CONGENITAL CARDIOLOGY TODAY

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

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Upcoming Medical Meetings

See website for additional meetings

10th International Workshop on Interventional Pediatric & Adult Cardiology (IPC Workshop)
March 19-21, 2015; Milan, Italy
www.workshopipc.com/main.php

PICS-AICS AP 2015 (Asia Pacific)
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www.picsymposium-ap.org

Imaging in Adult Congenital Heart Disease – Pearls for All Cardiac Providers
April 24-26, 2015; Ponte Verde Beach, FL USA
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SCAI 2015
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www.scai.org

25th International ACHD Symposium
June 3-6, 2015; Toronto, Canada
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ASE 2015
June 12-16, 2015; Boston, MA USA
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Methods of Administration of Intravenous Amiodarone in the Postoperative Setting: A Poll of Members of the Pediatric and Congenital Electrophysiology Society (PACES)

By James C. Perry, MD; Shubhayan Sanatani, MD, FRCPC

> ***"Practice patterns vary in the use of IV amiodarone, with half of reporting centers using only continuous infusion and half using either scheduled bolus doses and/or repeat bolus doses during infusion."***

Since investigation of its use in the early 1990's[1,2] intravenous amiodarone has secured a place in therapeutic strategies for postoperative tachyarrhythmia in patients with Congenital Heart Disease (CHD). The drug has proven particularly useful in the management of postoperative junctional ectopic tachycardia,[1-3] is used for other pediatric and adult congenital heart tachyarrhythmias and, since 2000, has been incorporated into the Advanced Cardiac Life Support and American Heart Association recommended treatment arms for ventricular tachycardia and fibrillation.[4]

Published, peer-reviewed studies on the use of intravenous (IV) amiodarone in pediatrics have incorporated both bolus and continuous infusion administration techniques.[1-3,5-7] Concerns about the drug's safety profile particularly relate to its vasodilatory effect and negative inotropy, which can result in mild to severe hypotension, especially during more rapid bolus push. Equally concerning, but more difficult to quantify is the drug's (and its diluent's) ability to cause micro-plasticizing[8] when exposure to tubing and other drug containers is prolonged, a high risk of phlebitis when given through a peripheral IV site,[9] and the fact that the drug vehicle causes precipitation of a wide variety of other medications and solutions when co-mingled in tubing and catheters.

The Pediatric and Congenital Electrophysiology Society (PACES) has become the representative body for pediatric and congenital heart electrophysiologists over the past three decades and actively participates in the formulation of

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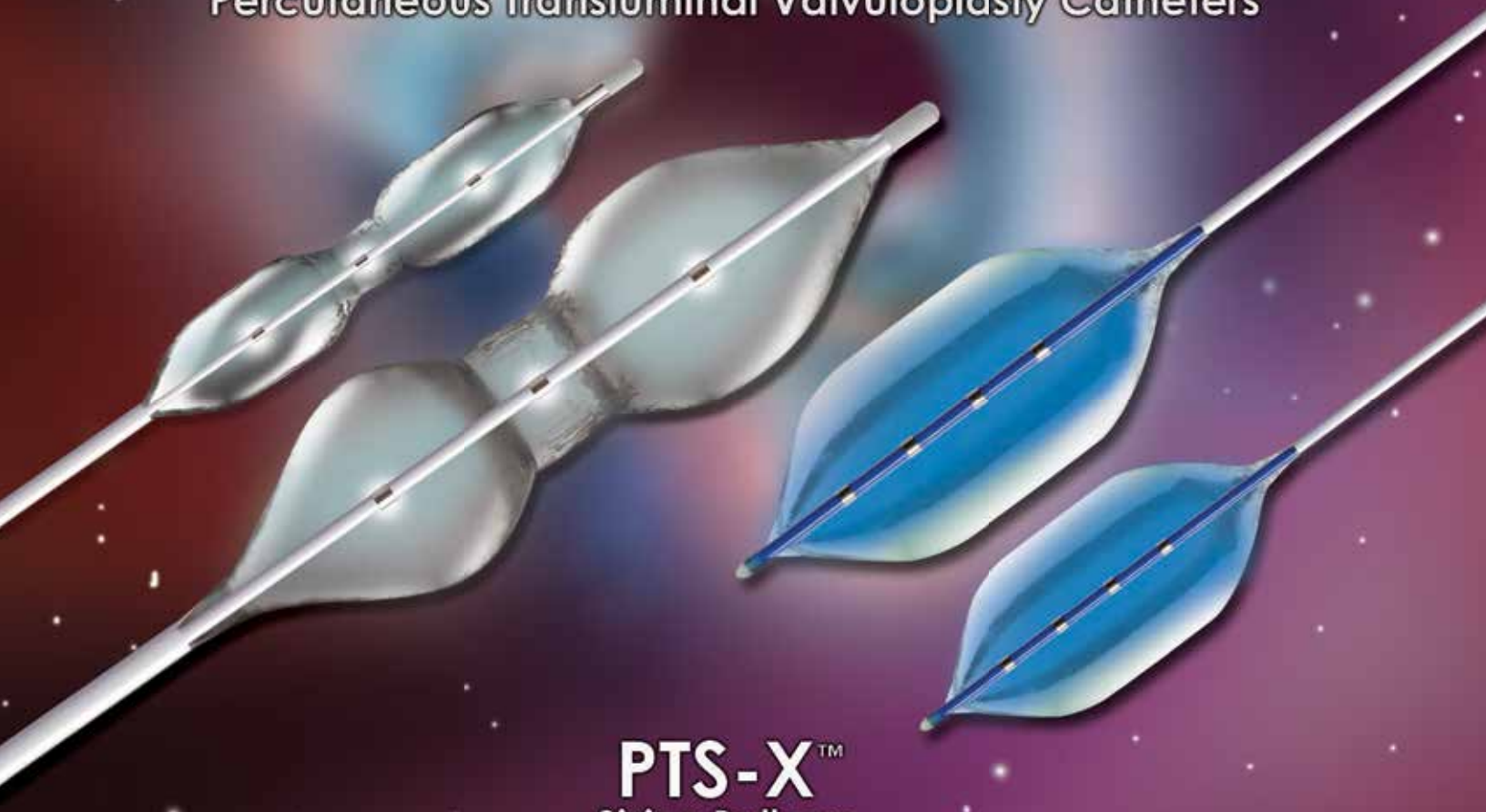

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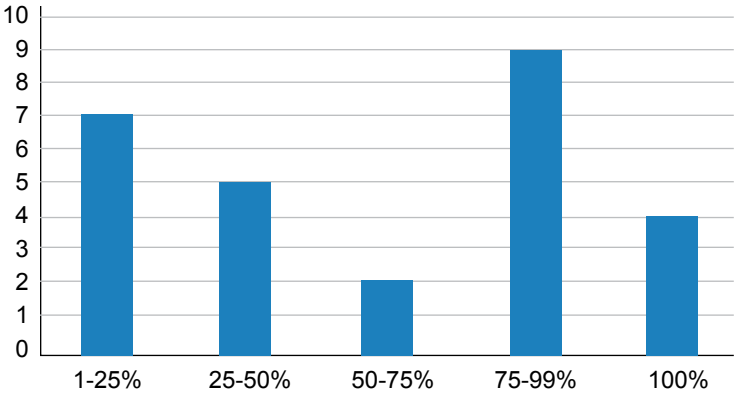

Figure 1. Frequency of bolus only IV amiodarone administration (no infusion).

clinical management consensus documents, multicenter studies, and training and certification guidelines in the field.[10-12] The PACES membership is uniquely responsive to internal requests for input on a wide range of topics, allowing a rapid assessment of the state of the field. The Society therefore provides a reliable platform for addressing questions in electrophysiologic and related critical care management issues.

Method

An email poll request was sent out to PACES members asking the following two initial questions related to practice patterns in the modes of administration of intravenous amiodarone in the postoperative setting (See Table 1):

1. Do you ever use IV amiodarone to manage postoperative arrhythmias?
2. When you use IV amiodarone, what is the estimated frequency of route of administration?

For those who answered Question 2b, reflecting use of an initial bolus of amiodarone followed by continuous infusion, three follow-up questions were asked:

3. During the continuous infusion phase, how often do you repeat a bolus dose to maintain rhythm control?
4. Any complications of continuous infusion seen? (rough estimate of %).

Table 1.

1. Do you ever use IV amiodarone to manage postoperative arrhythmias?	
a. Yes	63
b. No	0
2. When you use IV amiodarone, what is the estimated frequency of route of administration?	
a. OPTION 1: Always by IV bolus technique (e.g. bolus and then administer Q6H)	5
b. OPTION 2: Always by initial bolus, then continuous infusion	33
c. We use OPTION 1: 75-99% of the time, otherwise OPTION2	9
d. We use OPTION 1: 50-75% of the time	2
e. We use OPTION 1: 25-50% of the time	5
f. We use OPTION 1: 1-25% of the time	7
g. Always by continuous infusion technique ONLY, no bolus at all	2

Table 2. Frequency of Use of Repeat Amiodarone Boluses, Complications and Duration of Use

3. During the continuous infusion phase, how often do you find you need to repeat boluses?	33
a. Always	2
b. 75-99%	4
c. 50-75%	6
d. 25-50%	11
e. 1-25%	10
f. Never	0
4. Any complications? (rough estimate of # or %)	
a. Phlebitis (0.5-10%, most 5%)	10
b. Precipitate with other in-line solutions (< 5%, couple cases)	3
c. Hypotension (rare 15%, most 5%)	26
5. Average duration of IV amiodarone continuous infusion?	
a. < 24 hours	0
b. 24-36 hours	3
c. 36-48 hours	18
d. > 48 hours	12

5. Average duration of IV amiodarone continuous infusion at your institution?

Results

There were 63 rapid (within 48 hours) responses to the request, indicating institutional use of IV amiodarone (Table 1). Only five were from the same institution and four of those were used in the data as they reflected different preferred styles of management amongst attending staff.

While only five centers (8%) reported exclusive use of a scheduled bolus method (usually given Q6H), an additional 23 reported using either bolus only or bolus followed by infusion in varying degrees. The frequency with which centers used the bolus only method amongst these 28 centers is represented in Figure 1.

A total of 33 centers (52%) reported using a bolus plus infusion method only (answer 2b, above). For those 33 responses who indicated use of an initial bolus followed by continuous infusion (2b), Table 2 shows the frequency of use of repeat boluses, complications and duration of use.

In response to follow-up question 3, all 33 responded that they also used a repeat bolus during the infusion, with varying frequency as shown in Figure 2.

Discussion

There are wide practice pattern variations across pediatric centers with regard to the methods of administration of IV amiodarone, even amongst pediatric electrophysiologists. This rapid study had an excellent response from 63 centers within 48 hours.

The dosing of amiodarone is predominantly done as boluses, with or without a background infusion. While a minority of centers (8%) report using an IV amiodarone bolus method exclusively, nearly half of all centers (45%) use a bolus method while other times using a bolus plus continuous infusion method. Additionally, of all those centers who reported using an initial amiodarone bolus

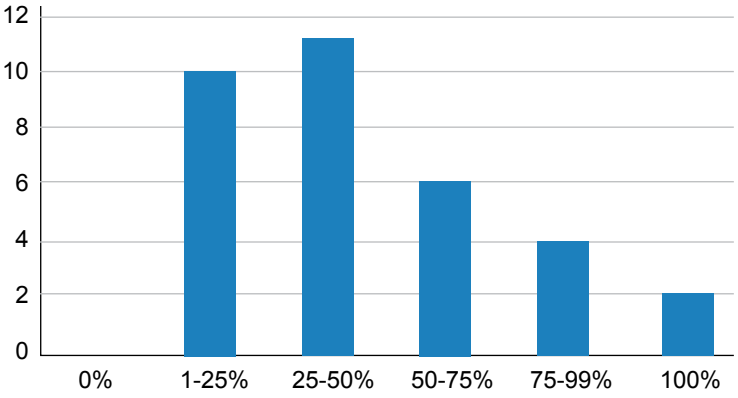

Figure 2. Frequency of repeat amiodarone bolus administration for centers using infusion protocol.

followed by continuous infusion as their method of administration, 100% of those centers reported that they give bolus amiodarone during that continuous infusion. Based on this data, centers are giving amiodarone boluses, on average, 44% of the time during continuous infusion. Looking at any use of bolus IV amiodarone in addition to initial bolus therapies, 61/63 centers (97%) are using bolus amiodarone on a scheduled or intermittent basis, with or without continuous background infusion. The pharmacokinetics of such IV amiodarone practices were recently reported.[13] If one makes the broad assumption of equal frequency of need for amiodarone between centers, 49.7% of cases will receive IV amiodarone bolus therapy beyond the initial dose. Infusions were maintained for 24-48 hours for most patients, with approximately 1/3 extending beyond 48 hours.

Side effects are uncommon in the postoperative setting with amiodarone. Hypotension during amiodarone bolus remains the most common encountered side effect. While these are often critically ill patients, no center reported needing to discontinue amiodarone as a result. Centers reported in comments to the poll that slow bolus over 30-60 minutes, calcium administration and fluid boluses were used to counter low blood pressure. A total of 13 centers (21%) reported rare to 10% frequency of phlebitis or precipitate of co-administered medications with continuous amiodarone infusion.

Conclusions

Practice patterns vary in the method of use of IV amiodarone for postoperative tachyarrhythmias, with nearly half of reporting centers using a technique of continuous infusion only and half using a blend of scheduled bolus doses and/or repeat bolus doses during infusion. Risk of hypotension is felt to be reduced by giving bolus doses of amiodarone over 30-60 minutes. Drug efficacy and side effect profiles are not apparently different amongst the 63 centers, based on this limited polling data. There does not appear to be a "recommended" method of administration, as both infusion and bolus techniques appear to have similar efficacy and side effect profiles. While the risk of plasticizing and phlebitis may be reduced by bolus technique, the risk of hypotension may be reduced by continuous infusion and/or by giving bolus doses over a longer period of time than utilized in the initial amiodarone investigative studies. This survey has demonstrated the feasibility of obtaining input from a broad range of centers to inform current practice in pediatric and congenital electrophysiology.

Brief Biographical Sketch

James C. Perry MD is Professor of Pediatrics, University of California San Diego and the Director for the Electrophysiology and Adult CHD Programs at Rady Children's Hospital San Diego. He is a past President of the Pediatric and Congenital Electrophysiology Society (PACES), and a fellow and diplomate of the Heart Rhythm Society.

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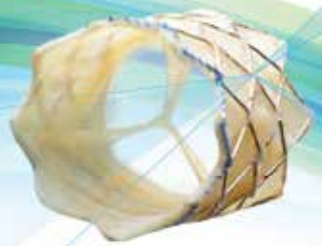

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**The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.*

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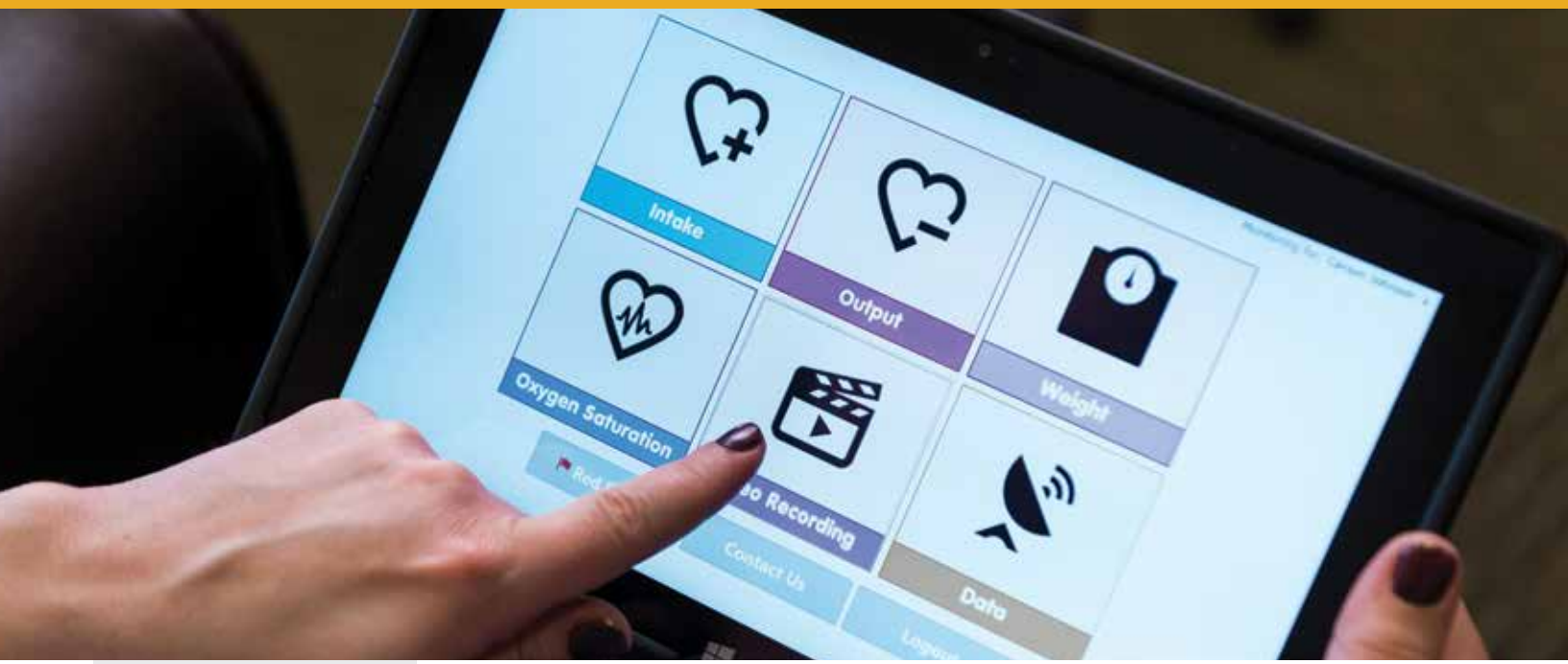

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PICES: Representing Young Congenital Interventional Cardiologists at Leading Worldwide Conferences

By Gareth J. Morgan, MB, BaO, BCh, MRCPCH, MPhil

The PICES (Pediatric Interventional Cardiology Early Career Subgroup) group represents the interests of interventionists at an early stage in their faculty and staff careers. The group was started as an SCAI initiative. Over the last 3 years we have expanded our remit, and have just recruited our 120th member. We started in the USA, but spread rapidly over the last 4 years, with 25% of our membership now working outside of the US in a network that includes the Middle East, Japan, Australia and the Indian subcontinent.

The three major congenital interventional conferences are now fixed dates on the group's calendar with breakout sessions and networking events confirmed at SCAI, PICS and CSI Frankfurt in 2015. As well as a hike in our membership, last year produced three memorable interventional meetings for PICES.

PICES president, Dr. Brent Gordon, addressed each conference session, updating members and guests on the work PICES is doing to represent early careers interventionists and provide avenues for research and leadership development as well as acting as a network and educational resource.

On each occasion an update on a raft of PICES research studies was presented by Dr. Bryan Goldstein, (VP for Research). With poster and oral presentations delivered on behalf of PICES and several manuscripts in development for publication, our research network is developing into an effective and enthusiastic international collaboration.

SCAI Las Vegas: PICES, May 28th, 2014

The PICES break-out session proved to be a very dynamic and engaging opening act for the SCAI general sessions. It was attended by approximately 30 PICES members, as well as a number of senior interventionists, and interested observers. The session did not disappoint with the lively discussion being adjourned to avoid delaying the opening of the general sessions. Our invited speaker was Dr. Andrew Glatz, MD from the Children's Hospital of Philadelphia who outlined his career development as a clinical interventionist researcher in an excellent talk. Dr. Glatz has successfully carved out a unique and rewarding career path with an extensive publication record on a variety of diverse topics and is, as such, an example to PICES members.

Darren Berman, MD, Nationwide Children's Hospital, presented a challenging percutaneous valve implantation involving both unusual anatomy, complex comorbidities and the threat of coronary compression. The audience was fully engaged and there was tremendous debate and interaction through the presentation, a hallmark of case presentations at PICES breakout sessions.

Prof. Neil Wilson addresses the PICES breakout session at CSI in Frankfurt June 2015.

Dr. Shirhari Naidu, MD, Winthrop University Hospital, and Chair of SCAI's Emerging Leadership Mentorship Committee spoke about leadership opportunities and more extensive involvement for younger faculty members within SCAI.

PICS Chicago: PICES, June 7th-9th, 2014

PICES continued its links with the PICS conference with another lively and progressive set of fixtures at this year's meeting in Chicago. We had terrific turnout to our programmed sessions and were again well represented with poster presentations.

Our breakout session was very well attended with approximately 25 members and interested observers in the room. They were treated to a wide-ranging programme.

Our invited speaker was Dr. Larry Latson, who gave us a wonderful overview of his personal development to become a world leader in our field, including some candid and practical advice on career planning and politics.

We had two extremely challenging case discussions which took us through the full range of emotions, intellectual dilemmas and skill challenges which face us as interventional operators. Both cases attracted extensive debate and comment from the participants.

We discussed, as part of our career development platform, the possibility of a survey to establish pay scales and contract negotiations for those applying for their first staff jobs and those moving institutions within the first couple of years of staff status. We also updated the audience on our desire to expand PICES formally outside the US and try to incorporate significant membership from other countries.

CSI Frankfurt: PICES, June 25th-29th, 2014

In another milestone, PICES had its first breakout session at a major conference outside the USA. This was made possible with the support of the CSI course directors Professors Sievert, Wilson and Qureshi. As part of our geographical expansion of PICES membership, we engaged 16 new recruits prior to and during CSI, all of whom practice outside the USA.

Brent Gordon, PICES President, and Bryan Goldstein, Chair of Research, entered into the European spirit fully and couldn't resist trying on the national costumes (dirndl) and consumed their fair share of Frankfurters and sauerkraut.

Our breakout session had a small, but vocal turnout, all of whom were excited about the prospects of engaging in PICES' multicentre studies and the mailing list.

Professor Neil Wilson gave a short welcoming talk highlighting why the old guard is so keen to see groups such as PICES showing leadership and setting the agenda in research and clinical developments.

We also had time for a "clinical conundrum" case presentation giving me the opportunity to discuss treatment options for a particularly challenging complex coarctation awaiting interventional treatment in the cath lab in London.

The small group allowed lots of great discussion throughout the session with topics as far ranging as training programmes in the USA and Canada compared with the UK and Europe, and the availability and legality of covered stents in the USA.

This meeting highlights the networking capability of PICES and has given us a foundation to build on at the CSI meeting.

At all three conferences we had the opportunity to meet more informally at the PICES dinners; these provide great networking opportunities and have really helped in building relationships throughout the group as well as allowing the growth of discussions about potential collaborative research projects.

Thanks to the course directors of SCAI, PICS and CSI for hosting the PICES breakout sessions and to the PICES members and guest speakers for their participation and support.

CCT

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Medical News, Products & Information

Complied and Reviewed by Tony Carlson, Senior Editor

MEDTRONIC Receives Pre-Market Approval (PMA) for Melody TPV from the United States Food and Drug Administration (FDA)

Transcatheter Pulmonary Valve (TPV) received Pre-Market Approval (PMA) from the United States Food and Drug Administration (FDA) based on strong clinical evidence from three clinical studies demonstrating the valve's effectiveness in delaying open-heart reoperation.

The first transcatheter heart valve available anywhere in the world, the Melody TPV was originally approved in 2010 under a Humanitarian Device Exemption (HDE), a regulatory approval for treatments intended for fewer than 4,000 U.S. patients per year. HDEs are granted for medical devices that have demonstrated reasonable safety and probable benefit, but do not have evidence of clinical effectiveness. PMA approval has been issued based on the robust evidence now available that supports both safety and effectiveness of the Melody TPV.

Melody TPV is a minimally invasive therapy shown to effectively prolong the time between open-heart surgeries for patients with a dysfunctional Right Ventricular Outflow Tract (RVOT) conduit caused by Congenital Heart Disease (CHD). More than 7,300 patients worldwide have received the therapy to date, more than half of whom are children with CHD.

"The Melody valve has been a reliable option for patients suffering from CHD, and these data reinforce its strong performance since it was first introduced," said William E. Hellenbrand, MD, Chief of Pediatric Cardiology at the Yale School of Medicine. "This approval underscores the valve's importance in treating this small patient population, who over their lifetime will face several open-heart surgeries."

The PMA approval is based on accumulated data from three clinical studies that followed a total of 310 patients implanted with Melody TPV - the Melody U.S. IDE Study, the Melody U.S. Post Approval Study (PAS) and the Melody European and Canadian Post-Market Surveillance Study (PMSS). Data showed strong valve performance in all three studies in patients implanted with the Melody valve as approximately 98% of patients were free from conduit reoperation (open-heart surgery) at one year post-implant. Additionally, 91% of patients in the IDE cohort were free from conduit reoperation at five years post-implant.

"The transition from HDE to PMA is an important regulatory milestone, which truly emphasizes the significant clinical benefit that the Melody TPV can bring to people with CHD by providing a therapy option that may reduce the number of open heart surgeries they need throughout their lifetime," said Rhonda Robb, VP and General Manager of Heart Valve Therapies at Medtronic. "Today's approval reinforces Medtronic's ongoing commitment to a congenital heart disease program by providing innovative and successful therapies to this underserved patient group."

CHD is the most common birth defect in the United States; it affects an estimated 40,000 U.S. babies each year.[1,2,3] Approximately 20 percent of those infants have deformities that disrupt the blood flow from their RVOT to the pulmonary arteries.[4] A subset of these

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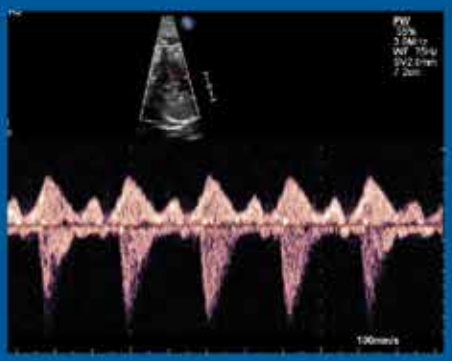

This conference offers the unparalleled exposure to national and international experts, creating an authoritative learning venue with an incredibly comprehensive and intensive program on fetal cardiology and fetal cardiology imaging. Lectures, procedure demonstrations and interactive case study formats will focus on expanding evidence-based care management strategies for clinical decision making.

This four-and-a-half day conference will:

- discuss important concepts in congenital heart disease as well as the most recent advances in imaging, diagnosis and management of fetal cardiac abnormalities.
- have added emphasis on the perinatal and genetics components, with advanced techniques in the assessment of the fetal circulation and extracardiac abnormalities
- have breakout workshops including 4D echo volume manipulation, hands on scanning, and Doppler assessment techniques are planned
- provide an opportunity for abstract submissions and poster presentations

Confirmed Guest Faculty Include:

Alfred Abuhamad, MD
Bettina Cuneo, MD
Mary Donofrio, MD
Helena Gardiner, MD, PhD
Edgar Jaeggi, MD
Anita Moon-Grady, MD
V. Mohan Reddy, MD
Abraham Rudolph, MD
Gary Satou, MD
Mike Seed, MD
Diane Spicer, PA
Wayne Tworetzky, MD
Simcha Yagel, MD

This symposium has been designed for physicians- both pediatric cardiology and maternal fetal medicine, sonographers and other paramedical colleagues. For more information regarding CME, please call (602) 933-0766.

For more information, email
Kathryn Poole at kpoole@phoenixchildrens.com

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children will receive a connecting conduit early in life to improve that blood flow. If a patient's RVOT conduit fails later in life, but is still of adequate size to address the patient's needs (i.e., the patient has not outgrown the conduit), then a Melody TPV may be implanted to help delay a surgical pulmonic valve replacement, which is a much more invasive procedure than transcatheter valve replacement.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

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Materialise's HeartPrint® Now Listed as a Class 1 Medical Device

Materialise NV, a leading provider of additive manufacturing software and of sophisticated 3D printing solutions in the medical and industrial markets, has listed its 3D-printed cardiovascular HeartPrint® models as a medical device in the USA and EU markets. After years of 3D printing anatomical models for educational and research purposes, the company addressed the need for models that can assist with diagnosing, planning and practicing complex cardiovascular procedures. This move strengthens the company's unique position in the market and is a natural extension of its Mimics® Innovation Suite of software for medical image processing which has an existing 510(k) clearance and CE mark.

A recent example of Materialise's 3D printed HeartPrint services was evident when surgeons at New York-Presbyterian/ Morgan Stanley Children's Hospital used the model to plan a surgery to repair the newborn's congenital heart disease.

By listing HeartPrint as a Class 1 medical device, the company is able to add HeartPrint models to their offering for pre-operative planning. The 3D-printed, patient-specific cardiovascular models are created from medical image data to provide cardiologists and surgeons with supplemental information to determine the best treatment for each unique patient.

"Where I think clinically 3D printing will take us is to the next generation of imaging. As we've seen in the history of medicine, the better and better our imaging, the more precise we are to pre-operatively be able to say what operation we're going to do." David Morales, MD, Chief of Cardiovascular Surgery for the Heart Institute at Cincinnati Children's Hospital Medical Center.

Nearly every week, the added-value of 3D printed solutions in the medical arena makes headlines. A recent story covered a 1-week-old baby who was born with a complex form of Congenital Heart Disease in which both the aorta and pulmonary arteries arise from the right ventricle as well as a large hole in the heart called a Ventricular Septal Defect (VSD). Only one day after he was born, an extremely low dose chest CT scan was acquired and data was sent to Todd Pietila, Cardiovascular Business Development Manager at Materialise, who created a digital 3D model of the baby's heart using Mimics® and then 3D-printed a replica where even the smallest details were visible. With the walnut-size model in hand, the team of clinicians at the NewYork-Presbyterian/ Morgan Stanley Children's Hospital were able to find a solution for repairing all of the baby's defects in one procedure rather than the typical series of palliative operations which can be life threatening.

"After the success of this surgery, it's hard to imagine entering an operating room for another complex case without the aid of a 3D printed model. It's definitely going to be standard of care in the future and we're happy to be leading the way." said Dr. Emile Bacha, a congenital heart surgeon and Director of Congenital and Pediatric Cardiac Surgery at NewYork-Presbyterian/ Morgan Stanley Children's Hospital.

Regulatory entities have raised concerns about 3D printing in a clinical environment as a validated quality system is critical for ensuring accuracy and safety. Materialise is the only company who is actively addressing these issues with their Mimics Innovation Suite for segmenting the medical image data and Streamics, which is dedicated to automating, controlling and tracking the 3D printing process to ensure traceability and clinical-level quality standards.

"We're proud that the Mimics Innovation Suite is one of the few engineering packages with the appropriate validation to be considered a medical device. This

makes it easier for Materialise and our customers to bring patient-specific, 3D-printed treatments to the market. It's important for us to stay ahead of the regulatory requirements." Koen Engelborghs, Director of Biomedical Engineering at Materialise, states. "We saw the advantages for patients when HeartPrint models were used in a clinical environment and are looking forward to continuing our collaborations with hospitals to address their 3D printing needs."

For more information on HeartPrint, visit http://heartprint.materialise.com.

Ten Percent of Heart Patients May Be Inappropriately Prescribed Aspirin

More than 10% of patients treated with aspirin therapy for primary cardiovascular disease prevention were likely inappropriately prescribed medication, according to a new study in the *Journal of the American College of Cardiology* that examined practice variations in aspirin therapy.

Accessing data from the National Cardiovascular Disease Registry Practice Innovation and Clinical Excellence (PINNACLE) Registry, researchers examined a nationwide sample of 68,808 patients receiving aspirin for primary cardiovascular disease prevention. By evaluating aspirin guidelines by the American Heart Association, the U.S. Preventative Services Task Force, and other organizations, researchers determined aspirin use to be inappropriate in patients with a 10 year cardiovascular disease risk of less than 6%.

Researchers identified patients from 119 practices who were prescribed aspirin between January 2008 and June 2013, excluding patients receiving aspirin as a secondary prevention due to history of cardiovascular disease such as myocardial infarction, prior stroke, and atrial fibrillation. The study found nearly 12% of the patients receiving aspirin for primary prevention were receiving it inappropriately. The frequency of inappropriate aspirin use was higher among women, at nearly 17% compared to men at 5%. Patients inappropriately receiving aspirin were, on average, 16 years younger than those receiving aspirin appropriately. Inappropriate aspirin use decreased from 14% in 2008 to 9% in 2013.

In practices with more than 30 patients receiving aspirin for primary prevention, researchers found a median practice-level frequency of inappropriate use of 10% and varied significantly across practices at a range of 0 to 72%. Researchers used median rate ratio to suggest that between two "identical" patients treated at two random practices, one patient was 63% more likely to be prescribed aspirin inappropriately than similar patients due to the practice where they receive care.

Aspirin therapy is not shown to reduce adverse cardiovascular events in patients without cardiovascular disease and a low risk of developing disease. However, it is associated with an increased risk of gastrointestinal bleeding and hemorrhagic strokes which often outweighs any potential benefits. The U.S. Food and Drug Administration (FDA) recently denied a request to allow the marketing of aspirin for primary prevention; following that decision the FDA also issued a public advisory against the general use of aspirin for primary prevention. As aspirin is available over the counter, it is also possible inappropriate aspirin use is higher if patients are taking it by their own choosing.

"Medical providers must consider whether the potential for bleeding outweighing the potential benefits of aspirin therapy in patients who don't yet meet the guidelines for prescribing aspirin therapy," said the study's lead and senior author, Ravi S. Hira, MD and Salim S. Virani, MD, PhD, of the Baylor College of Medicine in Houston. "Since aspirin is available over the counter, patient and public education against using aspirin without a medical provider's recommendation will also play a key role in avoiding inappropriate use."

In an accompanying editorial, Freek W.A. Verheugt, MD, of Onza Lieve Vrouwe Gasthuis Radboud University Nijmegen Medical

Centre in Amsterdam said, "Major coronary events are reduced 18% by aspirin, but at the cost of an increase of 54% of major extra cranial bleeding. Each two major coronary events have shown to be prevented by prophylactic aspirin at the cost of one major extracranial bleed. Yet, primary prevention with aspirin is widely applied."

The American College of Cardiology is a 47,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications. For more information, visit cardiosource.org/ACC.

Medtronic Completes Acquisition of Covidien

Medtronic plc (NYSE: MDT), a global leader in medical technology, services and solutions, announced today that it has successfully completed the previously announced acquisition of Covidien plc (NYSE: COV). Under the terms of the acquisition agreement, Medtronic, Inc. and Covidien plc are now combined under Medtronic plc. Shares of Medtronic plc are expected to begin trading on the New York Stock Exchange (NYSE) under the symbol "MDT" on Tuesday, January 27, 2015.

"The culmination of this acquisition marks a significant milestone in our industry, creating a company uniquely positioned to alleviate pain, restore health and extend life for more patients around the world. We can now bring together the extensive and innovative capabilities of both Medtronic and Covidien with an underlying objective to solve healthcare's biggest challenge - expanding access and improving clinical outcomes, while lowering costs," said Omar Ishrak, Chairman and CEO of Medtronic. "This is an exciting day for our employees as we officially join forces to pursue our shared commitment to addressing universal healthcare needs and accelerating Medtronic's three fundamental strategies of therapy innovation, globalization and economic value. We know that our combined businesses can have a real and meaningful impact on people's lives - helping to treat more people, in more ways and in more places around the world."

The cash-and-stock transaction is valued at approximately $49.9 billion, based on Medtronic's closing stock price of $75.59 per share on January 26th, 2015. Under the terms of the transaction, each ordinary share of Covidien outstanding as of the closing has been converted into the right to receive $35.19 in cash and 0.956 of an ordinary share of Medtronic plc. Each share of Medtronic, Inc. common stock outstanding as of the closing has been converted into the right to receive one ordinary share of Medtronic plc.

Medtronic's financial advisor is Perella Weinberg Partners LP and its legal advisors are Cleary Gottlieb Steen & Hamilton LLP and A&L Goodbody. Covidien's financial advisor is Goldman Sachs and its legal advisors are Wachtell, Lipton, Rosen & Katz and Arthur Cox. The closing of the transaction does not affect the results of Medtronic, Inc.'s fiscal third quarter, which ended January 23rd, 2015. The company provided a financial update on its fiscal third quarter earnings conference call on Tuesday, February 17th, 2015. For more detailed information on anticipated Medtronic plc revenue reporting changes and combined historical financials, see Medtronic plc Revenue Reporting Changes and Historical Financials.

Medtronic plc has its principal executive offices in Ireland, where both companies have a longstanding presence. The company's operational headquarters will continue to be based in Minneapolis. Medtronic has a comprehensive product portfolio, a diversified growth profile and broad geographic reach, with more than 85,000 employees in more than 160 countries.

For more information, please visit www.medtronic.com.

Jennifer D. Walker, MD Named Chief of the Division of Cardiac Surgery at UMass Memorial

UMass Memorial Medical Center has appointed Jennifer D. Walker, MD, as Chief of the Division of Cardiac Surgery and Surgical Director of the Heart and Vascular Center of Excellence. She has worked at the Medical Center since October and began her new role on December 31st. Dr. Walker now joins a very short list of female chief of cardiac surgery at academic medical centers in the United States.

"We believe Jennifer will make significant contributions to the Heart and Vascular Center of Excellence, which will allow our cardiac surgery program to continue to be among the leaders nationally in access, outcomes and patient satisfaction. We are very excited to have Jennifer join our team," said Demetrius Litwin, MD, Chair of the Department of Surgery, UMass Memorial and Harry M. Haidak Professor of Surgery, University of Massachusetts Medical School.

Dr. Walker is a summa cum laude graduate of the University of South Carolina. She completed her medical education at the Medical University of South Carolina, where she also completed her internship and residency in surgery. Dr. Walker completed cardiothoracic surgery training at Massachusetts General Hospital (MGH) and Boston Children's Hospital.

Dr. Walker comes to UMass Memorial from MGH where she was Director of Cardiothoracic Resident Education. Under her guidance, many general surgery residents have chosen a career path in cardiac surgery. In 2009, she became Director of the Cardiac Surgical Simulation Laboratory and Training Program at Mass General. She is the recipient of numerous excellence in teaching awards.

Her clinical interests include: acquired heart disease; valve repair and reconstruction; coronary artery disease; all arterial grafting; adult congenital heart disease; cardiac transplantation and heart failure; and resident cardiac surgical stimulation training.

"I have been fortunate to learn/train under and work alongside some of the nation's finest doctors at world-class organizations and those experiences have prepared me for this position," Dr. Walker said. "UMass Memorial has a terrific team. More importantly, it is a vital resource for the people of Central Massachusetts. I am looking forward to continuing the UMass Memorial commitment to excellence in cardiac surgery services."

During her career Dr. Walker served on a number of committees including the Heart Center Operations Committee at Mass General, committees for the Society of Thoracic Surgeons, the American Board of Thoracic Surgery, the American Heart Association and the Massachusetts Medical Society.

European Market Could Facilitate Prosthetic Heart Valve Advancements, Says GlobalData Analyst

In light of a recent American Heart Association report stating that US mitral valve regurgitation prevalence was 1.7% in 2014, a significant opportunity exists for prosthetic heart valve manufacturers to develop an effective transcatheter mitral valve replacement (TMVR) device as an alternative treatment to surgery for inoperable patients, says an analyst with research and consulting firm GlobalData.

Furthermore, according to Premdharan Meyyan, GlobalData's Analyst covering Medical Devices, TMVR device makers are expected to utilize the relatively lax regulatory approval process in the European market to test new products and amass clinical data, with first-generation devices likely to be approved within the next five years.

As mitral valve regurgitation patients comprise the largest segment of the US population suffering from heart valve-related disorders, some of whom cannot be treated by conventional surgical repair methods due to associated comorbidities or other risk factors, there is a need for minimally-invasive therapies that will ultimately improve clinical outcomes.

Meyyan says, "Following the shake-up of the surgical heart valve market with the emergence of minimally-invasive Transcatheter Aortic Valve Replacement (TAVR) procedures, key opinion leaders have asserted that a similar opportunity exists for companies to discover the easiest and safest way to put devices into the mitral position."

"Although the complex anatomy of the mitral annulus makes successful implantation of a prosthetic device in this position more difficult than in the aortic position, major prosthetic heart valve manufacturers, such as Edward Lifesciences, are already executing TMVR development alongside their existing product lines."

The analyst adds that numerous smaller companies, including Neovasc and Micro Interventional Devices, are making a focused effort to develop technologies that overcome the clinical barriers specific to mitral valve replacement.

"While these devices are still years away from commercialization, early movers in the TMVR space are poised to seize considerable shares from key players in the billion-dollar prosthetic heart valve market, due to the large patient base," Meyyan concludes.

GlobalData is a leading global research and consulting firm offering advanced analytics to help clients make better, more informed decisions every day. For more information visit: www.globaldata.com.

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