers of what is called the DNA damage response in cardiomyocytes (heart-muscle cells) of these patients,” said Dr. Sadek. “The response is composed of a cascade of proteins that is activated in response to DNA damage and in turn shuts off the ability of cardiomyocytes to divide. We found that patients who were on LVAD for more than six months had significantly decreased levels of DNA damage response.”

Next, the investigators examined the paired tissue samples for markers of cell division. They found that patients who were on LVADs for six months or longer had a significant increase in cardiomyocyte proliferation. The increase in cell proliferation was nearly triple, in fact.

“This result shows that patients with mechanical assist devices have the ability to make their muscle cells divide,” said Dr. Sadek. “And the obvious question now is, ‘Are these hearts regenerating? Could LVADs be used as a cure for heart failure?’ ”

Heart failure is a debilitating and deadly disease in which the heart, as a result of injury, cannot pump blood efficiently and hence cannot provide sufficient oxygen to organs throughout the body. About 6 million people in the United States are living with heart failure, according to the American Heart Association, and the incidence is expected to soar over the next 20 years as the population ages and as heart-attack treatments improve and more people survive heart attacks.

Dr. Pradeep Mammen, Associate Professor of Internal Medicine at UT Southwestern, is co-senior author of the study. “Putting in a mechanical pump rests the heart and apparently sends a signal to make new heart cells. This is the first time that this phenomenon has been shown to occur in human heart failure.”

Dr. Sadek said the next step is to document that the cell division they observed produces viable heart tissue and a stronger pump.

The Chief of Cardiology at UT Southwestern called the new research “exciting.” “Dr. Sadek's findings raise the prospect of reawakening otherwise quiescent cardiac muscle cells, coaxing them into regenerating new and healthy cells. This has been an over-arching objective of the field for many years. The next step will be to leverage these exciting results to rebuild the failing heart,” said Dr. Joseph Hill Professor of Internal Medicine and Molecular Biology.

“This is an exciting advance. We have a long way to go, but hopefully this study will be an important first step toward uncovering methods of promoting myocardial recovery,” said Dr. Mark Drazner, Professor of Internal Medicine and Medical Director of the Heart Failure, LVAD, and Cardiology Transplant Program.

Drs. Sadek and Mammen are members of the newly established Hamon Center for Regenerative Science and Medicine, made possible by a $10 million endowment gift from the Hamon Charitable Foundation. The Center's goal is to understand the basic mechanisms for tissue and organ formation, and then to use the knowledge to regenerate, repair, and replace tissues damaged by aging and injury.

Dr. Eric Olson, Professor of Molecular Biology and Chairman of the Department of Molecular Biology, is the head of the Hamon Center. "This is a fascinating study and a wonderful example of the translation of a discovery in basic science to an important new insight into human disease," said Dr. Olson. "Dr. Sadek's work provides fresh new ideas for stimulating heart regeneration, which is one of the biggest challenges in cardiovascular medicine today."

Other UT Southwestern investigators involved in this study are: Dr. Diana Canseco, Assistant Instructor in Internal Medicine; Dr. Wataru Kimura, Assistant Instructor in Internal Medicine; Dr. Sonia Garg, Cardiology Fellow; Dr. Shibani Mukherjee, Instructor in Psychiatry; Dr. Souparno Bhattacharya, Research Assistant; Salim Abdisalaam, graduate student; Dr. Sandeep Das, Associate Professor of Internal Medicine; and Dr. Asaithamby Aroumougame; Assistant Professor of Radiation Oncology.

Dr. Drazner holds the James M. Wooten Chair in Cardiology. Dr. Hill holds the Frank M. Ryburn, Jr. Chair in Heart Research and the James T. Willerson, MD Distinguished Chair in Cardiovascular Diseases. Dr. Olson holds the Annie and Willie Nelson Professorship in Stem Cell Research, the Pogue Distinguished Chair in Research on Cardiac Birth Defects, and the Robert A. Welch Distinguished Chair in Science.

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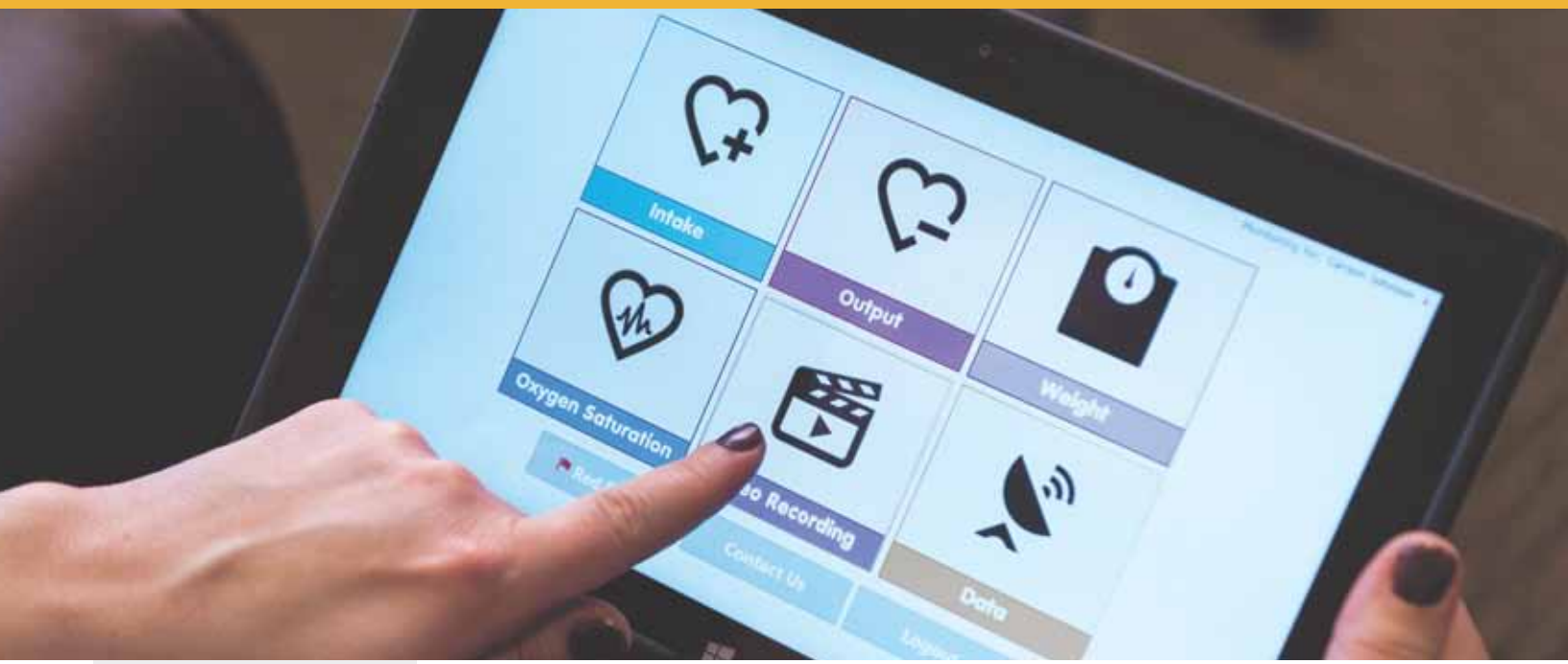

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–Girish S. Shirali, MBBS, FACC, FASE, Co-Director, the Ward Family Heart Center

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