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The Role of Optical Coherence Tomography in PCI: A Case Example

By Franco Fabbiocchi, MD, PhD

Selective coronary angiography remains a mainstay for the visualisation and assessment of coronary artery anatomy and the guidance of percutaneous coronary interventions (PCIs).[1] While technological advances and refinements have improved the diagnostic accuracy of conventional angiography (e.g. use of quantitative coronary angiography (QCA) to measure plaque-lesion length and percent stenosis, and non-invasive CT-angiography), it remains that the 2-dimensional visualization of an inherently complex 3-D structure (especially in the setting of often complex vessel pathology) provides a limited picture of vessel anatomy and may underestimate the extent and nature of plaque-associated pathologies.[2] Furthermore, angiography allows only an indirect assessment of operative stent placement rather than direct visualization.

Adjunctive intravascular imaging modalities, principally intravascular ultrasound (IVUS) and subsequently high-resolution light-based imaging technology i.e. optical coherence tomography (OCT), including OCT systems from Abbott, have been developed and deployed to provide greater clinical information about coronary vessels and allied-plaque dimensions and characteristics in order to optimize stent size selection and placement. Both IVUS and OCT allow more precise and direct evaluation of the stenting process and, in particular, the necessary stent expansion (as measured by the minimal stent area [MSA], an important predictor of stent stenosis and stent thrombosis[2]) required to guide secondary manoeuvres such as post-dilatation. This offers the potential to achieve greater clinical success and reduce post-procedure complications compared to standard visual angiography.[2-4] In this article we present the current evidence to support use of OCT- and IVUS-guided PCI and data on one of the first subjects undergoing OCT-guided PCI from a new randomized controlled trial (RCT), ILUMIEN IV.

Benefits of Alternatives to Conventional Angiographic-Guided PCI

Data from observational studies, RCTs and meta-analyses indicates that compared with angiographic visualization, reductions in clinically important outcomes, major adverse cardiac events (MACE), cardiovascular mortality and stent thrombosis are achieved with IVUS.[3,5-11] It should be noted that, due to study underpowering, only trends in clinical benefit rather than statistically significant outcomes were reported in most individual studies, with significant reductions seen in the pooled analyses. In their recent meta-analysis of RCTs, Elgendy et al found that use of IVUS realized 40% and 54% reductions in MACE and cardiovascular mortality respectively, with 51% reductions in stent thrombosis compared with conventional angiography.[8]

OCT systems comprise an imaging catheter and allied system console containing the optical imaging and signal acquisition software. Due to approximately >10-fold greater image resolution, OCT offers potentially more benefits than IVUS in accurate identification of vessel anatomy and pathology, along with greater sensitivity to detect post-stenting complications.[4,12]

Although data is more limited for OCT than for IVUS, and particularly data for clinical outcomes, the evidence-base is growing,[4,13] with a number of large RCTs recently reported

(from the ILUMIEN, DOCTORS and OPINION study programs) which compared outcomes with angiography and/or IVUS (although chiefly reporting stent-related outcomes rather than clinical outcomes per se).[14-16] Overview of these data are outlined below.

OCT Compared with Angiography and IVUS

To date, most studies have used surrogate rather than clinical outcomes, although an early registry study reported lower rates of MACE and cardiac death in patients undergoing OCT--guided PCI compared with matched patients undergoing angiography guidance.[17] More recently, the DOCTORS RCT, which compared OCT vs angiographic guidance in 240 patients with non-ST-segment elevation ACS, found that OCT was associated with some improvement in post-intervention fractional flow reserve (FFR) and improved stent expansion. In addition, OCT influenced procedural strategy in 50% of the patients in the OCT-guidance arm.[15]

The initial prospective, non-randomized, observational ILUMIEN-I study, which utilized both OCT and angiography, helped define and evaluate stent-guidance parameters for future studies.[18] Of some importance was that pre-procedural OCT-guidance impacted physician's decision-making (regarding stent length, diameter, and number placed) in 57% of cases, with subsequent post-PCI OCT assisting in stent optimization in 27% of cases, notably in those with more complex disease.[18] A reduction in stent number with OCT-guidance compared to that used with angiography has also been reported in a recent registry study.[19]

Naturally, great interest over the relative merits of IVUS and OCT exists. Observational data from the CLI-OPCI study, which compared patients undergoing PCI with angiographic + OCT-guidance with matched patients undergoing PCI with angiographic-guidance alone found that those receiving OCT-guided PCI had significantly lower risk of cardiac death, (1.2% vs. 4.5%), cardiac death or MI (6.6% vs. 13.0%), and a composite of cardiac death, MI, or repeat revascularisation (9.6% vs. 14.8%) after 1 year.[17] Subsequently, the ILUMIEN-II study, a post-hoc 'matched-paired' analysis of patients from ILUMIEN-1 (OCT) and the ADAPT-DES study (IVUS)[6,20] found that stent expansion was comparable between OCT and IVUS.[21]

More recently, a small number of RCTs have sought to directly compare OCT vs IVUS. The ILUMIEN III study was an international, multicenter study involving 450 patients randomly allocated to OCT-guided, IVUS-guided, or angiography-guided stent implantation.[14] OCT-guidance was non-inferior to IVUS guidance (but not superior) for the primary endpoint (post-PCI MSA assessed by OCT) and not superior to angiography guidance, with post-procedural MSAs in the three study arms of 5.79 mm^2 (OCT), 5.89 mm^2 (IVUS), and 5.49 mm^2 (angiography). OCT guidance was associated with significantly greater minimum and mean stent expansion than angiography guidance (and comparable to IVUS), with significantly fewer untreated major dissections and malappositions than with IVUS guidance.[14]

A key aspect of ILUMIEN III was standardised stent selection based on preintervention OCT measurements of the external elastic lamina (EEL) in the proximal and distal reference segments of the target lesion. This was in response to previous observational data indicating that OCT-guided luminal measurements may underestimate the optimal stent diameter, in particular in lipid-rich lesions due to incomplete visualisation of the vessel wall, leading to selection of stents that are smaller in terms of MSA achieved (compared to stents selected on the basis of luminal dimensions measured via IVUS or angiography).

In the OPINION Trial, which utilized an alternative OCT platform to that used in the ILUMIEN program, researchers compared OCT-guided PCI with IVUS, and found that OCT guidance was non-inferior to IVUS with respect to target vessel failure (a composite of cardiac death, target vessel–related MI, or ischemia-driven target vessel revascularization) occurring in 5.2% vs. 5.1% respectively at 12-months.[16] In a subsequently reported pre-specified sub-study of OPINION, which evaluated the post-PCI MSA in a proportion of patients in both treatment arms, no significant differences in MSA were apparent.[22]

With larger data sets capturing information from real world practice, the actual impact, on outcomes of intravascular imaging and OCT, in particular, becomes more evident. In a very recent retrospective analysis conducted in over 87,000 patients in the London region of the UK, a statistically-significant difference in mortality was seen between patients treated with OCT-guidance and angio-guidance (with multivariate analysis and propensity matching), as well as greater procedural success and in-hospital MACE for OCT-guided PCI.[23] In the large network meta-analysis which included over 31,000 patients from 17 RCTs comparing outcomes of PCI guided by different imaging modalities (angiography, IVUS, OCT), a rankogram indicated that OCT-guided PCI resulted in the highest probability of having the lowest rates of MACE, all-cause and cardiovascular mortality, and target lesion revascularization.[9]

In addition to a recent Consensus Statement, a number of excellent reviews of the data and relative merits of OCT and IVUS have also been published.[13,24] Across all studies, safety was broadly comparable in patients undergoing PCI guided by OCT, IVUS or angiography, with other recent registry data also showing safety of OCT-guidance in clinical practice.[25]

A new RCT, ILUMIEN IV, is now comparing OCT-guided PCI with angiographic-guided PCI.

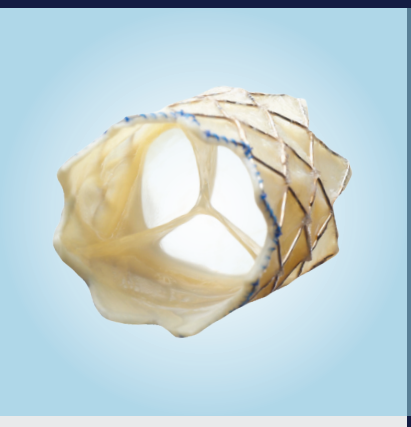
A Case Example

One OCT-guided PCI was treated at the Centro Cardiologico Monzino in Milan in August 2018. Here we describe aspects of this case.

The patient was a 73-year-old male, an active smoker, with a history of Coronary Artery Disease, hypertension, and type 2 diabetes mellitus. The patient was referred for PCI on the basis of a previous anterior S-T elevation myocardial infarction, with transthoracic echocardiography at that time showing evidence of left-ventricle apical dyskinesia.

During pre-PCI planning, coronary angiography showed calcific occlusion in the mid-left anterior descending artery with evidence of faint vascular reconstitution by coronary collateral circulation (Figure 1a). Pre-PCI coronary angiography was performed (after gentle predilatation to enable dye flow), which demonstrated diffuse

RIGHT DATA.



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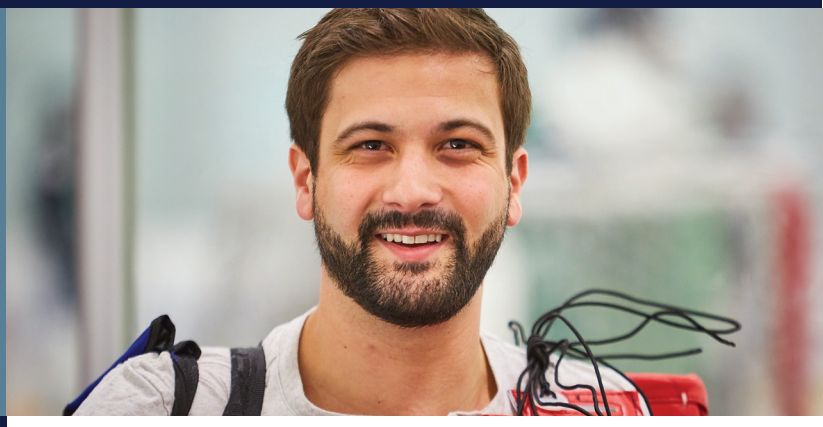

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Potential device-related adverse events that may occur following device implantation include the following: stent fracture*, stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (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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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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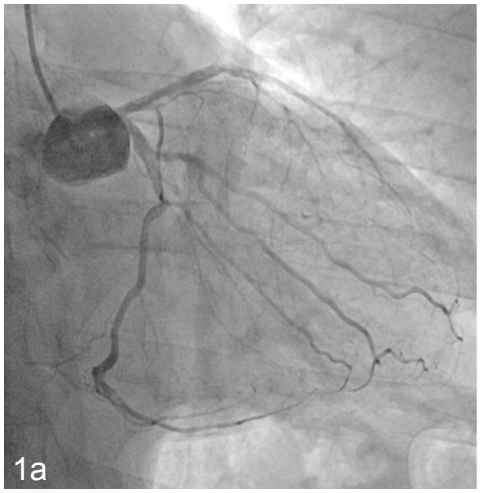
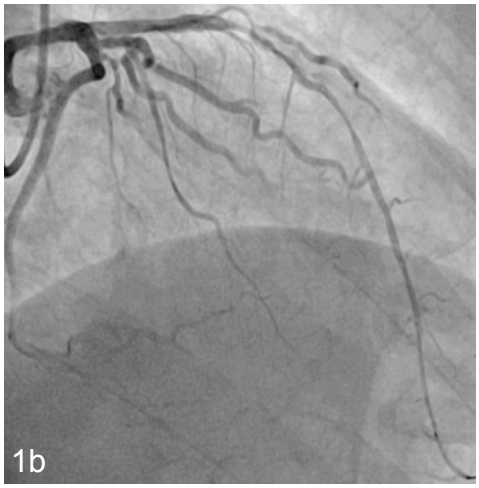




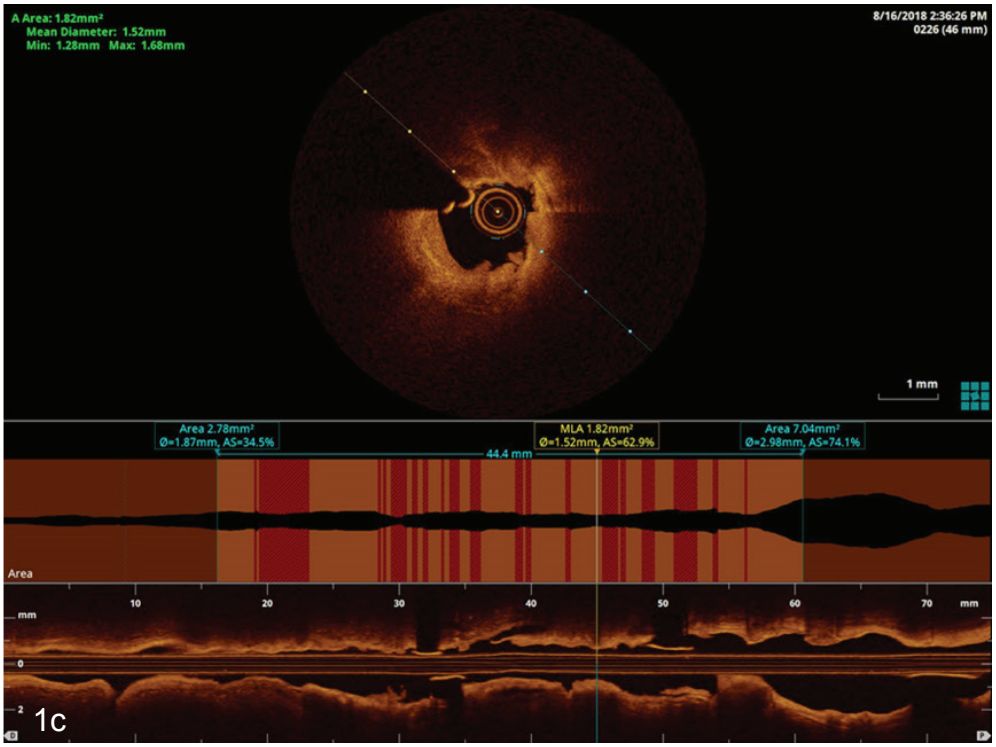
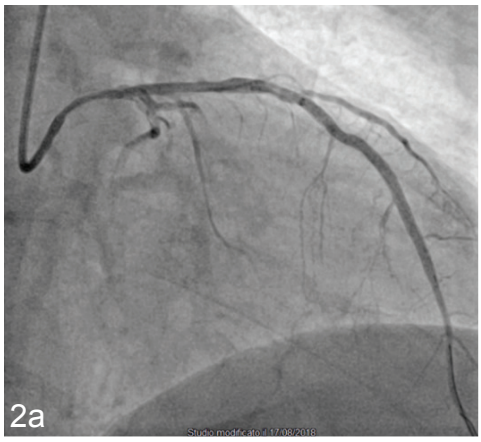


Figure 1. Pre-PCI angiography and OCT scan.
a. Diagnostic angiography showing calcific occlusion in the mid-LAD.
b. Pre-procedural angiogram shows diffuse LAD disease.
c. OCT scan demonstrates target lesion measurements.



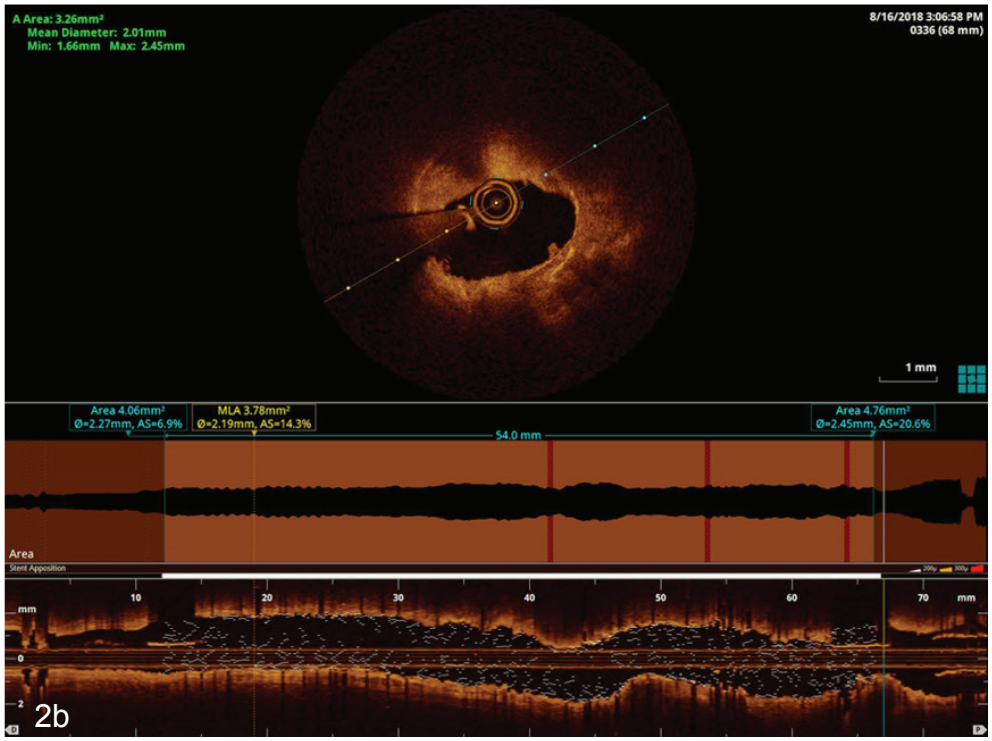


Figure 2. Stent-optimizing imaging.
a. Angiography shows a satisfactory result.
b. Pre-stent optimization OCT scan shows suboptimal (<4mm^2) minimal luminal area in the proximal stent.

LAD Disease while pre-PCI OCT scan demonstrated a distal reference diameter of the target lesion of 2.76 mm (Figure 1b and c). Two everolimus-eluting stents (Xience, Abbott Vascular) were placed; one 2.75 X 33 mm stent placed distally, and a second 3.0 x 23 mm stent placed proximally. Post-dilatation with a non-compliant (NC) balloon at 18 atmospheres was then performed. Post-stenting optimization imaging was then performed. Although a satisfactory result was seen on angiography, the pre-stent optimization OCT scan showed suboptimal expansion of the distal portion of the stent, while the minimal luminal area in the proximal stent edge was <4mm^2 (Figure 2). In accordance with the study protocol, a third stent was placed proximally, followed by NC balloon post-dilatation at 18 atmospheres. Post-preocedural OCT scanning demonstrated good stent expansion, with no malapposition, no plaque prolapse, and no edge dissections (Figure 3). A post-procedural angiogram is also shown for comparative purposes. No procedural complications developed in the immediate (24 hour) period. Further data on short-term and longer-term outcomes are being collected.

FACULTY POSITION IN PEDIATRIC CARDIOLOGY
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As part of efforts to expand its scholarly and clinical activities, the Department of Pediatrics at the University of South Alabama College of Medicine is currently seeking a BC/BE candidate for a faculty position in Pediatric Cardiology.

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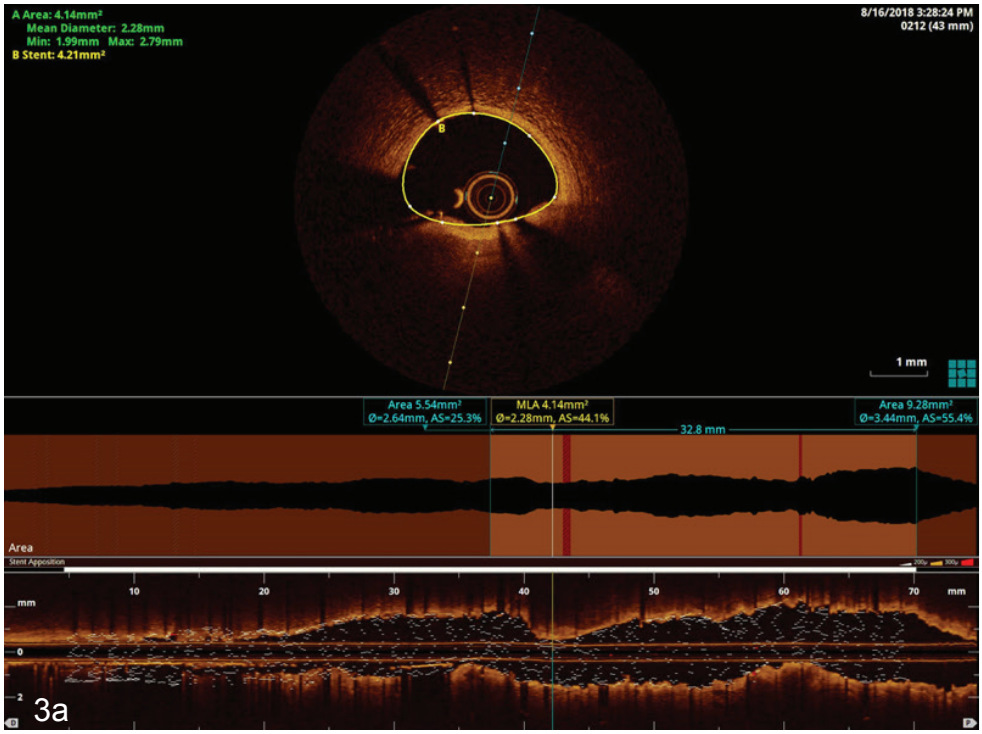

Figure 3a. Post-procedural OCT scan shows good stent expansion.

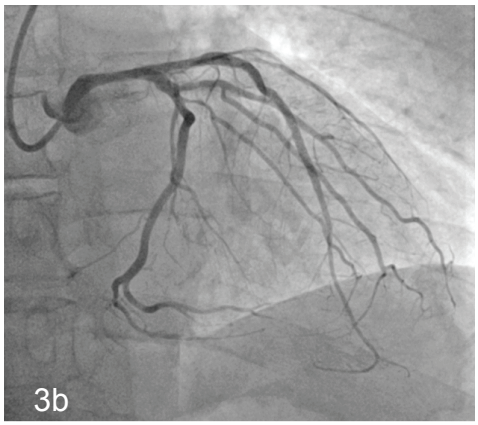

Figure 3b. Post-procedural OCT angiography.

Summary

Data indicate that OCT can improve PCI procedural success. In the case presented, which represents one of the first subjects randomized to the OCT arm of ILUMIEN IV, use of OCT facilitated stent selection and identified suboptimal initial stent placement.

Disclosure

Abbott Vascular is the sponsor and sole funding source for the ILUMIEN IV study (NCT03507777). Dr. Fabbiocchi reports no conflicts of interest.

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Review of PICS-AICS 2018 in Las Vegas

By Karim Diab, MD, FACC

The *21st Annual Pediatric and Adult Interventional Cardiac Symposium* (*PICS-AICS*) meeting was held in the "City of Lights" at the MGM Grand Las Vegas from September 5th-8th, 2018. With over 800 attendees from fifty countries, the meeting continues to be relentlessly successful!

Thirty-five percent of the attendees were from outside the US. Eight cardiac centers transmitted 16 live cases from North America, South America, Europe and the Middle East! There were 167 abstracts submitted this year to the meeting!

The meeting featured a comprehensive program that covered various aspects of interventional therapies together with imaging modalities applied during interventional procedures in Congenital and Structural Heart Disease. This year's meeting focused on how decisions in cardiac interventions can affect outcome. It included sessions that focused on topics such as the native RVOT, novel approaches to stenting, new device development, ductal interventions, and registries and how they can impact outcomes.

The meeting was preceded by a full day of imaging in collaboration with 3DI3 focused on Advanced Imaging Modalities for Congenital and Structural Interventions. Dr. Krings from The Netherlands and Dr. Armstrong from Nationwide Children's Hospital brought 3DI3, an international conference on 3D imaging, to the first day of *PICS Imaging Symposium*. This allowed attendees to learn how to use 3DRA, obtain high quality images quickly, get introduced to fusion of CTA and MRA data with the x-ray system, and how to understand vessel-vessel and vessel-airway interactions to enhance procedural success and safety in pulmonary artery stenting, aortic arch interventions and TPVR. The imaging symposium highlighted why and how to bring 3D into your cath lab to improve your safety, efficiency, and therapeutic decision-making.

The day included a 3D Rotational Angiography (3DRA) boot camp to give an overview about this technique. Three-dimensional RA brings a sophisticated modality that provides a thorough anatomic evaluation with 2D CT-like images and 3D reconstruction of complex structures and interactions, with views from various angles. It also provides image-guided therapy with overlay of the 3D reconstruction on live fluoroscopy. It can also allow decreasing radiation exposure by limiting the number of required 2D angiograms. The advantages of this technique were discussed including its use in the setting of different lesions such as for TOF/ MAPCAs to be able to see all MAPCAs in one view and help surgeons with planning unifocalization.

Three versions of 3DRA post-processing systems available from three vendors were presented including those from Philips, Siemens, and Canon Medical. Some tips and technical steps were also discussed including using 3DRA of the airway and esophagus by Dr. Molenschot, the role of the cath lab technician by Dr. Laurence, and how to perform measurements using 3DRA by Dr. Fagan.

The second session of the imaging day went over collaborating with the non-invasive imaging team during cardiac interventions, including incorporating 3D echo imaging with 3DRA during cardiac interventions. Dr. Sathanandam gave some tips and tricks for such multi-modality image fusion and how Digital subtraction RA as a modality can reduce contrast volume. Fusion can help with

PEDIATRIC CARDIOLOGY
YALE UNIVERSITY SCHOOL OF MEDICINE

The Section of Pediatric Cardiology at the Yale University School of Medicine and Yale New Haven Children's Hospital is recruiting a BE/BC pediatric cardiologist with major interest, expertise and experience in non-invasive cardiac imaging and outpatient cardiology at the Assistant Professor level. The ideal candidate has received advanced training in advanced cardiac imaging. Outstanding communication, collaboration and clinical skills are required.

This individual will join a division of dedicated faculty and advanced nursing practitioners to provide congenital heart care and cardiovascular imaging to patients throughout the state and region. The Section has an active research program, an extensive and growing clinical program, an outstanding fellowship program and a nationally recognized Pediatric Residency Program at the Yale New Haven Children's Hospital.

The successful candidates will receive a faculty appointment in the Yale Department of Pediatrics at the academic level commensurate with experience and qualifications. Yale University and the Department of Pediatrics offer an excellent benefits package. The greater New Haven and Connecticut Shoreline area offers an excellent quality of life with immense cultural and recreational opportunities.

Review of applications will begin immediately and will continue until the position is filled.

Interested applicants should submit Curriculum Vitae, Cover Letter and 3 references electronically to:

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Yale University is an equal opportunity, affirmative action employer. Women, minorities, persons with disabilities and protected veterans are encouraged to apply.

device positioning, creating a fenestration, and transeptal approach. It is fast and accurate, has many utilities and can potentially improve outcomes.

Dr. Cheatham went over the use of 3D ICE imaging and its advantages during various interventions including PVR, ASD closure, and LAA closure. Dr. Srivastava talked about intraventricular blood flow dynamics including intraventricular blood flow and vortex patterns in normal subjects as well in patients with complex CHD such as TOF, SV, and transplanted hearts giving an insight on shear wall stress and energy loss in such patients. She emphasized that Vortex could be a novel index for assessment of diastole and systole. A live case example was transmitted from Nationwide Children's Hospital in Columbus, OH using 3DRA for transcatheter PVR in a patient s/p TOF repair.

Another session during the imaging symposium focused on imaging and intervention in TOF, emphasizing some hot topics in caring for patients with this lesion. Dr. Valente tackled the question of when to replace the PV in TOF emphasizing the need for modified criteria for PVR in order to improve clinical outcomes and highlighting that we are likely still waiting too long on these patients. Dr. McElhinney discussed predicting coronary compression in TVPVR, highlighting some limitations of balloon angioplasty coronary artery balloon testing and introducing a simulation methodology with Finite Element Analysis to better assess the risk. Dr. Hanley discussed what surgeons need to know before TOF/PA/MAPCA repair, going over an institutionalized protocol for surgical management of these patients. Dr. Benson then talked about 3D printing and its use for surgical and interventional planning in unusual cases. He also discussed 3D stereoscopic and holographic imaging which provide visual depth and spatial information, providing the capability to move, slice and measure structures and to guide intracardiac procedures.

Another session focused on the use of biomedical engineering techniques in assessing coarctation of the aorta. Dr. Armstrong talked about the use of computational fluids dynamics for aortic interventions and discussed the CFD feasibility study in progress generating data with virtual stenting. Dr. Krings discussed the use of 4DRA by applying ECG gating to 3DRA allowing high spatial and temporal resolution in complex morphology, as well as measurements in dynamic geometry. Dr. Collins discussed the use of 4D MRI specifically in coarctation, which helps evaluate re-narrowing, peak velocity, and quantification of collateral flow.

The symposium also featured a hands-on session in the late afternoon with vendor rooms for 3DRA post-processing from four vendors.

PICS-AICS 2018 started officially on Thursday and kicked off with live cases transmitted from major centers around the world. This year, live cases were transmitted from eight national and international venues with experienced operators that demonstrated the latest in medical device technology using approved and investigational devices/valves/stents. The live cases this year were transmitted via internet from: Doha, Sao Paolo, London, New York, San Diego, Seattle, Cincinnati and Memphis.

Six cases were transmitted on the first day of the meeting:

- From Sidra Heart Center in Doha, Qatar, Drs. Boudjemline and Al-Saloos and their team presented a case of a 43-year-old

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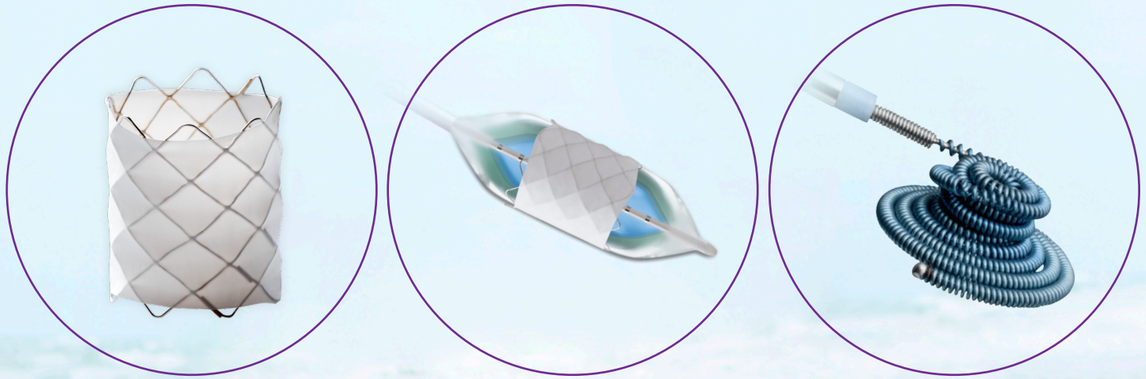

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The CP Stent is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving a compliant aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery and balloon angioplasty is contraindicated or predicted to be ineffective.

The Covered CP Stent is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery associated with one or more of the following: acute or chronic wall injury; nearly atretic descending aorta of 3 mm or less in diameter; a non-compliant stenotic aortic segment found on pre-stent balloon dilation; a genetic or congenital syndrome associated with aortic wall weakening or ascending aortic aneurysm.

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Contraindications: Clinical or biological signs of infection. Active endocarditis. Pregnancy. Contraindications (CoA only): Patients too small to allow safe delivery of the stent without compromise to the systemic artery used for delivery. Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty. Curved vasculature. Occlusion or obstruction of systemic artery precluding delivery or the stent. Known allergy to aspirin, other antiplatelet agents, or heparin. Contraindications (RVOT only): Patients too small to allow safe delivery of the stent without injury to a systemic vein or to the right side of the heart. Warnings / Precautions: Radiofrequency heating during MRI scans on overlapped, 10 zig CP Stents has not been evaluated. Excessive force while crimping may weaken welds of the stent. Crimping the 8 zig stent on a balloon catheter smaller than 12mm, and the 10 zig on a balloon catheter smaller than 26mm, may cause damage to the stent. The stent is rigid and may make negotiation through vessels difficult. Warnings / Precautions (CoA only): Coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta should be confirmed by diagnostic imaging. The NuMED CP Stent has not been evaluated in patients weighing less than 20kg. As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess. Over-stretching of the artery may result in rupture or aneurysm formation. Warnings / Precautions (Covered CP Stent only): Excessive handling and manipulation of the covering while crimping the stent may cause the covering to tear off of the stent. Crimping the device in the opposite direction of the folds in the covering may cause the covering to catch while inserting into the hemostasis tool and introducer. This could cause the covering to tear off the stent. Pulling the Covered stent back through the introducer and/or hemostasis valve may cause the covering to catch and tear off of the stent. Warnings / Precautions (RVOT only): During the Premarket Approval study the Medtronic Melody valve was used for valve restoration. The safety and effectiveness of the Covered CP Stent for pre-stenting of the right ventricular outflow tract (RVOT) landing zone (i.e. prophylaxis or prevention of either RVOT conduit rupture or TPVR fracture; use as a primary RVOT conduit) in preparation of a transcatheter pulmonary valve replacement (TPVR) has not been evaluated. As with any type of implant, infection secondary to contamination of the stent might lead to endocarditis, or abscess formation. The Covered Stent can migrate from the site of implant potentially causing obstruction to pulmonary artery flow. Over-stretching of the RVOT may result in rupture or aneurysm of the RV-PA conduit or the native pulmonary artery. The inflated diameter of the stent should at least equal the diameter of the intended implant site. Reference the IFU for a complete listing of indications, contraindications, warnings and precautions.

BIB® Indications for Use:
The BIB® Catheter Balloon is indicated for CP Stent™/Covered CP Stent™ placement in vessels over 8mm in diameter.

Refer to the Instructions for Use for complete indications, relevant warnings, precautions, complications, and contraindications.
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Nit-Occlud® Indications for Use:
The Nit-Occlud® PDA coil is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of small to moderate size patent ductus arteriosus with a minimum angiographic diameter less than 4mm.

Nit-Occlud® Brief Statement:
Do not implant the Nit-Occlud PDA into patients who have endocarditis, endarteritis, active infection, pulmonary hypertension (calculated PVR greater than 5 Wood Units), thrombus in a blood vessel through which access to the PDA must be obtained, thrombus in the vicinity of the implantation site at the time of the implantation or patients with a body weight < 11 lbs. (5kg). An angiogram must be performed prior to implantation for measuring length and diameter of the PDA. Only the pfm medical implantation delivery catheter should be used to implant the device. Administration of 50 units of heparin per kg bodyweight should be injected after femoral sheaths are placed. Antibiotics should be given before (1 dose) and after implantation (2 doses) to prevent infection during the implant procedure. Do not implant the Nit-Occlud PDA in an MR environment. Do not pull the Nit-Occlud coil through heart valves or ventricular chambers. Contrast media should not be injected through the implantation catheter. The catheter must not be connected to high pressure injectors. Patients may have an allergic response to this device due to small amounts of nickel that has been shown to be released from the device in very small amounts. If the patient experiences allergic symptoms, such as difficulty in breathing or swelling of the face or throat, he/she should be instructed to seek medical assistance immediately. Antibiotic prophylaxis should be performed to prevent infective endocarditis during first 6 months after coil implantation. Potential Adverse Events: Air embolism, Allergic reaction to drug/contrast, Apnea, Arrhythmia requiring medical treatment or pacing, Arteriovenous fistula, Bacterial endocarditis, Blood loss requiring transfusion, Chest pain, Damage to the tricuspid or pulmonary valves, Death, Embolization of the occluder, requiring percutaneous or surgical intervention, Endarteritis, False aneurysm of the femoral artery, Fever, Headache/ Migraine, Heart failure, Hemolysis after implantation of the occluder, Hypertension, Hypotension or shock, Infection, Myocardial infarction, Occluder fracture or damage, Perforation of the heart or blood vessels, Stenosis of the left pulmonary artery or descending thoracic aorta, Stroke/TIA, Thromboembolism (cerebral or pulmonary), Valvular Regurgitation, Vessel damage at the site of groin puncture (loss of pulse, hematoma etc.).

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male with a large 19 mm ASD that was closed with Occlutech Figulla Flex II ASD device, using TEE with 3D imaging without balloon-sizing. The next case was a PDA closure using the Occlutech PDA Occluder in a 15-year-old girl with silent PDA, which was a bit controversial, but was closed successfully.

- From Sao Paolo, Brazil, Drs. C. Pedra, S. Pedra and L. Companha performed percutaneous closure of a mid-muscular VSD using the Occlutech Muscular VSD device in a 5-year-old boy. The team presented a second case of RPA stenting, RMBTT shunt occlusion and ASD occlusion in a 9-year-old boy with a PA/IVS s/p BTT shunt and RF-assisted PV valvuloplasty.
- From Brazil, performed by Dr. A. Peirone, included a case of percutaneous PFO closure using the PFM PFO-R device with 3D TEE guidance in a 54-year-old female with a history of stroke. The PFM PFO-R device is still not approved in the US: it comes in 3 sizes (20, 26 and 30 mm), has a 3 mm waist and both discs have the same size with single layer on the left disc and double layer on the right disc, and comes pre-mounted.
- From London, UK, Drs. I. Malik and C. Baker performed PFO closure with balloon-sizing in a 25-year-old diver with decompression illness using 3D TEE imaging.

Dr. Boudjemline from Doha also presented an interesting talk on reversed Potts shunt in the setting of pulmonary hypertension. This aims at creating a post-tricuspid valve shunt in order to help decompress the RV and improve LV function. In case a tiny PDA is present, the PDA is made larger; otherwise, several covered stents are used after RF perforation to connect the aorta to the LPA. He also presented the current experience since 2012 with 27 patients (13 with and 14 without a PDA) with 93% procedure success rate to create the shunt and a complication rate of 20%. Follow-up showed improvement in clinical status, weaning of pulmonary vasodilator therapy and improvement of RV/ LV function.

The popular Taped Case Sessions also continued this year, as well as in the morning and during lunch.

Wednesday afternoon featured a Native RVOT Symposium focusing on the assessment and treatment of the native RVOT. The first part of the session went over imaging of the RVOT. Dr. C. Fleishman discussed the echocardiographic assessment of the RVOT to help select patients for Transcutaneous Pulmonary Valve implantation in the native RVOT. Although CMR is the standard for quantification, echo helps the physician select patients who need further assessment and determine RV volumes and the degree of PR. Echo can also evaluate RV myocardial deformation pre- and post-intervention on the RVOT. Blood speckle tracking by echo also helps evaluate energy loss and vortex formations. Dr. Garg talked about MRI assessment beyond volumes and regurgitant fractions, including the use of late gadolinium enhancement and T1 mapping and strain imaging by CMR. Dr. Kutty discussed how the CT, with 3D modeling, can help for pre-procedural planning and virtual deployment of the PV. Dr. Amin talked about the evolving indications for PVR from current indications to what we expect in the near future. Some factors predictive of poor outcome (death/sustained VT) after PVR were recently published and include older age (>28 years), BMI> 30, RV dysfunction (EF<40 %) or hypertrophy or RVP >40 mmHg.

The second part of the RVOT symposium focused on treatment options for the native RVOT. An exciting talk by Dr. Hanley went over newer approaches to primary repair of TOF arguing that early repair in neonatal life can, if anything, help the RVOT grow better. He highlighted that the use of the monocusp valve repair is not beneficial; similarly, like other techniques such as intra-op balloon dilatation, as all cause trauma to the PV tissue and introduce foreign material. He hence favors a minimalist approach with “No touch leaflet sparing

limited trans-annular patch” in primary TOF repair in those patients with reasonable RVOT/PV morphology. This allows late PV repair with removal of the patch and PV repair which might avoid the need for PVR in some cases. Dr. Bacha discussed the best surgical approach for dysfunctional RVOT after TOF repair. A dysfunctional RVOT is being defined as too small or too large (not just one that cannot place

HEALTH
UNIVERSITY OF UTAH

DIVISION CHIEF OF PEDIATRIC CARDIOLOGY

DEPARTMENT OF PEDIATRICS, UNIVERSITY OF UTAH SCHOOL OF MEDICINE

The Department of Pediatrics at the University of Utah School of Medicine has initiated a nationwide search for an innovative academic pediatric cardiologist to serve as the Chief of the nationally recognized Division of Pediatric Cardiology. The Division Chief will define and execute the strategy needed to fulfill the mission of providing outstanding pediatric cardiovascular healthcare, performing high-quality cardiovascular research, and educating future pediatric cardiovascular physicians and healthcare professionals.

The Division Chief will lead the Division's growing and thriving group of 31 faculty physicians, advanced practice clinicians, and other members of the care team in high quality, fiscally-responsible care delivery that serves an extensive area of the intermountain west. The Division Chief will play a significant leadership role as Co-Director of the Heart Center at Intermountain Healthcare's Primary Children's Hospital (ranked in the 2018 U.S. News and World Report) and will work closely with leaders and teams from pediatric cardiothoracic surgery, cardiac critical care, cardiac anesthesia, cardiac nursing, and hospital leadership in advancing the mission and goals of the Heart Center.

The successful candidate will be a Diplomate of the American Board of Pediatrics or the American Osteopathic Board of Pediatrics with subspecialty certification in Pediatric Cardiology. She/he will be an accomplished academician recognized in the field of pediatric cardiology who demonstrates the ability to lead a large and complex pediatric division within a large department at a major public university and which operates within the children's hospital of a large, integrated healthcare delivery system. The selected candidate must meet the requirements for appointment as Professor of Pediatrics at the University of Utah School of Medicine on the Clinical or Tenure Track.

For further information about the position and to apply, please visit:

http://utah.peopleadmin.com/postings/82920

The University of Utah, an AA/EO employer, encourages applications from women and minorities, and provides reasonable accommodation to the known disabilities of applicants and employees. The University of Utah values candidates with experience working in settings with students from diverse backgrounds, and possess a strong or demonstrated commitment to improving access to higher education for historically underrepresented students.

a percutaneous stented valve). For patients needing a transannular patch repair, he favors a cusp augmentation with a patch technique. Dr. Cabalka discussed the growing experience with currently approved valves in the native RVOT. Dr. Gewillig then discussed creative approaches in treating the native RVOT. Dr. Zahn presented an update on Native RVOT Valve trials and Dr. Levi discussed future approaches with tissue engineering. The last part of the RVOT symposium featured a hot debate on surgical vs tPVR with Dr. Ilbawi taking the surgical side and Dr. Gillespie defending the interventional side.

Breakout sessions also took place as usual. This included a session on novel approaches to stenting, a session for nursing and associated professionals, and a session on the atrial septal and left atrial appendage interventions. Another breakout session focused on the PICES (Pediatric Interventional Cardiology Early-Career Society) projects and went over topics such as venous recanalization in SVC Syndrome, antegrade stent implantation for coarctation post-Norwood, and research updates.

The day ended with the *PICS-AICS Achievement Award*. This award is designed to encourage and recognize investigators who have contributed exceptionally to the field of interventional cardiology in Congenital and Structural Heart Disease. This year, the award went to Dr. Dietmar Johannes Schranz from Germany.

In addition, the evening included a new sponsored session at *PICS-AICS* to support new ideas for device development: PediaVascular Supporting Device Development: The Shark Tank. This showed impressive new ideas to develop devices that were presented from colleagues from various institutions. The winner was Dr. Damien Kenny who received a $25,000 cash grant and complimentary business services from PediaVascular.

Friday at *PICS-AICS 2018* started early with the *5th Annual PICS-AICS 5K Run*, which took place at 6 am at the MGM Grand Resort on the Vegas strip. A total of 102 people arose with the sun to run. The urban course provided an excellent tour of the Vegas strip at sunrise. There were a few tourists left over from the night before to act as cheerleaders for the runners! The overall winner of the race was Romell Valladares with an outstanding time of 18:09. Other top finishers were Dr. Allen Ligon and Dr. Chris Petit second and third male finishers, as well as Dr. Alyssa Vermeulen, Alyssa Glennon and Dr. Heike Schneider as the top 3 female finishers. Although it was an early start for the *PICS-AICS* attendees, participants had fun and contributed to making a difference by supporting CHIMS - Congenital Heart Intervention Mission Support, a project that was launched during *PICS-AICS 2013*. This organization has been very active in providing a coordinated and sustainable benefit to interventional catheterization for Structural Heart Disease in developing countries through centralizing and consolidating pre-existing charitable mission work. For more info, visit the website at www.chimsupport.com.

Friday sessions at *PICS-AICS 2018* were marked by a day full of live cases in the morning with six cases transmitted from major centers in the US. After a quick update on the live cases from *PICS-AICS 2017*, the live cases on the second day of *PICS-AICS* were transmitted live: New York, Cincinnati, and San Diego and included the following:

- From New York Presbyterian Morgan Stanley Children's Hospital: Drs. Torres, Crystal and Turner presented a case of covered stent implantation across an obstructed RV-PA conduit and new Melody valve implantation in a 26-year-old TOF patient. Their second case included a tPVR using the RIJ approach in a 19-year-old boy with a history of PA/IVS s/p RVOT patch and BDG.
- From Cincinnati Children's Hospital: Drs. Goldstein, Hirsch and colleagues presented two cases: a 14-month-old boy with biliary atresia s/p liver transplant who developed hepatic venous outflow obstruction and they performed hepatic vein and IVC stent implantation, and a case of 11-month-old TOF patient with discontinuous PAs s/p repair with stented RPA unifocalization that needed RPA stenting.
- From San Diego Rady Children's Hospital: Drs. El Said, Moore and Ratnayaka presented three cases including PDA closure in a 28-week-old, premature 890 gms baby, a case of coarctation for stenting in a 17-year-old boy, and a case of transjugular liver biopsy in a 32-year-old with TA/TGA/VSD s/p Fontan.

The popular Taped Case Sessions also continued on Friday. This included a case illustrating percutaneous lymphatic embolization for abnormal lymphatic flow in patients with CHD by Dr. Dori from CHOP.

In the afternoon, a special Global Summit on device development took place to help determine pathways to simplify international device approval. In addition, representatives from regulatory bodies in North America, Europe and Asia were present and they added important international input concerning this matter. Dr. Gillepsie went over the challenges to bring a device to the market emphasizing the need to build a team instead of working alone in order to navigate the internal and external challenges to get the idea launched. Dr. Ibrahim from the FDA talked about the strategies introduced by the FDA to streamline device approval and gave examples of some processes, such as: the "off-label" data used from TVT registry. The use of "compassionate use" cases, for example, for the Berlin Heart EXCOR and others. Dr. Forbes discussed how to use registries to support new device approvals. Dr. Ho discussed the Japanese regulatory perspective, Dr. Tomita discussed the US-Japanese initiatives to harmonize device approval, and Dr. Melvin went over the European experience. There was a large board and audience discussion focusing on the concern for approval of the devices by industry and regulatory bodies, as well as approval by insurance companies that in many countries do not cover the cost, as opposed to what is being done in the field of Adult Heart Disease.

The afternoon also included a session on Registries, Decision-Making, Quality and Outcomes. This session went over the data generated from registries and their impact and how to utilize these variables to allow interventionalists to plan interventions with riskier cases.

The popular breakout for the Spanish-speaking attendees also took place later in the afternoon. In addition, a session on ductal interventions discussed standardized approaches to PDA stenting, dealing with PPS, and PDA closure in premature infants. Friday also included a session with CCISC Case Presentations that focused on topics such as: abnormal venous anatomy in pre-Fontan, pre-stenting the native

RVOT for tPVR, ECMO cannulation and the role of the interventionalist. There was also a session on ductal intervention. Dr. Petit reviewed the known complications and risk of femoral artery occlusion in young infants and discussed the umbilical artery approach. He also discussed the carotid artery and the flip technique as ideal, especially in cases of sole pulmonary blood flow and tortuous PDAs to avoid complications like arterial occlusion and shorten procedure time. Following Dr. Petit, was Dr. Alwi, one of the pioneers of this topic. He discussed techniques for dealing with branch PA stenosis. Both Dr. Petit and Dr. Alwi agreed on the importance of non-invasive imaging, most commonly CTA, in defining anatomy. There were multiple examples in both talks about the concern of LPA stenosis and the importance of guiding your stent more toward the MPA in order to avoid isolating the RPA. Dr. Alwi then reviewed cases and examples of stenosis of LPA and interventions in his experience.

Dr. Javois then discussed comparative outcomes with BTT Shunt. He discussed recent studies that showed the mBTS shunt is the only congenital cardiac surgery that has an increase in mortality over the years. Other recent multicenter studies showed death or unplanned re-intervention occurred more commonly in the mBTS shunt group. Dr. Qureshi then followed with a talk on the standardized approach to PDA stenting. Dr. Qureshi discussed the current AHA guidelines (*Circulation*, 2011) and the need for updating these guidelines. He reviewed Texas Children's Hospital protocol in depth, also re-iterating the use of CTA for anatomy definition when further delineation is needed to define the ductal anatomy.

Dr. Zahn then transitioned the session to closing of the PDA, with a discussion of closure in premature infants. He discussed devices in the US such as the AVP II and the MVP, as well as the ADO II AS, available in Europe, currently in trials in the US, where there is excitement about use in premature PDA procedures. Complications with devices were discussed, with an emphasis on LPA and aortic obstruction, as well as avoiding femoral arterial occlusion with venous-only access. Dr. Narin then reviewed the studies (retrospective) that have shown no statistical difference in complications comparing surgical and percutaneous closure in infants less than 2 kg, with the most common complication being LPA stenosis, which was shown to resolve in six months.

The last day at *PICS-AICS 2018* was as busy as well! More live cases were transmitted from national sites all morning. Four cases were transmitted live from Memphis and Seattle. Cases included the following:

- From Memphis, Le Bonheur Children's Hospital: Drs. J. Sathanandam, Waller, Agrawal, Johnson and Philip performed two cases: PDA closure using the MVP plug in a premature newborn, and recanalization of occluded RPA/stenting in an 11-year-old boy with severe RPA stenosis secondary to fibrosing mediastinitis/histoplasmosis.
- From Seattle Children's Hospital: Drs. Jones, Morray and Rubio performed two cases: re-stenting of an undersized coarctation stent in a 7-year-old boy with coarctation s/p repair s/p balloon angioplasty and stenting, and tPVR with Melody valve and pre-stenting in an 8-year-old boy with truncus arteriosus s/p repair with 12 mm Contegra RVOT conduit.

The live cases were interposed by a session on Developments in Structural Heart Disease, including topics such as Mitraclip in Congenital Heart Patients, percutaneous therapies for TV Disease, management of coronary artery fistula, TAPVR in Bicuspid Aortic Valve Disease, and atrial septal interventions for heart failure.

The lunch session featured the famous "My Nightmare Case in the Cath Lab" session, moderated by Dr. S. Qureshi and Dr. D. Kenny. This was, again, an exciting session where interventionalists from the audience presented their challenging cases and whereby the audience chose the most deserved case to be the winner. The winner this year was Dr. Dhaval Patel from Adovate Heart Institute in Chicago, IL.

The afternoon featured a session focusing on various Hybrid approaches in coarctation, Hybrid interventions in small infants, Hybrid PA stenting, and Hybrid PVR. A session focusing on pushing the boundaries in Asia also took place in the afternoon and included topics such as transcatheter VSD closure in smaller infants, self-expanding PVR and PDA closure in severe PAH.

During the final afternoon, the fun "Battle of the Continents" session took place! This quiz-based session on all aspects of catheterization, returned for its third year and the winner was the team from Europe which was able to knock North America off after its winning run over the last two years.

PICS-AICS 2018 then ended with closing remarks by Dr. Z. Hijazi. It will return on September 4th-7th, 2019 at the Marriott Marquis & Marina in San Diego, CA, for another fascinating and educational *PICS Symposium*!

For registration, check the website at www.picsymposium.com.

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New Column Coming Soon
Contributors Needed
more information on p. 19

Heart to Heart with Anna: A Podcast for the Congenital Heart Defect Community

By Anna Jaworski

"Have you ever thought about having your own radio show?" Josh Bernstein asked me out of the blue one day.

I didn't know Josh Bernstein. I didn't know about VoiceAmerica, either, and I was afraid that maybe I was being scammed, but something amazing happened.

"Mary, have you ever heard of VoiceAmerica?" I asked the friend I was visiting when I received that unusual phone call. To my surprise, Mary's answer was, "Yes!"

Mary had just interviewed someone who had a program on VoiceAmerica and she quickly pulled up the author's website.

"You're in a unique position," Josh had said to me. "As a heart mom, you seem to have a lot of experience talking about living with heart defects and I think you could have a great show. If you were on the radio today, what would you talk about?"

Since I had just written a blog that day, it wasn't hard to come up with a topic. That conversation was the beginning of "Heart to Heart with Anna."

VoiceAmerica is a talk radio network that produces and distributes original online radio shows. Today most people refer to online radio shows as "podcasts." Josh Bernstein was a producer for VoiceAmerica and he believed that a show devoted to the Congenital Heart Defect (CHD) community would be a good deed, a "mitzvah" and he asked me if I wanted to help him create such a program. November 12, 2013, was the date of the first broadcast program. The title of the first show, and the theme for the first season, was "You are Not Alone" and featured a number of guests from the CHD community. I actually flew out to Phoenix, Arizona to visit with the VoiceAmerica (www.voiceamerica.com/show/2259/heart-to-heart-with-anna) staff and to record the first three programs.

There are currently over 200 "Heart to Heart with Anna" programs encompassing over 100 hours of listening reaching people all over the globe. We have talked about all kinds of topics from finding out in utero that a baby would be born with a heart defect, to losing a child with a CHD, to advancements in pediatric cardiology. We devoted an entire season to Siblings of Heart Warriors and most recently we have devoted a season to organ donation and transplantation. Guests on "Heart to Heart with Anna" include parents of children with CHDs, pediatric cardiologists, cardiothoracic surgeons, grandparents of children with CHDs, Heart Warriors and other professionals who help CHD families, such as psychologists, nutritionists and even a chiropractor. You can learn more about being a guest on the program by visiting our website (www.tinyurl.com/ybhpztmh).

It's easy to find "Heart to Heart with Anna" because it's available on multiple platforms. The first season of the program is still available at VoiceAmerica but the program moved after the first season. You can easily find the program on our website (www.hug-podcastnetwork.com/h2h-with-anna.html), on iTunes, YouTube (www.youtube.com/channel/UCGPKwIU5M_YOxvtWepFR5Zw), and Spreaker (www.spreaker.com/show/1256958).

We are always looking for new guests to talk about a wide range of topics. One of our most popular seasons was Advancements in Pediatric Cardiology and that topic continues to be a fan favorite. "Heart to Heart with Anna" will be changing its format beginning in October 2018. Instead of having an entire season (usually 13 shows) devoted to one topic, we'll be discussing a variety of topics in Season 13, which will allow us more flexibility when it comes to talking about topics that are currently of interest to the CHD community.

"Heart to Heart with Anna" is a weekly podcast sponsored by Hearts Unite the Globe (HUG): A Nonprofit Organization for the Congenital Heart Defect Community (www.heartsunitetheglobe.org). In addition to producing "Heart to Heart with Anna," HUG also produces a monthly podcast - "Heart to Heart with Michael: A Program for the Bereaved Community."

"Heart to Heart with Michael: A Program for the Bereaved Community" features Michael Liben as the Host. Michael Liben is a bereaved father whose daughter, Liel, was born with a congenital heart defect. Sadly, Liel was born with autism and, as she aged, she developed

There are over 100 pages of free information on our website www.CongenitalHeartDefects.com ranging in topics from summer camps for CHD families, to hospitals treating children with CHDs, to an extensive list of resources for the CHD community. Josh Bernstein founded my website and had a vision for me that I didn't have for myself. I'll be forever indebted to him for his kind heart and for his belief that the CHD community deserved a voice and a platform to reach out to one another. It was indeed a mitzvah to start "Heart to Heart with Anna", and we've had a chance to change lives all over the world – and even to save a life, but that's a story for another day.

Anna Jaworski
Host of "Heart to Heart with Anna"
Producer of "Heart to Heart with Michael"
Owner of Baby Hearts Press, LLC
Immediate Past President of Heart Unite the Globe

www.CongenitalHeartDefects.com

The Heart Institute at the
UPMC CHILDREN'S HOSPITAL OF PITTSBURGH
Is *EXPANDING*!

With a strategic plan for growth and expansion, the Division of Cardiology within the Heart Institute of the UPMC Children's Hospital of Pittsburgh / University of Pittsburgh School of Medicine is recruiting additional faculty positions.

DIRECTOR OF PEDIATRIC ELECTROPHYSIOLOGY (EP) PROGRAM

For this leadership level position, the applicant should have expertise in the management of pediatric EP and adult congenital heart disease electrophysiology with excellent clinical, teaching and research skills. Clinical skills should include radiofrequency/cryoablation, transvenous pacemaker/AICD insertion, ventricular tachycardia ablation and complex congenital heart disease EP cases. In addition, he or she should have sufficient experience to serve as director of the EP program, working closely with division chief and hospital leadership to lead EP program development. Candidates must have completed a 4th year pediatric electrophysiology advanced fellowship. The well-established pediatric electrophysiology program is currently staffed by two experienced EP physicians and a dedicated EP RN. The EP team also works in close conjunction with the Heart-Vascular Institute of UPMC-Presbyterian adult hospital.

Two IMAGING FACULTY WITH EXPERTISE IN CARDIAC MRI or FETAL ECHOCARDIOGRAPHY

We are recruiting for two imagers with a focus on FETAL echocardiography or cardiac MRI. Completion of a 4th year imaging fellowship plus skill and independence in transesophageal echocardiography is a requirement. Faculty will join an outstanding imaging team: Including eleven echocardiographers, 16 pediatric sonographers in a highly productive echo lab – with over 18,000 echocardiograms, including over 1200 fetal echo's and 550 TEE's.

Echocardiography program covers Children's Hospital, Magee Women's hospital and multiple outreach sites and a robust tele-echo program. The cMR pediatric cardiology position is to join a strong partnership between cardiology and radiology. CHP has a state-of-the-art MRI facility with a new 3D lab and plans for growth with an additional cardiac MRI scanner. Further collaboration with the adult cardiology program for ACHD cMR program is anticipated. Candidates must be board-eligible/certified in pediatric cardiology.

ADULT CONGENITAL HEART DISEASE FACULTY

The Division of Cardiology at UPMC Children's Hospital of Pittsburgh / University of Pittsburgh School of Medicine is recruiting for additional faculty to join the Adult Congenital Heart Disease (ACHD) program. The well-established ACHD program is currently supported by one ACHD physician, 2 advanced practice providers, a dedicated RN, research coordinator and social worker. The applicant should have expertise in the management of adult congenital heart disease with prominent clinical, teaching and research skills. He or she will be working closely with division chief and hospital leadership to lead program development. Candidates must be board-eligible/certified in pediatric cardiology or adult cardiovascular diseases and in adult congenital heart disease.

INPATIENT CARDIOLOGY – HOSPITALIST

The division of cardiology is seeking a pediatric cardiologist with interest in inpatient cardiology – to join our pediatric cardiology hospitalist program, currently staffed by three hospitalists. Interest in developing clinical pathways, quality outcomes and cost-analysis research is preferred. Educational skill and passion are a must.

The Heart Institute provides comprehensive pediatric and adult congenital cardiovascular services to the tri-state region and consists of 26 pediatric cardiologists, 4 pediatric cardiothoracic surgeons, 7 pediatric cardiac intensivists and 9 cardiology fellows along with 12 physician extenders and a staff of over 100. The Heart institute is currently ranked 6th in the US News and World report ranking for pediatric cardiac programs and best in the region. The Cardiac surgical program is one of the top in the country, with a 3-star rating from Society of Thoracic Surgery (STS).

UPMC Children's Hospital of Pittsburgh has been named one of the top U.S. News & World Report's Best Children's Hospitals. Consistently voted one of America's most livable cities, Pittsburgh is a great place for young adults and families alike.

The positions come with a competitive salary and faculty appointment commensurate with experience and qualifications at the University of Pittsburgh School of Medicine. The University of Pittsburgh is an Equal Opportunity/Affirmative Action Employer. Interested individuals should forward letter of intent, curriculum vitae and three (3) letters of references. Informal inquiries are also encouraged.

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Medical News, Products & Information

Compiled and Reviewed by Kate Baldwin, Senior Editor of Special Projects

Newly Published Data Show Daxor Corporation's BVA-100 is Superior to Formula-Based Estimates of Blood Volume in Assessing Patients with Heart Failure

Daxor Corporation (NYSE MKT: DXR), an innovative medical instrumentation and biotechnology company focused on blood volume measurement, today announces the publication of an investigator-initiated study from Duke University and The Mayo Clinic demonstrating that despite the widespread use of formula-derived estimates of plasma volume in heart failure patients, these methods are inaccurate compared to measured volume using the company's BVA-100 blood volume measurement diagnostic. The study, "Calculated Estimates of Plasma Volume in Patients with Chronic Heart Failure – Comparison to Measured Volumes" was recently published in the *Journal of Cardiac Failure*.

"This study shows that indirect assessments of plasma volume or blood volume are limited by their inaccuracy. Our study shows that this is true for formula-based volume assessment or the measure of hemoconcentration and similarly poor correlation has previously been shown for the physical exam and even intra-cardiac pressure assessments," said Marat Fudim, MD, Fellow, Division of Cardiology, Duke University and one of the study authors.

"This study confirms that Daxor's technology of direct volume measurement is of the highest clinical utility in diagnosing fluid volume overload in heart failure patients," said Daxor's CEO, Michael Feldschuh. "Many physicians have relied on formula-based estimates of plasma volume overload. This study quantified the very poor correlation of these calculated estimates with direct measured volume of the patients, which could potentially hinder optimal treatment and result in re-hospitalization or even death."

In the study, plasma volume was measured using Daxor's BVA-100 in 110 patients with clinically stable chronic heart failure. These measurements were correlated using two different plasma volume estimation techniques. The first was the Kaplan-Hakim formula, which calculates blood volume using a formula calculating hematocrit relative to dry body weight. The second, the Strauss formula, estimates changes in plasma volume over time using hemoglobin and hematocrit measurement. The study ultimately showed neither formula demonstrated an accurate blood volume estimate compared to the BVA-100. These formulas varied in their accuracy between just 16 and 68% compared to Daxor's BVA-100, the acknowledged 'gold-standard' of volume measurement.

"This study is further evidence showing why BVA-guided treatment of heart failure leads to significantly better results in mortality and readmission. Proxy measures such as formulas, hemodynamics, and clinical assessment alone do not allow the individualization of care needed for optimal treatment of HF. Based on these results, we continue to work to educate physicians about direct blood volume measurement and to expand the availability of the BVA-100 across the US," said Jonathan Feldschuh, Daxor's Chief Technology Officer.

Daxor Corporation is an innovative medical instrumentation and biotechnology company. The company's mission is to help hospitals and physicians incorporate DAXOR's BVA-100 diagnostic to significantly improve the quality of patient care. For more information please visit our website at www.daxor.com.

Edwards' SAPIEN 3 Ultra Transcatheter Heart Valve Receives CE Mark

Edwards Lifesciences Corporation (NYSE: EW), the global leader in patient-focused innovations for structural heart disease and critical care monitoring, today announced it has received CE Mark for the SAPIEN 3 Ultra system for transcatheter aortic valve replacement in severe, symptomatic aortic stenosis patients.

Edwards Lifesciences logo. (PRNewsFoto/ Edwards Lifesciences Corporation)

"The SAPIEN 3 Ultra system incorporates enhancements to the valve, as well as a new delivery system, which are designed to further build on the exceptional outcomes of the SAPIEN 3 valve, which has shown extremely low rates of mortality and disabling stroke," said Larry L. Wood, Edwards' corporate vice president, transcatheter heart valves. "With the SAPIEN 3 Ultra system, we are building on our best-in-class performance to further advance and improve patient care."

The Edwards SAPIEN 3 Ultra system (valve sizes 20, 23 and 26mm) features enhancements to the valve, and a new delivery system and sheath. The valve features a heightened outer skirt designed to eliminate paravalvular leak. The SAPIEN 3 Ultra delivery system, which consists of a new low-profile 14-French Axela expandable sheath, introduces an "on balloon" design, removing the need for valve alignment during the procedure.

"The Edwards SAPIEN 3 Ultra system incorporates features designed to help simplify and improve the efficiency of the procedure," said John Webb, MD, Director of Interventional Cardiology and Cardiac Catheterization Laboratories at St. Paul's Hospital, Vancouver, and Professor of Cardiology at the University of British Columbia. "This design innovation represents a meaningful advancement over previous generations of this technology."

The SAPIEN 3 Ultra system builds on Edwards' decades of engineering and experience in the development of tissue heart valves, and the proven benefits of the Edwards SAPIEN valves.

As previously announced, Edwards will introduce the SAPIEN 3 Ultra system in Europe as part of a controlled rollout, which includes training, to ensure high procedural success of this advanced valve and delivery system.

The SAPIEN 3 Ultra system will not be launched at this time in Germany, as a result of the preliminary injunction that Boston Scientific chose to implement in the country. Edwards is disappointed in Boston Scientific's tactic to limit access of this new therapy. The German court will hold a full hearing on the merits of the dispute in mid-2019, and Edwards continues to believe that it will ultimately prevail in this matter. The SAPIEN 3 and CENTERA valve systems remain available in Europe. The German case pertains to a European patent that Boston acquired in 2017 (No. EP 2 949 292).

The SAPIEN 3 Ultra system is not approved in the United States; Edwards previously discussed that it anticipates it will receive U.S. Food and Drug Administration approval for the SAPIEN 3 Ultra system around the end of 2018.

Dr. Webb is a consultant to Edwards Lifesciences.

Edwards Lifesciences, based in Irvine, Calif., is the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, the company collaborates with the world's leading clinicians and researchers to address unmet healthcare needs, working to improve patient outcomes and enhance lives. For more information, visit www. www.Edwards.com.

PEDIATRIC CARDIOLOGY
YALE UNIVERSITY SCHOOL OF MEDICINE

The Section of Pediatric Cardiology at the Yale University School of Medicine and Yale New Haven Children's Hospital is recruiting a BE/BC pediatric cardiologist with major interest, expertise and experience in non-invasive cardiac imaging at the Assistant Professor level. The ideal candidate has received advanced training in advanced cardiac imaging with major interest, expertise and leadership in Cardiac Imaging at the Assistant or Associate Professor level.

This individual will join a division of dedicated faculty and advanced nursing practitioners to provide congenital heart care and cardiovascular imaging to patients throughout the state and region. The Section has an active research program with numerous opportunities for participation in basic, translational, and clinical research.

The successful candidates will receive a faculty appointment in the Yale Department of Pediatrics at the academic level commensurate with experience and qualifications. Yale University and the Department of Pediatrics offer an excellent benefits package. The greater New Haven and Connecticut Shoreline area offers an excellent quality of life with immense cultural and recreational opportunities.

Review of applications will begin immediately and will continue until the position is filled.

Interested applicants should submit Curriculum Vitae, Cover Letter and 3 references electronically to:

http://apply.interfolio.com/41531

Yale University is an equal opportunity, affirmative action employer. Women, minorities, persons with disabilities and protected veterans are encouraged to apply. Review of applications will begin immediately and continue until the position is filled.

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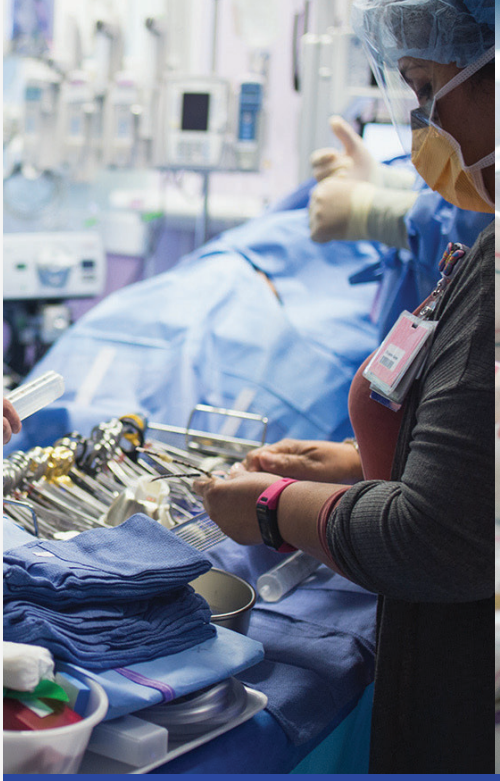
New Column Coming Soon - Contributors Needed

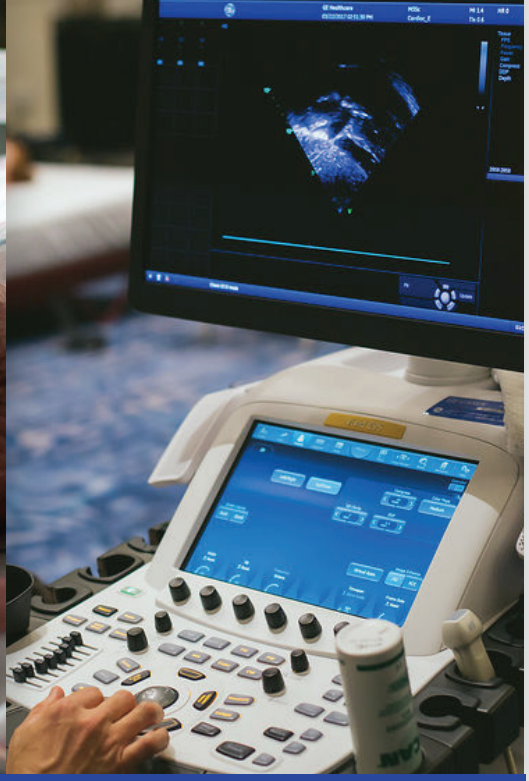
Have you ever had a colleague explain to you how they approach a certain issue or situation and your response was "I never thought of doing it like that"?

We all appreciate getting tips and tricks from our peers. Now it's your turn to share your insights with us!

Brief submission
- 400 words or less
- Useful tip or trick
- 1-2 figures

Contact Kate@cct.bz





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