CONGENITAL CARDIOLOGY TODAY

Timely News and Information for BC/BE Congenital/Structural Cardiologists and Surgeons

August 2016; Volume 14; Issue 8 North American Edition

IN THIS ISSUE

Interventional Cardiac MRI By Kanishka Ratnayaka, MD and Robert J. Lederman, MD ~Page 1

Double-Orifice Tricuspid Valve: Case Report with a Review

By DR Hakim Irfan Showkat, MBBCh, MD; Rekha Mishra, MD; Vinod Sharma, MD, DM; Lokesh Chandra Gupta, MD, DM; Sadaf Anwar, PGDCC ~Page 7

Medical News, Products & Information ~Page 12

Upcoming Medical Meetings

2016 Pediatric and Adult Congenital Cardiology Review Course Aug. 21-26, 2016; Dana Point, CA USA ce.mayo.edu/cardiovascular-diseases/ content/pediatric-and-adult-congenitalcardiology-review-course-2016general-session

Specialty Review in Pediatric Cardiology Course Sep. 19-23, 2016; Chicago, IL USA www.pediatriccardiology2016.com/

Sixth Annual Fetal Echocardiogaphy Symposium at UCLA Oct. 15, 2016; Los Angeles, CA, USA https://www.cme.ucla.edu/courses/ event-description? registration_id=124261

Visit www.CCT.bz and click Events tab for more meeting information

CONGENITAL CARDIOLOGY TODAY Editorial and Subscription Offices 16 Cove Rd, Ste. 200 Westerly, RI 02891 USA www.CongenitalCardiologyToday.com

Official publication of the CHiP Network

© 2016 by Congenital Cardiology Today Published monthly. All rights reserved.

> Recruitment ads on pages: 6, 10, 13, 15

Interventional Cardiac MRI

By Kanishka Ratnayaka, MD and Robert J. Lederman, MD

Interventional cardiologists specializing in Congenital Heart Disease (CHD) have grown adept at using what is available, whether devices or imaging modalities, to treat their patients. Nevertheless, while procedures increase in complexity, operators continue to rely on twodimensional imaging guidance of gray and white shadows, pattern recognition, and contrast angiography. Complex 3-dimensional spatial relationships are not addressed by current techniques, which can expose patients to significant radiation. Growing and developing children are particularly radiosensitive and carry a lifetime of oncologic risk. Chromosomal damage in the peripheral blood of children exposed to catheterization-related radiation has been detected.^{1,2} Interventional cardiac MRI (ICMR) guidance offers a potential solution.³

Cardiac MRI is a radiation-free, robust imaging modality used to: evaluate cardiac anatomy and function, measure volume and flow, measure tissue infarction, evaluate perfusion and viability, and allow for three-dimensional reconstruction of cardiac and vascular anatomy. Real-time cardiac MRI can provide excellent soft tissue imaging at approximately 5-15 frames/second in many simultaneous planes in any orientation. Combining invasive catheter hemodynamic measurements and MRI physiologic assessment power enables us to realize the full potential of catheterization diagnosis and intervention.

State of the Art

Diagnostic (Invasive)

In patients requiring invasive diagnostic studies, particularly serial studies (single ventricle, heart

transplant) the radiation-sparing argument may be most compelling; the cumulative X-ray dose may be significant.⁴ MRI offers a radiation and contrastfree alternative to those patients who may benefit most from the wealth of structural, functional, and biochemical information MRI can provide. In some critical instances, such as calculating pulmonary vascular resistance in patients with pulmonary artery hypertension and undergoing staged surgical palliation, MRI catheterization evaluation can be superior to the current methods.⁵ While MRI guided catheterization emerged over a decade ago,⁶ it has been non-glamourous, incremental workflow and user interface enhancements that have fueled steady progress. The worldwide experience approaches onethousand patients. An understandable critique of ICMR is the lack of compatible catheter and guidewire tools, but for invasive diagnostic studies, off-the-shelf balloon endhole wedge catheters are sufficient (Figure 1).

A commercially available MR safe and visible guidewire would enable MRI guidance for most patients requiring diagnostic cardiac catheterization. A polymer guidewire is undergoing final stage clinical testing in Europe,⁷ and safe metallic guidewires are approaching clinical testing.⁸ Another typical critique is that MRI catheterization is timeconsuming when compared to current standard X-ray catheterization. In our experience, simple workflow enhancements and experience have substantially decreased time to approximately 15 minutes per hemodynamic condition tested.

The majority of worldwide experience has been performed at three centers (King College London, Great Ormond Street, and National Institutes of Health), but clinical progress has increased attention. Attendance at the Society for Cardiovascular Magnetic Resonance

CONGENITAL CARDIOLOGY TODAY

CALL FOR CASES AND OTHER ORIGINAL ARTICLES

Do you have interesting research results, observations, human interest stories, reports of meetings, etc. to share? Submit your manuscript to: RichardK@CCT.bz



We are committed to the lifetime management of congenital heart disease.

Transcatheter and Surgical Heart Valves

RVOT Conduits

Ablation Technologies

ICDs

Oxygenators and Filters

Cannulae

Pacemakers

Pulse Oximetry Monitoring for CCHD Screening

3rd Generation PFO, ASD, and PDA Occluders^{*}

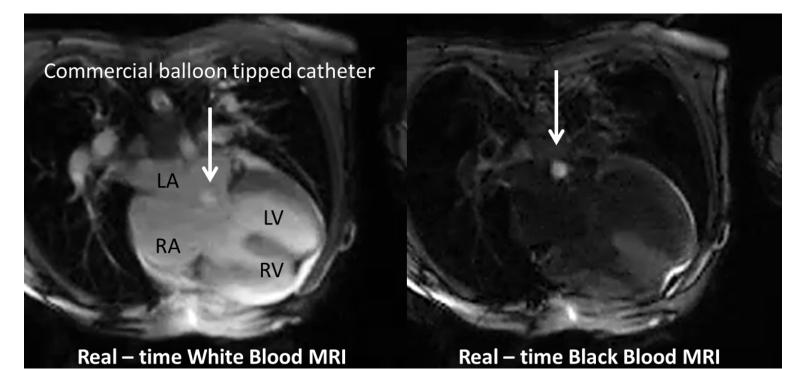
Cerebral/Somatic Monitoring

*These products are not available in the US.

Melody-TPV.com Medtronic | Minneapolis, MN 55432-5604 Toll-free: 1 (800) 328-2518 UC201601683 EN ©2015 Medtronic. All rights reserved. 08/2015

INNOVATIVE TECHNOLOGIES. EVERY STEP OF THE WAY.







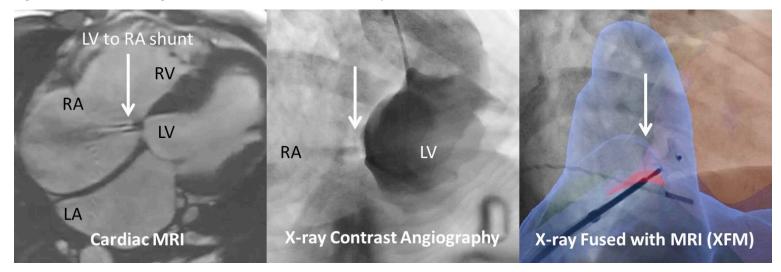


Figure 2. X-ray fused with MRI (XFM) guided device closure of left ventricle to right atrium shunt.

(www.scmr2017.org) annual scientific sessions "interventional cardiac MRI" one day pre-conference has steadily grown with over one hundred participants each of the last three years. In the past year, the National Institutes of Health (NIH) has hosted two hands-on MRI catheterization courses for eighty guests coming from twenty centers in the North America and Europe; future training courses are being scheduled for interested centers.

X-ray Fused with MRI

While MR-guided intervention remains the eventual goal, XFM (X-ray fused with MRI) is an interim step that harnesses the soft tissue information from MRI to guide anatomically and spatially complex procedures. It can be

viewed as a step toward wholly MRI-guided intervention. XFM allows operators to take advantage of the superiority of MRI soft tissue visualization in the familiar working environment of the fluoroscopy suite. The goal of fusion imaging is to enhance the capabilities of X-ray interventional procedures by co-registering MRI-derived roadmaps, to depict soft-tissue features not evident on Xray. MRI-derived cardiac regions of interest are manually segmented and presented to the operator as image overlay on live X-ray fluoroscopy. Several groups have published on XFM radiation/contrast sparing and enhanced operator confidence in clinical cases.9,10 Other groups have shown that registration of static MRI images to live X-ray fluoroscopy takes little time¹¹ with minimal target registration error.¹² Nevertheless, loss

of operator confidence in pre-acquired roadmaps outdated by cardiac and respiratory motion as well as stiff wires and bulky device/delivery systems, continues to be a challenge. XFM may prove most useful in guidance of unconventional interventional Congenital Heart Disease procedures¹³ (Figure 2).

Intervention

Real-time MRI-guided cardiovascular intervention promises superb tissue imaging in multiple views and any orientation to guide traditional and emerging interventional procedures. Pre-clinical MRI guided cardiac intervention has ranged from aortic stenting¹⁴ to aortic endografting to peripheral artery recanalization.¹⁵ MRI guided catheter

MRI Cavopulmonary Shunt

MRI Transthoracic Left Atrial Access

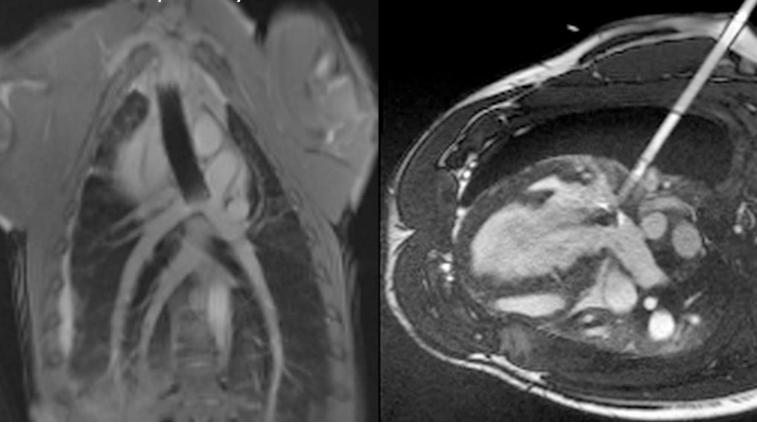


Figure 3. Real time MRI guided percutaneous cavopulmonary shunt and transthoracic left atrial access.

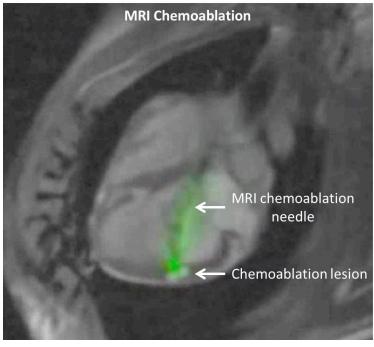


Figure 4. Real time MRI guided chemoablation.

intervention in patients has been limited.^{16,17} Progress in ICMRguided intervention continues to encounter inadequate MR safe and visible catheter devices. Increasing numbers of small companies focused on delivery of such devices is encouraging.^{7,18} Interventional cardiac MRI's true potential is in providing surgical-type visualization to enable closed chest, off-bypass novel cardiovascular intervention. One representative example is percutaneous navigation of extra-vascular space under direct (MRI) visualization to join vessels as our surgical colleagues do today with surgical shunts.¹⁹ ICMR provides complete thoracic context imaging that may permit new access routes to the heart for cardiac intervention such as from the patient's back²⁰ (Figure 3).

MR Invasive Electrophysiology

The rationale of MRI guidance for invasive electrophysiology is straight forward - direct observation of myocardial injury during tissue ablation would be attractive to guide procedural conduct; this premise has been explored by a number of groups in animals and most recently in clinical studies.²¹ MRI safe and visible electrophysiology device development has enjoyed tremendous recent progress. An MRI safe and visible integrated catheter mapping and ablation system has been used in clinical translation.²² The device advancement in MRI guided electrophysiology will likely permit significant progression in the coming years. Perhaps more exciting, an alternative approach to tissue ablation using injected caustic agents (acetic acid or ethanol), instead of radiofrequency ablation, exploits the unique capabilities of MRI to map and target arrhythmia substrates and interactively visualize irreversibly necrotic ablation lesions²³ (Figure 4).

MRI Inspired, X-Ray Guided

Cardiac MRI provides operators with a "big picture" view of the entire thoracic context with impressive anatomic detail. Real-time imaging is presented in multiple slices and any orientation that can be manipulated quickly and easily. This ability allows an appreciation of

4

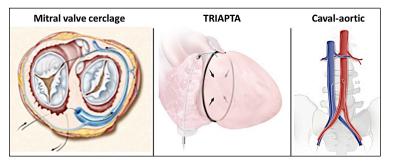


Figure 5. MRI inspired novel percutaneous procedures: mitral valve cerclage, transatrial intrapericardial tricuspid annuloplasty (TRIAPTA), caval-aortic access.

anatomic relationships that is difficult to capture with traditional imaging. Pursuing MRI guided cardiac intervention has inspired innovative X-ray guided procedures. One novel X-ray procedure is percutaneous mitral valve repair by accessing the coronary sinus and tunneling through the myocardium to create a tensioned cerclage loop.²⁴ Exiting the right atrial appendage to deploy a circumferential loop in the pericardium to reduce tricuspid regurgitation is another.²⁵ Exiting the inferior vena cava and entering the aorta to permit vascular entry of large catheter delivery systems and devices is yet another example.²⁶ Clinical translation of caval-aortic access continues to grow. To date, there have been 204 patients at 27 centers (Figure 5).

Conclusions

Minimally invasive and catheter-based therapies are targeting increasingly complex pathologies. This agenda requires better procedural image guidance. Interventional cardiac MRI provides a range of potential radiation-sparing opportunities for conventional and novel therapy.

References

- Andreassi MG, Ait-Ali L, Botto N, Manfredi S, Mottola G, Picano E. Cardiac catheterization and long-term chromosomal damage in children with congenital heart disease. European heart journal 2006;27:2703-8.
- Beels L, Bacher K, De Wolf D, Werbrouck J, Thierens H. gamma-H2AX foci as a biomarker for patient X-ray exposure in pediatric cardiac catheterization: are we underestimating radiation risks? Circulation 2009;120:1903-9.
- Ratnayaka K, Faranesh AZ, Guttman MA, Kocaturk O, Saikus CE, Lederman RJ. Interventional cardiovascular magnetic resonance: still tantalizing. J Cardiovasc Magn Reson 2008;10:62.
- Johnson JN, Hornik CP, Li JS et al. Cumulative radiation exposure and cancer risk estimation in children with heart disease. Circulation 2014;130:161-7.
- Muthurangu V, Atkinson D, Sermesant M et al. Measurement of total pulmonary arterial compliance using invasive pressure monitoring and MR flow quantification during MR-guided cardiac catheterization. American journal of physiology 2005;289:H1301-6.
- Razavi R, Hill DL, Keevil SF et al. Cardiac catheterisation guided by MRI in children and adults with congenital heart disease. Lancet 2003;362:1877-82.

- 7. Kos S, Huegli R, Hofmann E et al. Feasibility of real-time magnetic resonance-guided angioplasty and stenting of renal arteries in vitro and in Swine, using a new polyetheretherketone-based magnetic resonance-compatible guidewire. Invest Radiol 2009;44:234-41.
- Basar B, Rogers T, Ratnayaka K et al. Segmented nitinol guidewires with stiffness-matched connectors for cardiovascular magnetic resonance catheterization: preserved mechanical performance and freedom from heating. J Cardiovasc Magn Reson 2015;17:105.
- Abu Hazeem AA, Dori Y, Whitehead KK et al. X-ray magnetic resonance fusion modality may reduce radiation exposure and contrast dose in diagnostic cardiac catheterization of congenital heart disease. Catheter Cardiovasc Interv 2014;84:795-800.
- Glockler M, Halbfabeta J, Koch A, Achenbach S, Dittrich S. Multimodality 3D-roadmap for cardiovascular interventions in congenital heart disease--a single-center, retrospective analysis of 78 cases. Catheter Cardiovasc Interv 2013;82:436-42.
- Tomkowiak MT, Klein AJ, Vigen KK et al. Targeted transendocardial therapeutic delivery guided by MRI-x-ray image fusion. Catheter Cardiovasc Interv 2011;78:468-78.
- 12. Dori Y, Sarmiento M, Glatz AC et al. X-ray magnetic resonance fusion to internal markers and utility in congenital heart disease catheterization. Circ Cardiovasc Imaging 2011;4:415-24.
- Grant EK, Faranesh AZ, Cross RR et al. Image Fusion Guided Device Closure of Left Ventricle to Right Atrium Shunt. Circulation 2015;132:1366-7.
- 14. Raval AN, Telep JD, Guttman MA et al. Real-time magnetic resonance imaging-guided stenting of aortic coarctation with commercially available catheter devices in Swine. Circulation 2005;112:699-706.
- 15. Raval AN, Karmarkar PV, Guttman MA et al. Real-time magnetic resonance imaging-guided endovascular recanalization of chronic total arterial occlusion in a swine model. Circulation 2006;113:1101-7.
- Krueger JJ, Ewert P, Yilmaz S et al. Magnetic resonance imagingguided balloon angioplasty of coarctation of the aorta: a pilot study. Circulation 2006;113:1093-100.
- Tzifa A, Krombach GA, Kramer N et al. Magnetic Resonance-Guided Cardiac Interventions Using Magnetic Resonance-Compatible Devices: A Preclinical Study and First-in-Man Congenital Interventions. Circ Cardiovasc Interv 2010.
- Sommer P, Grothoff M, Eitel C et al. Feasibility of real-time magnetic resonance imaging-guided electrophysiology studies in humans. Europace 2013;15:101-8.
- Ratnayaka K, Rogers T, Schenke WH et al. Magnetic Resonance Imaging-Guided Transcatheter Cavopulmonary Shunt. JACC Cardiovasc Interv 2016;9:959-70.
- Rogers T, Ratnayaka K, Schenke WH et al. Fully percutaneous transthoracic left atrial entry and closure as a potential access route for transcatheter mitral valve interventions. Circ Cardiovasc Interv 2015;8:e002538.
- 21. Bhagirath P, van der Graaf M, Karim R et al. Interventional cardiac magnetic resonance imaging in electrophysiology: advances toward clinical translation. Circ Arrhythm Electrophysiol 2015;8:203-11.
- 22. Hilbert S, Sommer P, Gutberlet M et al. Real-time magnetic resonance-guided ablation of typical right atrial flutter using a combination of active catheter tracking and passive catheter visualization in man: initial results from a consecutive patient series. Europace 2016;18:572-7.



For more information: Sara Meslow, Executive Director Camp Odayin 651.351.9185 – phone; 651.351.9187 – fax sara@campodayin.org www.campodayin.org



- 23. Rogers T, Mahapatra S, Kim S et al. Transcatheter Myocardial Needle Chemoablation During Real-Time Magnetic Resonance Imaging: A New Approach to Ablation Therapy for Rhythm Disorders. Circ Arrhythm Electrophysiol 2016;9.
- Kim JH, Kocaturk O, Ozturk C et al. Mitral cerclage annuloplasty, a novel transcatheter treatment for secondary mitral valve regurgitation: initial results in swine. J Am Coll Cardiol 2009;54:638-51.
- Rogers T, Ratnayaka K, Sonmez M et al. Transatrial intrapericardial tricuspid annuloplasty. JACC Cardiovasc Interv 2015;8:483-91.
- Greenbaum AB, O'Neill WW, Paone G et al. Caval-aortic access to allow transcatheter aortic valve replacement in otherwise ineligible patients: initial human experience. J Am Coll Cardiol 2014;63:2795-804.

ССТ

Biographical Sketch

Dr. Kanishka Ratnayaka is an interventional pediatric cardiologist at Rady Children's Hospital-University of California San Diego. His clinical practice focuses on congenital and structural heart interventions. Dr. Ratnayaka has worked in research collaboration with the National Heart, Lung, and Blood Institute and the National Institutes of Health on interventional cardiovascular MRI for 10 years. Dr. Ratnayaka's other research work includes device development, novel procedures for congenital heart disease, bioresorbable stents for pediatric use.

Corresponding Author

Kanishka Ratnayaka, MD Department of Cardiology Rady Children's Hospital 3020 Children's Way San Diego, CA 92123 USA Tel. +1.858.966.5855 kratnayaka@rchsd.org

Robert J. Lederman, MD Cardiovascular and Pulmonary Branch Division of Intramural Research National Heart Lung and Blood Institute, Bethesda, MD USA

Washington University in St.Louis

SCHOOL OF MEDICINE

Pediatric Cardiac Intensivist Faculty Positions

The Divisions of Pediatric Critical Care Medicine and Pediatric Cardiology in the Department of Pediatrics at Washington University School of Medicine seek applicants for faculty positions in the Cardiac Intensive Care Unit (CICU) at Saint Louis Children's Hospital (SLCH). The positions include an appointment at appropriate rank in the Washington University School of Medicine. Successful candidates will serve on a team consisting of eleven attending cardiac intensivists and will also provide consultation in the neonatal and pediatric intensive care units at SLCH. Participation in house staff and fellow education as well as clinical, translational or laboratory-based investigators at the School of Medicine and other departments throughout Washington University.

The Saint Louis Children's and Washington University Heart Center is a highly ranked pediatric cardiac program and includes 3 pediatric cardiothoracic surgeons, 18 pediatric cardiologists, 10 pediatric cardiac intensivists (1 dual boarded in Critical Care and Cardiology, 5 CCM boarded with advanced training in CICU, 2 Cardiology boarded with advanced training in CICU, and 2 anesthesiologists with advanced training in CICU), and 5 cardiac anesthesiologists who provide clinical care, teach, and perform clinical, translational and basic research. See the following links for details on the Divisions of Pediatric Cardiac Critical Care Medicine, Pediatric Cardiology and the section of Pediatric Cardiothoracic Surgery:

http://pediatrics.wustl.edu/criticalcare/Home.aspx http://pediatrics.wustl.edu/cardiology/Home.aspx http://cardiothoracicsurgery.wustl.edu/Pediatric

Our CICU is a state-of-the-art, 16-bed, dedicated unit that provides all forms of cardiovascular intensive care for children and adults with congenital and acquired cardiovascular diseases. Approximately 400 patients are admitted to the CICU per year, with 60% surgical admissions. Patients range in age from premature neonates to adults, and patient complexity and acuity are amongst the highest in the nation. A full range of clinical services is available, including mechanical circulatory support for heart failure patients with ventricular assist devices (Thoratec, Berlin Heart, HeartMate II, HeartWare), the paracorporeal lung assist device system (Novalung and Quadrox oxygenators) and ECMO. We have an internationally renowned heart failure/transplant program and perform approximately 20 heart transplants each year. Critically ill pre- and post- transplant patients are managed in the CICU.

Please visit our website at http://hr.wustl.edu to view a summary of benefits.

The ideal candidate should be board certified/eligible in Pediatric Critical Care Medicine, Pediatric Cardiology, or Pediatric Anesthesia and have completed advanced training in pediatric cardiovascular intensive care (either via dual fellowships in pediatric cardiology and critical care medicine or via completion of an advanced cardiovascular intensive care fellowship).

Interested candidates should send a letter of intent and curriculum vitae to:

Avihu Z. Gazit, M.D., Medical Director, Cardiac Intensive Care, Washington University in Saint Louis, 1 Children's Place, Campus Box 8116, Saint Louis, MO 63110. Email: gazit a@kids.wustl.edu

Washington University is an equal opportunity employer and is committed to increasing the diversity of its faculty. It welcomes nominations of and applications from women and members of minority groups, as well as others who would bring additional dimensions to the university's research, teaching and clinical missions. All qualified applicants will receive consideration for employment without regard to sex, race, ethnicity, protected veteran, or disability status.



Archiving Working Group

International Society for Nomenclature of Paediatric and Congenital Heart Disease ipccc-awg.net

Double-Orifice Tricuspid Valve: Case Report with a Review

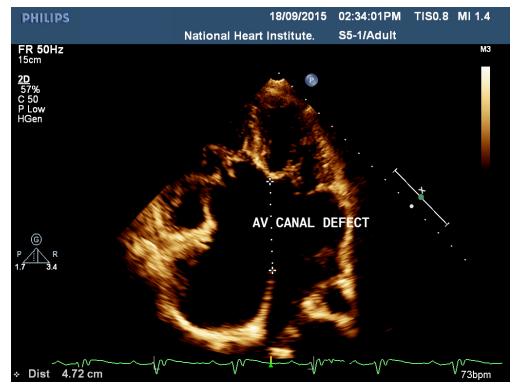
By DR Hakim Irfan Showkat, MBBCh, MD; Rekha Mishra, MD; Vinod Sharma, MD, DM; Lokesh Chandra Gupta, MD, DM; Sadaf Anwar, PGDCC

Duplication of an atrioventricular valve is an extremely uncommon congenital anomaly that generally affects the mitral rather than the tricuspid valve.^{1–7} The isolated occurrence of this condition seems extremely rare and, in most cases, it is associated with other congenital cardiac malformations that determine a patient's outcome. Even though the Double-Orifice Tricuspid Valve (DOTV) is a rare anomaly and can be easily missed if the physician is unaware of it; it is necessary to scan for an accessory orifice in all patients in whom the atrioventricular valve appears to be small or excessively large.

Case

An 18-year-old girl presented to Outdoor Medical Department with a history of palpitations with mild breathlessness with NYHA Class II-III for a few months. On examination, she had a lean and thin build with cardiac examination showing left parasternal heave and normal S1 with split S2. There was a a systolic murmur well heard at apex. Electrocardiography showed sinus tachycardia with right bundle branch block. Two-D Echocardiography revealed Acyanotic Congenital Heart Disease, a Partial-Atrioventricular Canal Defect, a Double-Orifice Tricuspid Valve, gooseneck deformity of LV outflow and a large Primum ASD measuring 4.1 cm with left-to-right shunt. A right atrium and ventricle were markedly dilated with

"Even though the Double-Orifice Tricuspid Valve (DOTV) is a rare anomaly and can be easily missed if the physician is unaware of it, it is necessary to scan for an accessory orifice in all patients in whom the atrioventricular valve appears to be small or excessively large."





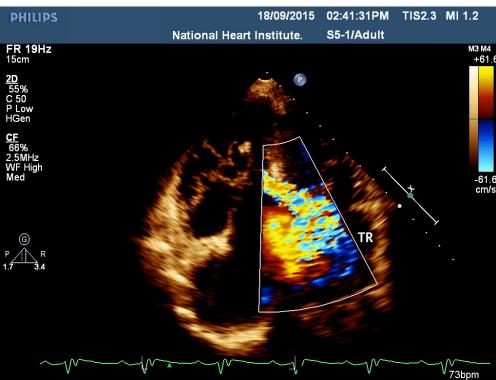
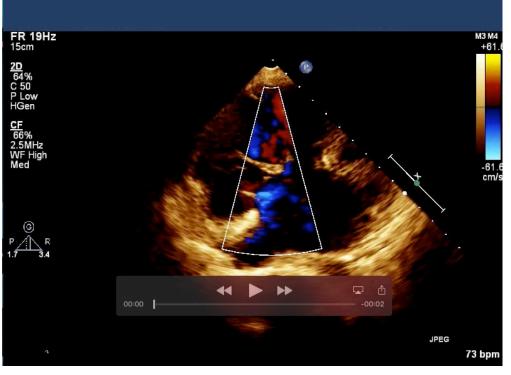


Figure 2.

redundant tricuspid valve. There were two orifices of the tricuspid valve with severe regurgitation from one of the valves (valve towards the interventricular septum), low pressure TR jet was eccentric and directed into the left atrium (Figures 1, 2; Video1).



Watch video at: http://www.congenitalcardiology.com/V.mov

The patient was advised to get admitted, but was lost to follow-up.

Discussion

The division of an atrioventricular valve into two similar and functioning units is described as a duplication of the valvular apparatus or a double-orifice valve. Although this anomaly is well known in the mitral position, duplication of the tricuspid valve is rare. In these situations, it is the presence of an accessory subvalvular component that distinguishes true duplication from a simple fenestration of the valvar leaflet.^{1–7}

DOTV is rare and is usually associated with other congenital anomalies, most commonly with septal defects (45%), malformations of the mitral valve, Ebstein Anomaly, and Tetralogy of Fallot.^{3,4,8} To the best of our knowledge, of the 42 reported cases in the literature, only six were isolated.⁴

The first classification of DOTV was given by Hartmann in 1937.^{1–7} The L-type of defect was characterized by two ostia of unequal sizes, the B-type of defect had two equal-sized ostia without an independent set of chordae and a papillary muscle for each ostia and S-type anomalies had two similar sized ostia and each orifice had an independent set of chordae and a papillary muscle.¹ This classification was revised by Sanchez et al. into three types:

- (1) Commissural-type (Hartmann's type L) in which the accessory orifice is at the end of a valve commissure and its subvalvar apparatus is the normal one for that commissure, though sometimes accessory papillary muscles maybe present;
- (2) Central-type (Hartmann's types B and S) where a fibrous band divides the atrioventricular orifice into either equal or unequal parts as was seen in our case;
- (3) Hole-type, in which the accessory orifice is a hole in a cusp.² This form of double-valve orifice is to be distinguished from a simple fenestration or cleft which has no subvalvar apparatus.

The use of magnetic resonance imaging is helpful in diagnosis as well as its functional significance.⁶

"DOTV is rare and is usually associated with other congenital anomalies, most commonly with septal defects (45%), malformations of the mitral valve, Ebstein Anomaly, and Tetralogy of Fallot.^{3,4,8} To the best of our knowledge, of 42 reported cases in the literature, only six were isolated.⁴"

No grants or funds were received from any foundation for this publication.

Bibliography

- Hartmann B. Zur Lehre der Verdoppelung des linken Atrioventrikularostiums. Arch Kreisl-Forsch 1937;1:286.
- Sanchez Carlos A, Rabago P, Sokolowski M. Duplication of the tricuspid valve. Br Heart J 1967;29:943-6.
- Tutarel O, Westhoff BM. The doubleorifice tricuspid valve: a review. J Heart Valve Dis 2007;16:508–10.
- Zhang J, Ma WG, Pan SW. Surgical management of double-orifice tricuspid valve. Journal of Cardiac Surgery 2011;26:425–8.
- Miyamura H, Matsukawa T, Maruyama Y, Nakazawa S, Eguchi S. Duplication of the tricuspid valve with Ebstein anomaly. Jpn Circ J 1984; 48:336–8.
- Quiroga JLS, Alvarez JR, Siebert MF, Carrewio CI, Duran D, Bengochea JBG. Duplication of the right atrioventricular orifice in a patient with common atrium and mitral cleft. Texas Heart Inst J 1988;15:68–71.
- Yoo SJ, Houde C, Moes CA, Perrin DG, Freedom RM, Burrows PE. A case report of double-orifice tricuspid valve. Int J Cardiol 1993;39:85–7.

8



American Academy of Pediatrics Section on Cardiology & Cardiac Surgery in collaboration with the Society of Pediatric Cardiology Training Program Directors

pediatriccardiology2016.com



PROVEN PERFORMANCE. SIMPLY DELIVERED.

MELODY TPV DELAYS CONDUIT REPLACEMENT

98% Patients at 2 years

91% Patients at 5 years

Data from US IDE Study



Melody[®] Transcatheter Pulmonary Valve Therapy

Melody-TPV.com Medtronic | Minneapolis, MN 55432-5604 Toll-free: 1 (800) 328-2518

UC201601525a EN ©2015 Medtronic. All rights reserved 08/2015



Important Labeling Information for United States

Indications: The Melody TPV is indicated for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted AND
- Dysfunctional RVOT conduits with a clinical indication for intervention, AND:
 - regurgitation: ≥ moderate regurgitation, AND/OR
 - stenosis: mean RVOT gradient ≥ 35 mm Hg

Contraindications: None known.

Warnings/Precautions/Side Effects

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

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

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

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

For additional information, please refer to the Instructions For Use provided with the product.

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

Melody is a registered trademark of Medtronic.

Medical City Children's Hospital

The City Just for Kids Medical Director and Staff Level Pediatric Cardiovascular Critical Care Physicians General Pediatric Cardiologist Pediatric Cardiac Interventionalist Geneticist

Medical City Children's Hospital has an unwavering focus on patient care and offers world-renowned excellence in comprehensive pediatric services. Since 1996, our specialists haven't let anything distract them from serving children. As a result, we've helped thousands of children from more than 75 countries. We are a comprehensive children's hospital with specialists in virtually every pediatric subspecialty. Medical City is the only facility in north Texas where fetal diagnosis, maternal, neonatal and pediatric transport, high risk delivery stabilization in the NICU, corrective surgery, state of the art postoperative monitoring and care and long term follow-up of patients with complex congenital heart disease can all be delivered under one roof.

The Congenital Heart Surgery Unit (CHSU) accommodates around 400 children annually who undergo heart operations performed by Dr. Eric Mendeloff. 30% of our cases are neonates and 58% are under the age of 2 years. Cases range in complexity from palliation of hypoplastic left heart syndrome to closure of atrial and ventricular septal defects. Highly specialized care in the CHSU is provided by subspecialitytrained physicians and an excellent group of long term nurses and respiratory therapists. This focus on pediatric cardiac critical care has resulted in superlative patient outcomes that exceed national norms. The heart program's success has attracted referrals from across the country. With the addition of a second Congenital Heart Surgeon to our already robust program, we anticipate growth that will require a sixth member for our CICU team in addition to our need for a Medical Director of the Unit. Preferred candidate for the director level position will possess leadership attributes with evidenced experience, along with a strong clinical skill set.

All candidates are preferred to be BC/BE in Pediatric Cardiology and Pediatric Critical Care or boarded in one of these with additional training in Pediatric Cardiac Critical Care. Those with certification in one discipline and solid experience in the alternate subspecialty should also apply. Positions are employed and offer a competitive salary and excellent benefits packet.

Our hospital has immense current capabilities and is positioned to grow.

Kathy Kyer National Director of Pediatric Subspecialty Recruitment Kathleen.Kyer@HCAHealthcare.com 937.235.5890



8. Anil SR, Rao SG, Kumar RK. Duplication of the tension apparatus of the Tricuspid valve. Cardiol Young. 2003;13:106-8. [PubMed].

ССТ

Dr. Showkat is Editor for World Journal of Clinical Cases, and also writes for many other international journals. He has published more than 30 articles and written book chapters on different topics in the field.

Corresponding Author



DR Hakim Irfan Showkat, MBBCh, MD, DNB Cardiology Scholar National Heart Institute New Delhi. India docirfanshahi512@gmail.com 09990390305/09419028326

Rekha Mishra, MD Consultant Non-invasive Cardiology National Heart Institute New Delhi. India rekhacare@rediffmail.com

Vinod Sharma, MD, DM Head & Vice-CEO National Heart Institute New Delhi. India drvs1994@rediffmail.com

Lokesh Chandra Gupta, MD, DM Consultant Cardiology National Heart Institute New Delhi, India lokeshcg@gmail.com

Sadaf Anwar, PGDCC Senior Resident Fortis Escortis Heart Institute New Delhi, india sadaf4u@gmail.com

CHIP NETWORK

CONGENITAL HEART INTERNATIONAL PROFESSIONALS

Get involved with CHiP (Congenital Heart International **Professionals Network)**

We need your help:

- · Finding news stories.
- · Creating journal watch.
- Keeping track of upcoming meetings.
- Building our presence on Linkedin, Facebook, and Twitter.
- Creating more value for our readers/ subscribers.
- Engaging our partner organizations.
- · Fundraising to support our activities.

Step up! Here's how to contact us:

www.chipnetwork.org/Contact

We'd like to know WHO you are, WHERE you are, and WHAT you do.

Please go to www.chipnetwork.org and let us know more about you. It only takes two minutes. Then we'll be able to send you messages targeted to your interests.

I hope you will consider joining the CHiP Network and help foster a strong congenital heart care community.

Sincerely,

Gary Webb, MD **CHiP Network** 215-313-8058 gary.webb@cchmc.org



The CHIP Network, the Congenital Heart Professionals Network, is designed to provide a single global list of all CHD-interested professionals.



SAVE THE DATE JAN. 16-19, 2017 LOEWS MIAMI BEACH HOTEL





LIVE CASE DEMONSTRATIONS • ABSTRACT SESSIONS • "MY NIGHTMARE CASE IN THE CATH LAB" • HOT DEBATES • WORKSHOPS • SMALLER BREAKOUT SESSIONS •



Featuring: Barry Maron, MD Martin Maron, MD Harry Lever, MD

October 21-22, 2016 **Courtyard Downtown Marriot** Boston, MA www.4hcm.org

Carolyn Ho, MD Lisa Salberg N.A. Mark Estes, MD Mark Link. MD

Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

EchoPixel Medical Virtual Reality System Ready for Clinical Implementation -

Breakthrough 3D Imaging Company Offers a New Approach to Surgical Planning and Imaging Diagnostics, Advancing Patient Care with Lifelike Virtual Reality of Patient Anatomy

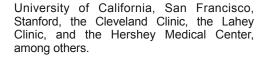
Marketwire - On July 21st EchoPixel announced that its breakthrough medical imaging solution is now available to clinical users in collaboration with the HP Zvr Interactive Virtual Reality Display and workstation. The HP Zvr, powered by zSpace technology, and the HP Z440 Workstation are customized to EchoPixel's True 3D Viewer cleared regulatory requirements, providing a turnkey solution for both diagnostic imaging and surgical planning.

The True 3D system is a powerful new tool for doctors to make reading medical images more intuitive, help physicians reach their diagnosis, and assist in the planning of complex surgical procedures. The partnership will capitalize on EchoPixel's exciting progress in the study of new clinical applications at prominent beta test sites, and HP's global relationships with medical institutions, to accelerate adoption of virtual reality technology in the medical imaging field.

Using True 3D, physicians can view and interact with images gathered from CT and MR data the way they would with real physical objects. The system enables radiologists, cardiologists, pediatric cardiologists, and interventional neuroradiologists (among others) to see patient-specific anatomy in an open 3D space.

"I believe our partnership with HP will be a formative moment in the development and distribution of virtual reality in the medical imaging space," said Ron Schilling, CEO of EchoPixel. "HP has a long record of leadership in this industry, a strong network of partnerships, and a powerful commitment to their customers. We believe that virtual reality is the next revolution in medical imaging, and with our FDA cleared system, together we can deliver this technology into hospitals, clinics, and medical schools around the world."

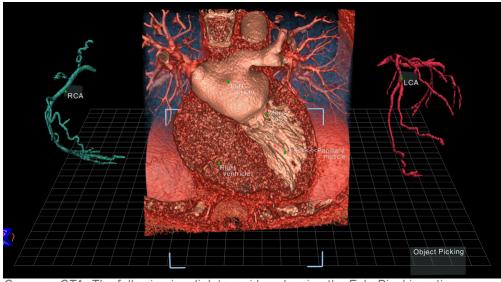
Since its market introduction in March 2015, EchoPixel's True 3D has generated excitement in the medical imaging community, with its promise to transform the ways that doctors work, students learn, and patients understand their unique anatomy. It is being used in clinical, educational, and research settings around the world, including the



"Our customers rely on HP to help transform lives through innovative solutions," said Reid Oakes, senior director, Worldwide Healthcare, HP Inc. "By working with valued partners like EchoPixel and leveraging emerging technologies like virtual reality, we can rethink how technology can blend the physical and digital worlds to change the face of healthcare."

For further information, or to order EchoPixel True 3D powered by HP, visit www.echopixeltech.com or www.hp.com/go/ healthcare.

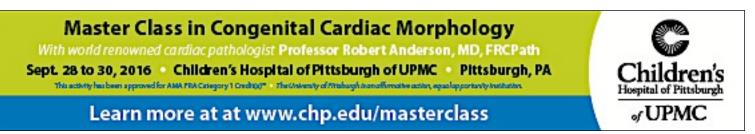
EchoPixel's FDA-cleared True 3D system uses existing medical image datasets to create virtual reality environments of patientspecific anatomy, allowing physicians to view and dissect images just as they would real, physical objects. The technology aims to make reading medical images more intuitive, help physicians reach diagnosis, and assist in surgical planning. Leading institutions, including Stanford University, the University of California, San Francisco, the Cleveland Clinic, the Lahey Clinic, and more are using True 3D in clinical and research applications.



Coronary CTA. The following is a link to a video showing the EchoPixel in action https://vimeo.com/138355486

First Clinical Use of Bioabsorbable Vascular Grafts in Children Shows Promise

Newswise - Current cardiovascular valve or blood vessel implants are generally associated with a number of complications, have limited efficacy over time, and may necessitate repeated interventions over a patient's lifetime, especially when implanted in a young child. In a presentation at the 96th AATS Annual Meeting, a team of surgeons from the Bakoulev Center for Cardiovascular Surgery Moscow, report their success with implantation of bioabsorbable vascular grafts used to correct a congenital cardiac malformation. Over time, the grafts are designed to biodegrade as a patient's own cells and proteins reconstitute natural functioning tissue, thus reducing permanent implantrelated complications.



Bioabsorbable heart valves or blood vessels are designed to harness the body's innate healing process, enabling the natural restoration of complex body parts as the synthetic graft is absorbed. At the 96th AATS Annual Meeting, surgeons from the Bakoulev Center for Cardiovascular Surgery, Moscow, report the results of implantation of bioabsorbable vascular grafts placed into five children born with serious cardiovascular anomalies. According to the investigators, this is the first-ever clinical trial of a bioabsorbable cardiovascular device.

"The positive results of the study provide hope for a new therapeutic approach in cardiovascular valve replacement called Endogenous Tissue Restoration (ETR). This is potentially a revolutionary approach to regenerative medicine in cardiovascular treatment," says lead investigator Leo Bockeria, MD.

The procedure was designed to help children born with single ventricle anomalies, a term used to describe a group of cardiac defects that shares the common feature that only one of two ventricles functions adequately. This can be due to lack of a heart valve, abnormal pumping ability of the heart, or other problems. The surgical procedure, known as a Fontan procedure, involves diverting the venous blood from the right atrium to the pulmonary arteries without passing through the area of the right ventricle.

In this prospective, single-center feasibility study, five children aged 4.5 to 12.5 years born with a single-ventricle congenital malformation were implanted with a bioabsorbable graft connecting the inferior vena cava with the right pulmonary artery during an extracardiac Fontan procedure. Patients were followed for 12 months after surgery using echocardiography, CT-scan and MRI. No device-related adverse events were reported.

The grafts are composed of supramolecular bioabsorbable polymers, manufactured using a proprietary electrospinning process by European medical device company Xeltis. The grafts have no size limitations, although this study used grafts that were 18 and 20 mm in diameter. Histological studies of the grafts in sheep have shown that graft implantation is followed by initial infiltration of inflammatory cells, which induces physiological healing and tissue formation. This is followed by degradation of the implant scaffold with eventual reduction of the inflammatory response.

The investigators report that all five patients successfully recovered from the procedure, with significant improvement noted in the patients' general condition. Imaging studies demonstrate anatomical and functional stability of the grafts.

Although longer follow-up is needed, the investigators say that the procedure has the potential to improve cardiac and vascular surgical procedures by reducing complications resulting from permanently-placed implants. This is especially important for a child who must live with the after-effects of surgery over his lifetime.

For more information on The American Association for Thoracic Surgery (AATS), visit www.aats.org.

The CongenitalUniversity Hospitals
Rainbow Babies & Children'sHeart CollaborativeNationwide Children's

Ambulatory Pediatric Cardiologist

The Congenital Heart Collaborative (TCHC), an affiliation between University Hospitals Rainbow Babies & Children's Hospital (Cleveland OH) and Nationwide Children's Hospital (Columbus OH) heart programs, seeks candidates at any professorial levels* for a faculty position in the Division of Cardiology at Rainbow Babies & Children's Hospital to be a primarily-based ambulatory pediatric cardiologist. He or she would be expected to be proficient at outpatient assessment of patients including skills such as physical examination and noninvasive cardiology testing interpretation. The candidate would work closely with a multidisciplinary team to provide high quality care to TCHC patients in Northern Ohio. The candidate would be responsible for developing and maintaining positive relationships with referring providers while working to expand the reach of TCHC. In addition, the candidate would have hospitalbased clinical duties such as night call, case management and inpatient service time. The candidate would also have opportunities to participate in quality improvement, clinical research, and education of medical students, residents, and cardiology fellows.

The candidates would be well-supported at a world-class children's hospital that has over 60 years of experience in the care of pediatric and adult congenital heart disease patients; an outstanding educational and research enterprise at Case Western Reserve University School of Medicine and an internationally recognized program partner with the Nationwide Children's Hospital Heart Center. TCHC is a dedicated service line with a common executive administration and functions as one program on two campuses with the commitment to expand access to high-quality cardiac care to the communities we serve while equally embracing an educational mission. The candidate would be immediately accountable to the Cardiology Division Chief and to TCHC medical leadership.

Please send letter and curriculum vitae to: Christopher Snyder, MD, Chief of Pediatric Cardiology Rainbow Babies & Children's Hospital, Christopher.Snyder@uhhospitals.org.

In employment, as in education, Case Western Reserve University is committed to equal opportunity and diversity. Women, veterans, members of underrepresented minority groups and individuals with disabilities are encouraged to apply.

* If tenure track is desired, associate professor candidates must demonstrate national recognition of their research program; professors must demonstrate sustained excellence and enhanced recognition.

Among the nations leading academic medical centers, University Hospitals Case Medical Center is primary affiliate of Case Western University School of Medicine, a nationally recognized leader in medical research and education.

University Hospitals





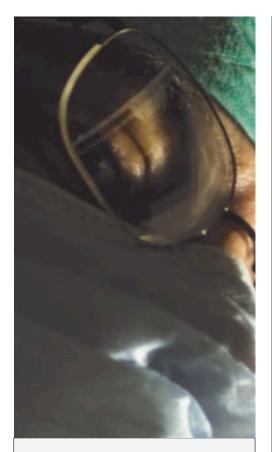


Volunteer / Get Involved www.chimsupport.com

HOW WE OPERATE

The team involved at C.H.I.M.S. is largely a volunteer group of physicians nurses and technicians who are involved in caring for children with congenital heart disease.

The concept is straightforward. We are asking all interested catheter laboratories to register and donate surplus inventory which we will ship to help support CHD mission trips to developing countries.



Congenital Cardiology Today

Can Help You Recruit:

- Pediatric Cardiologists
- Pediatric Interventional Cardiologists
- Adult Cardiologists Focused on CHD
- Congenital/Structural Heart
 Surgeons
- Echocardiographers, EPs
- Pediatric Transplant Cardiologist

Reach over 6,000 BC/BE Cardiologists focused on CHD worldwide:

- Recruitment ads include color!
- Issues's email blast will include your recruitment ad!
- We can create the advertisement for you at no extra charge!

Contact:

Tony Carlson +1.301.279.2005 or tcarlsonmd@gmail.com

CONGENITAL Cardiology today

CALL FOR CASES AND OTHER ORIGINAL ARTICLES

Do you have interesting research results, observations, human interest stories, reports of meetings, etc. to share?

> Submit your manuscript to: RichardK@CCT.bz

- Title page should contain a brief title and full names of all authors, their professional degrees, and their institutional affiliations. The principal author should be identified as the first author. Contact information for the principal author including phone number, fax number, email address, and mailing address should be included.
- Optionally, a picture of the author(s) may be submitted.
- No abstract should be submitted.
- The main text of the article should be written in informal style using correct English. The final manuscript may be between 400-4,000 words, and contain pictures, graphs, charts and tables. Accepted manuscripts will be published within 1-3 months of receipt. Abbreviations which are commonplace in pediatric cardiology or in the lay literature may be used.
- Comprehensive references are not required. We recommend that you provide only the most important and relevant references using the standard format.
- Figures should be submitted separately as individual separate electronic files. Numbered figure captions should be included in the main Word file after the references. Captions should be brief.
- Only articles that have not been published previously will be considered for publication.
- Published articles become the property of the Congenital Cardiology Today and may not be published, copied or reproduced elsewhere without permission from Congenital Cardiology Today.

CONGENITAL CARDIOLOGY TODAY

© 2016 by Congenital Cardiology Today (ISSN 1554-7787-print; ISSN 1554-0499online). *Published monthly. All rights reserved.*

www.CongenitalCardiologyToday.com

Editorial Office: 16 Cove Rd, Ste 200 Westerly, RI 02891 USA

Publishing Management:

- Tony Carlson, Founder, President & Sr. Editor *TCarlsonmd@gmail.com*
- Richard Koulbanis, Group Publisher & Editor-in-Chief - *RichardK@CCT.bz*
- John W. Moore, MD, MPH, Group Medical Editor - <u>JMoore@RCHSD.org</u>
- Allan Berthe, Contributing Editor-Special Projects

Editorial Board: Teiji Akagi, MD; Zohair Al Halees, MD; Mazeni Alwi, MD; Felix Berger, MD; Fadi Bitar, MD; Jacek Bialkowski, MD; Mario Carminati, MD; Anthony C. Chang, MD, MBA; John P. Cheatham, MD; Bharat Dalvi, MD, MBBS, DM; Horacio Faella, MD; Yun-Ching Fu, MD; Felipe Heusser, MD; Ziyad M. Hijazi, MD, MPH; Ralf Holzer, MD; Marshall Jacobs, MD; R. Krishna Kumar, MD, DM, MBBS; John Lamberti, MD; Gerald Ross Marx, MD; Tarek S. Momenah, MBBS, DCH; Toshio Nakanishi, MD, PhD; Carlos A. C. Pedra, MD; Daniel Penny, MD, PhD; James C. Perry, MD; P. Syamasundar Rao, MD; Shakeel A. Qureshi, MD; Andrew Redington, MD; Carlos E. Ruiz, MD, PhD; Girish S. Shirali, MD; Horst Sievert, MD; Hideshi Tomita, MD; Gil Wernovsky, MD; Zhuoming Xu, MD, PhD; William C. L. Yip, MD; Carlos Zabal, MD

Free Subscription to Qualified

Professionals: Send your name, title(s), hospital or practice name, work address and url, phone, fax and email to: sub@cct.bz.

Statements or opinions expressed in Congenital Cardiology Today reflect the views of the authors and sponsors, and are not necessarily the views of Congenital Cardiology Today.

SIXTH ANNUAL FETAL ECHOCARDIOGRAPHY SYMPOSIUM AT UCLA: *Practical Essentials* of Fetal Cardiac Screening

Course Chair: Mark Sklansky, MD October 15, 2016

UCLA Meyer & Renee Luskin Conference Center; Los Angeles, CA Partnering with Hopeful Hearts, ACC (California Chapter), CME Office of Continuing Education - David Geffen School of Medicine of UCLA

Mattel Children's Hospital UCLA

https://www.cme.ucla.edu/courses

Join Our Team



Career opportunities at the Pediatric Heart Center in Long Beach, California, part of the Memorial Healthcare System - Miller Children's and Women's Hospital. Join a team of three board certified pediatric cardiologists who provide an array of comprehensive services. This busy practice in Orange, San Diego and Riverside Counties with a large outpatient volume covers a number of outreach offices and is currently expanding into the Long Beach/South Bay area.

Medical Director - Interventional Pediatric Cardiologist

- Lead the program and support the hospital's strategic vision for the Pediatric Heart Center.
- Work collaboratively with the hospital's cardiac surgeon to develop and promote the premier program at Miller Children's and Women's Hospital throughout Southern California.

Requirements:

- ✓ Leadership experience in a nationally recognized congenital heart center and/or large tertiary children's hospital
- Previous experience and vision in planning, building and executing the development of a state-of-the-art congenital cardiac cath lab, working with a cardiac ICU
- ✓ Ability to assist the PICU team in the development of a new CVICU
- ✓ Help with program growth in collaboration with key hospital and practice leadership
- ✓ Program development and fundraising experience
- \checkmark Board certified interventional pediatric cardiologist

Medical Director - Non Invasive Imaging

Requirements:

- ✓ Expertise and experience in clinical imaging, research and teaching
- Leadership experience to serve as director of the non-invasive imaging program
- ✓ Ability to work closely with the Heart Center and hospital leadership to lead program development and expansion.
- ✓ Board certified pediatric cardiologist

BENEFITS:

- Located in desirable
 Southern California
- Competitive salary and excellent benefits including health/dental/vision, 401(k), annual CME allowance, employee stock purchase plan, professional liability insurance, and assistance with mandatory hospital credentialing and state licensing

For more information:



pediatrix.com/clinicalcareers



800.243.3839, ext. 5589



janet_friedman@mednax.com

OPENING DOORS TO THE FUTURE

CP Stent[™] For Coarctation of the Aorta

INDICATIONS FOR USE (COVERED CP STENT): 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. WARNINGS/PRECAUTIONS: Coarctation of the aorta involving the aortic istmus or first segment of the descending aorta should be confirmed by diagnostic imaging. The 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. Crimpting the stent on a balloon catheter smaller than 12mm may cause damage to the stent. Excessive handling and manipulation of the covering while crimping the stent may cause the covering to tear off of the stent. This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross-contamination. CONTRAINDICATIONS: 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 of the stent. Clinical or biological signs of infection. Active endocarditis. Known allergy to aspirin, other antiplatelet agents, or heparin. Pregnancy. Reference the IFU for a complete listing of indications, contraindications, warnings and precautions.

Rx only CV9048- 5/16 92016 B. Braun Interventional Systems Inc. CP Stent* is a trademark of NuMED, Inc.

Distributed by:

B. Braun Interventional Systems Inc. Bethlehem, PA 18018 | USA Tel: 877-836-2228 Fax: 610-849-1334 www.bisusa.org



