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The Paradigm of Patent Foramen Ovale and Cryptogenic Stroke

By Poay Huan Loh, MD; Olaf Franzen, MD; and Lars Søndergaard, MD

Abstract

The paradigm of patent foramen ovale (PFO) and cryptogenic stroke has continued for over a century. Although PFO closure in the context of cryptogenic stroke has become clinical routine in many places, there is no evidence to support this practice. Whilst a plethoric of data is available on PFO closure, mainly in the context of cryptogenic stroke, the data comes from non-randomised studies or anecdotal cases. Few studies have focused on medical treatment of cryptogenic stroke and PFO. The latest guidelines continue to reflect the lack of randomised data in this area. The report of the CLOSURE I Study marks the beginning of a series of randomised studies which would, hopefully, solve this paradigm and should not be taken as the conclusion or met with pessimism. Until then, physicians and interventionalists will continue to face the dilemma when dealing with these patients. This review discusses such dilemma and available data with some case vignettes. Consensus statements, consistency in local practice, clinical judgement and commitment to clinical trials may help to guide the management of such patients.

Introduction

Failure of the primum and secundum atrial septa to fuse following birth leads to patent foramen ovale (PFO). Paradoxical embolism (PrE) can occur under certain hemodynamic condition when there is a pressure gradient generating right-to-left shunting of blood across the PFO, such as during Valsalva manoeuvre. Systemic arterial embolization can occur in any organ but given the anatomy of aortic arch and the higher sensitivity of the brain to ischemic insult than other organs, most cases of clinically apparent paradoxical embolism manifest as transient ischemic attacks (TIAs) or strokes; whilst embolization to other organs are often silent.[1,2] Naturally, most data that link paradoxical embolism and PFO focus on cerebrovascular accidents (CVAs); and PFO, when present, are often implicated as the cause of cryptogenic stroke (CS).[3,4] To a large extent, this forms the basis for interest in device closure of PFOs over the last two decades.[5]

Although there is a wealth of data showing the benefit of PFO closure in the context of CS[6], this remains a highly controversial topic. The main reason is that these are non-randomised studies or anecdotal cases which are thought to be circumstantial by some. The results of the CLOSURE I trial,[7] the first randomised controlled trial (RCT) investigating the role of device closure compared to best medical therapy in CS, were reported in the 2010 American Heart Association (AHA) Scientific Sessions and met with contrasting reactions. To some, the lack of benefit and the increased incidence of vascular injury and atrial fibrillation is enough for them to draw a conclusion and 'put a nail in the coffin' for PFO closure. To many, the dilemma and unease when faced with patients in clinical practice goes on. This is reflected in the latest Guidelines from the AHA and American Stroke Association (ASA) on prevention of stroke.[8] Lessons learned from

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CLOSURE I trial should be taken as a step forward in the effort to solve the paradigm of PFO closure and CS. Many RCTs are currently in the recruitment or follow-up stages and their effort should be supported.

Historical Background

Leonardo Botallo, a 16th-century Italian anatomist and surgeon, was the first to describe PFO.[9] Although there were earlier accounts, Cohnheim was recognized as the first to trace an embolus through a PFO when he reported a case of a young lady who died of stroke in 1877.[10] The concept was strengthened in 1881 by Zahn's necropsy report on a case of uterine vein thrombosis and multiple systemic emboli with associated branched thrombus in the PFO.[11] In 1885, Zahn coined the term 'paradoxical embolism' to describe systemic arterial embolism caused by thrombus originated from the venous system via an abnormal communication between the heart chambers.[11] Interest in device closure of atrial septal defects started in the 1950's, but it was not until 8th, April 1975 that the first successful transcatheter device closure of atrial septal defect in man was performed by Dr. Terry D. King and Dr. Noel L. Mills, using the Umbrella device they developed with Edwards Laboratory.[12] In 1992, the first patient series of device closure of PFO for presumed PrE was reported.[5]

PFO, Cryptogenic Stroke and Extra Cerebral Paradoxical Embolism

Cryptogenic stroke is a general term to describe stroke of unknown cause despite extensive investigation, although there is no standardised investigation or criteria for the definition. As many as 40% of all strokes have undetermined cause.[13] The prevalence of PFO in the general population is approximately 15%– 25%[14,15]. In patient with CS, the prevalence is around 40% – 60%, with higher prevalence in younger patients.[16,17] In a meta-analysis of patients with strokes of known etiologies and CS, the likelihood of CS was 3 times higher in patients with a PFO, and 23 times higher in those with a PFO and atrial septal aneurysm (ASA), when compared to those without PFO or ASA.[4] In patients suffering from stroke, deep vein thrombosis has been found to be more common in patients with cryptogenic stroke compared to those with stroke of known etiology.[18] These suggest an association between PFO and cryptogenic stroke. However, a small population-based study of Olmsted residents did not find such association.[14] Another study based on 1100 stroke-free individuals older than 39 years (mean age 69 ± 10 years) from the North Manhattan Study (NOMAS) identified 164 individuals (14.9%) with PFO. The ischemic stroke rate was 6.2% during a mean follow-up of 80 ± 28 months, and PFO was not found to be associated with an increase in stroke.[19]

In clinical settings, the reported recurrent rate of stroke in patients with PFO and CS ranges from 3.8 – 12% in medically treated patients and 0 – 4.9% after PFO closure[6]. In the CLOSURE I study,[7] the 2-year recurrent stroke and TIA rates were 3.1 – 3.4% and 3.3 – 4.6% respectively, and no difference was found between medical therapy and device closure groups. Approximately 80% of these were thought to have alternative explanations suggestive that the rate of recurrent CS may be relatively low and other conventional risk factors are highly relevant. One study found a low 4-year recurrent stroke rate of 2.3% in those with PFO alone, but 15.2% when there was co-existing ASA.[20] Although not a consistent finding, ASA and other features such as significant spontaneous right-to-left shunt, coagulopathy,

larger PFO and prominent Eustachian valve have been reported to be associated with higher risk of recurrent stroke.[21]

A postmortem series of patients with normal hearts reported that the prevalence of PFO decreased with age, from 34% in those aged 0 – 30 years, to 20% in those aged 80 – 99 years.[15] As spontaneous PFO closure is unlikely, this finding may imply a higher early death rate in those with PFO. In 132 consecutive patients presented with pulmonary

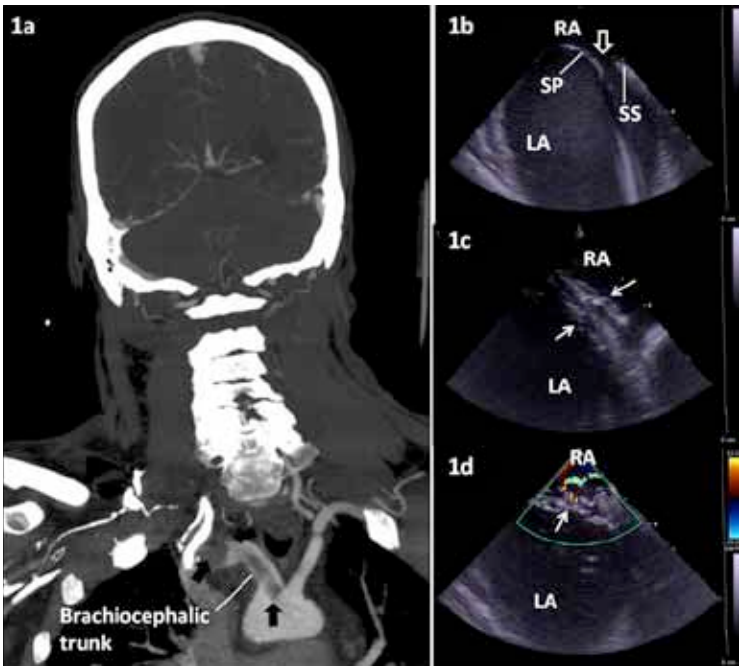

Figure 1. A previously fit and well 50-year-old businessman with frequent air travel history had flare-up of gout arthritis followed by right leg deep vein thrombosis confirmed on doppler ultrasound two days later. Despite anticoagulation therapy, he presented with left-sided hemipareisis five days later secondary to ischemic stroke confirmed on CT scan and was thrombolysed with acteplase therapy. A follow-up CT scan the next day showed a) extensive thrombus (black closed arrows) extending from the aortic arch into the brachiocephalic trunk causing almost complete occlusion of his right subclavian and common carotid arteries with relative reduction in the vascularity of the right hemisphere with associated edema. He required urgent decompression craniotomy 2 days later due to reduced mental state secondary to cerebral edema. Extensive investigation did not identify any coagulopathy or intracardiac embolic source. A transesophageal echocardiogram (TEE) with agitated saline and pressure on abdomen confirmed the presence of a small PFO with right-to-left shunt and no thrombus was seen in the PFO. Two weeks later, he underwent PFO closure under intracardiac echocardiography (ICE) and fluoroscopic guidance. The PFO b) measured 12 mm in diameter (white open arrow) using balloon sizing and was successfully closed using c & d) a 30-mm Gore Septal Occluder® (GSO) (white arrows) without residual shunt. He was discharged to local hospital for further rehabilitation a week later. Incidentally, this was the first clinical case of PFO closure using GSO in the world. LA, left atrium; RA, right atrium; SP, septum primum; SS, septum secundum.

embolism, those with PFO had higher rates of stroke, arterial embolism and death.[22] Therefore, presence of PFO may also be indirectly associated with increased adverse events[23] (Case 1, Figure 1).

Indeed, systemic extra cerebral PrE can cause serious conditions including acute myocardial infarction, ischemic limbs and renal infarction. These cases account for 5 – 10% of all clinically apparent PrE.[1,24,25] In two series on all patients referred for PFO closure due to PrE, the prevalence of extra cerebral manifestation is 3 – 6%. Importantly, approximately 50% of these patients had a history of previous stroke or evidence of cerebral infarction on magnetic resonance imaging and coexisting coagulopathy was common.[1,24] In a case review on PrE to the kidneys, PFO was commonly implicated and many patients had more than one end-organs affected, some with severe adverse outcome.[25]

Medical Therapy for Cryptogenic Stroke

The main medical therapy for Thromboembolic Syndrome has been coumadin, although newer agents are now available. However, the annual recurrent TIAs or stroke rate in patients with PFO being treated medically

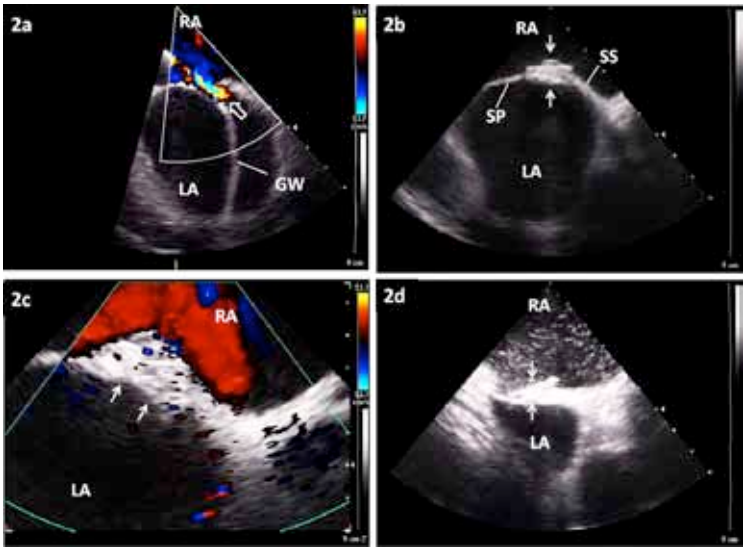

Figure 2. A 40-year-old active man who had no conventional cardiovascular risk factor presented with transient neurological signs and symptoms (lasting approximately 7 hours) consistent with, in the opinion of the treating neurologist, transient ischemic attack. There was no MRI evidence of ischemic lesion. He had extensive investigation and a patent foramen ovale with right-to-left shunt on Valsalva manoeuvre was identified. Despite aspirin therapy, he experienced a recurrent event 5 months later. This episode lasted for 12 hours without MRI evidence of ischemic lesion. It was felt that device closure should be offered to the patient, and after detailed discussion, he opted to undergo the procedure. Under ICE and fluoroscopic guidance, the PFO measured a) 6 mm in diameter and 10 mm in length on balloon sizing (white open arrow). This was successfully closed with a 20-mm GSO® (white arrows) and b) the ICE images showed low device profile with good conformity to the interatrial septum. No residual shunt was identified on c) colour flow mapping and d) agitation saline contrast on the release of Valsalva. GW, guide wire; LA, left atrium; RA, right atrium; SP, septum primum; SS, septum secundum.

can be as high as 12%.[6] The optimal medical therapy for these patients is yet to be defined. The PFO in CS sub-study (PICSS) of WARSS comparing aspirin and warfarin did not find any difference between the two therapies.[26] Maintenance of therapeutic level of warfarin may have been a confounding issue. A later extensive review by the Quality Standard Subcommittee of the American Academy of Neurology found no difference between aspirin or warfarin with regards to the risk of recurrent stroke in patients with CS and PFO or ASA, but warfarin was associated with an increase risk of minor bleeding.[23] No data is available on the use of other anti-platelet agents, alone or in combination with aspirin, and the efficacy of newer anti-thrombotic agents in secondary prevention for patients with PFO and CS. The latest Guidelines from the AHA and ASA recommend antiplatelet for secondary stroke prevention in CS associated with PFO (Class IIa; Level of Evidence B) and state that there are insufficient data to establish whether anticoagulant is equivalent or superior to aspirin for secondary stroke prevention in patients with PFO (Class IIb; Level of Evidence B).[8]

For the medically-treated patients in the CLOSURE I Study,[7] the 2-year recurrent stroke and TIA rates were 3.4% and 4.6% respectively, and there was no difference found between the patients who were taking warfarin compared to aspirin. Importantly, the investigators reported that the alternative explanation unrelated to PrE could be identified in 80% of the patients with recurrent stroke or TIA. This is understandable as the risk profile of patients is dynamic, and optimal medical therapy in these patients may not be limited to anti-thrombotic therapy alone, but encompasses a strategy that addresses concomitant risk factors. A more important question the investigators of CLOSURE I, or we as clinicians should ask is whether these cases could have been preventable. And if so, how or what could have been done better?

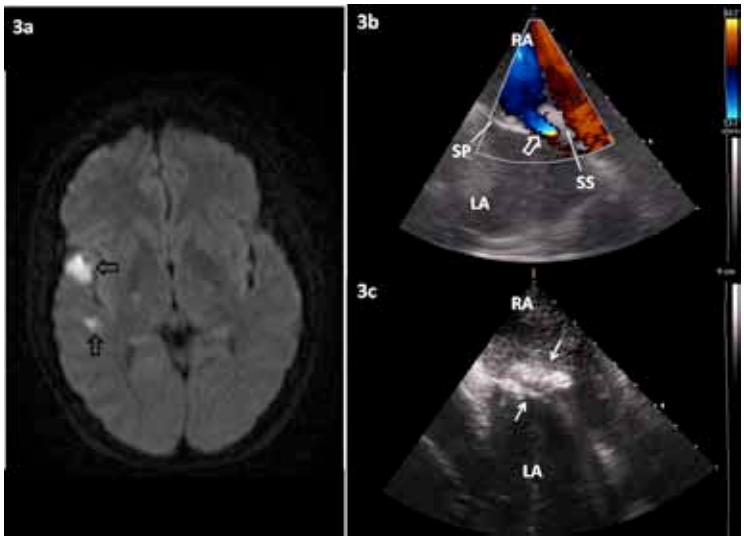

Figure 3. A 21-year-old non-smoking lady who did not have any pro-thrombotic risk factors or coagulopathy presented with transient left sided weakness lasting a few hours. An MRI of head a) confirmed the presence of two lesions consistent with infarction (black open arrows) and TEE confirmed the presence of a PFO with right-to-left shunt on Valsalva manoeuvre. She was started on aspirin therapy and participation in REDUCE trial was discussed with her. She gave informed consent and was randomised to PFO closure using Helex® septal occluder plus antiplatelet therapy. Under ICE and fluoroscopy guidance, b) the PFO measured 8 mm in diameter with an 11-mm tunnel on balloon sizing. This was c) successfully closed with a 25-mm Helex® septal occluder without residual shunt on agitated saline contrast upon release of Valsalva. LA, left atrium; RA, right atrium; SP, septum primum; SS, septum secundum.

PFO Closure in Cryptogenic Stroke

Prior to the report of CLOSURE I, all data regarding PFO closure in CS were from observational studies and case series using different closure devices.[27] In a single-center uncontrolled series comparing 158 medically-treated patients to 150 patients who received PFO closure due to CS, patients with complete PFO closure were at low risk of recurrent stroke or TIA after 4 years of follow-up (6.5% vs. 22.2%; p = 0.04).[28] Patients who had multiple strokes prior to PFO closure also had lower risk of recurrent

event after PFO closure when compared to medical therapy (7.3% vs. 33.2%; p = 0.01). In a meta-analysis including 1355 patients receiving device closure in 10 studies, and 895 patients treated medically in 6 studies, the 1-year recurrent neurologic thromboembolic event rates were 0 – 4.9% for device closure and 3.8 – 12% for medical therapy[6]. However, definitive conclusion could not be made due to the heterogeneity of the study populations.

The CLOSURE I trial is a prospective, multicenter, randomized, open label, two-arm superiority study that compared percutaneous PFO closure (n=447) using STARFlex® (NMT Medical, Boston, MA, USA – device no longer available) plus medical therapy with best medical therapy alone (n=462) in patients ≤ 60 years old with CS or TIA[7]. The primary endpoint was 2-year incidence of stroke or TIA, all-cause mortality for the first 30 days and neurological mortality from day 31 to 2 years. The results were reported in 2010 AHA Scientific Sessions. The study experienced poor recruitment and only 611 of the intended 1600 patients were recruited after 4 years leading to readjustment of the target to 800 patients. This was based on the expected absolute reduction of primary endpoint from 6% in medical therapy group to 2% in PFO closure patients. It was later increased to 900 patients on the recommendation of the Data Safety Monitoring Board.[7]

On intention-to-treat analysis, CLOSURE I trial found no difference in the 2-year primary endpoint in the PFO closure patients compared to medical therapy group (5.9% vs. 7.7%, p = 0.30). The rates of stroke and TIA were also similar in both groups (3.1% vs. 3.4%, p = 0.77 and 3.3% vs. 4.6%, p = 0.39, respectively). Similar trend was found on subgroup analysis based on the severity of the PFO shunt at baseline and the presence of ASA. On transesophageal echocardiography, effective closure (with no or trace residual shunt) was achieved in 86.7% of the patients after 2 years. However, major vascular complication and atrial fibrillation were more frequent in the patients who had PFO closure compared to those who received medical therapy alone (3.2% vs. 0%, p < 0.001 and 5.7% vs. 0.7%, p < 0.001, respectively). Although much debated, it is unclear if factors such as the inclusion of patients with small right-to-left shunt and TIA patients without the use of cerebral imaging and the fact that StarFlex has a higher rate of residual shunt and associated thrombus when compared to some other devices[29] would have played any part in the observed findings.

In the absence of data from randomised study, the recent AHA and ASA guidelines state that there are insufficient data to make recommendation regarding PFO closure in patients with stroke and PFO (Class IIb; Level of Evidence C).[8]

Looking into the Future

The findings in the CLOSURE I trial should be taken seriously and lessons should be learned. However, the trial findings do not constitute a definitive paradigm of PFO and CS, but has reiterated that much is still to be done in order to identify the best treatment strategy for the patients. Currently, 4 other on-going RCTs are at the recruitment or follow-up stages (Table 1). The PC-Trial that compares PFO closure using Amplatzer® PFO occluder (AGA Medical, Plymouth, MN, USA) to best medical therapy (warfarin, aspirin or Clopidogrel) in patients with cryptogenic PrE has completed enrolling 425 patients (target 411) in February 2009. Follow-up was expected to end in 2011 when the last patient enrolled in the study has completed at least a 2.5 year follow-up period.[30] Similar to CLOSURE I, PC-Trial started in 2000 and experienced slow recruitment although the target number of patients was achieved.

Likewise, RESPECT, which compares Amplatzer® PFO occluder to a few medical regimens (Aspirin, Clopidogrel, aspirin plus dipyridamole and warfarin) in patients with CS aged ≤60 years, started patient enrollment in 2003, and by June 2009 had only 576 of the target 900 patients.[31] The CLOSE Study aims to compare PFO closure using any committee-approved closure devices to aspirin or warfarin in patients with CT- or MRI-proven CS and PFO with evidence of right-to-left

Table 1: Summary of Ongoing RCTs Comparing Medical Therapy and PFO Closure

Study Year Began	Location Patients Enrolled/(Planned) Follow-up	Treatment Groups	Main Inclusion Criteria	Primary Endpoint
PC-Trial[30] 2000	Australia, Europe, Canada 425/(411) by February 2009 5 years	1. Amplatzer PFO occluder 2. Warfarin (INR 2 – 3) or aspirin 100 – 325mg/d or clopidogrel 75 – 150mg/d (investigator's decision)	< 60 years PFO with right-to-left shunt Stroke/TIA/extracranial arterial embolism without identifiable cause Sufficient recovery to allow independent daily activity	Composite death/non-fatal stroke/peripheral embolism
RESPECT[31] 2003	US 576/(900) by 30/06/2009 8 years	1. Amplatzer PFO occluder 2. Aspirin 3. Clopidogrel 4. Aspirin + dipyridamole 5. Warfarin	18 – 60 years Cryptogenic stroke within 270 days of enrollment	Composite non-fatal stroke/ post-randomisation mortality/ fatal ischemic stroke
CLOSE[32] 2008	Europe 213/(900) by 01/02/2010 5 years	1. Approved PFO closure device + antiplatelet 2. Warfarin (INR 2 – 3) 3. Antiplatelet (aspirin or clopidogrel or aspirin + dipyridamole)	16 – 60 years Ischemic stroke (≤ 6 months) confirmed on CT or MRI without a known cause Modified Rankin ≤ 3 PFO with right-to-left shunt or ASA	Stroke (fatal or non-fatal) during follow-up of 3 or 5 years
REDUCE[33] 2008	US, Europe -- /(664) 2 years post-randomization	1. HELEX septal occluder + antiplatelet 2. Antiplatelet therapy	16 – 60 years Cryptogenic ischemic stroke/TIA evident on CT or MRI within 180 days PFO with right-to-left shunt No identifiable systemic arterial thromboembolism or hypercoagulable state	Freedom from recurrent ischemic stroke/imaging-confirmed TIA/death due to stroke through 24 months post-randomization

CT, computed tomography; INR, International normalized ratio; MRI, magnetic resonance imaging

shunt or co-existing ASA. The recruitment started in 2008 and only 213 of the target 900 patients were enrolled by February 2010 despite having 29 active centers.[32] The REDUCE study aims to enroll 664 patients in order to compare PFO closure using HELEX® Septal Occluder (W. L. Gore & Assoc., Inc., Flagstaff, AZ, USA) plus antiplatelet therapy to antiplatelet therapy alone in patients with MRI- or CT-verified CS. The primary end-point is recurrent cerebral infarction after 24 months. The study started in 2008 has enrolled 175 patients.[33]

Many of these on-going RCTs have longer follow-up periods compared to the CLOSURE I. Study such as REDUCE has included follow-up cerebral MRI findings of ischemic lesions as a secondary endpoint. Therefore, these trials will add to what CLOSURE I has contributed so far. However, it is a worldwide experience that enrollment into these trials has lagged considerably despite the large gap in clinical evidence to guide the practice. This may be due to various reasons including strong opinion or established practice of clinicians or institutions, reimbursement policies in some countries and patient unwillingness to participate in RCT caused by the uncertainty in both medical therapy and device closure (Case 2, Figure 2). In some countries, the strategy of trial organisers or sponsors recruiting only centers that perform a certain number of procedures may be counterproductive as these centers may often have an established practice, whilst centers performing fewer procedures may have equally skillful interventionalists, but are unable to contribute more to patient enrollment. Some countries, such as Denmark, have taken a stance to establish a consensus approach among all clinicians involved to enroll all suitable patients who give informed consent into the REDUCE study (Case 3, Figure 3). This is in line with the call for supporting these landmark trials by the AHA, ASA and American College of Cardiology Foundation (ACCF).[34]

The STARFlex® device, which was used in CLOSURE I, but is no longer available, had the intrinsic disadvantages such as higher rate of residual shunt and associated thrombus when compared to some other devices.[29] This may be the reason that despite the on-going uncertainty about the benefit of PFO closure in CS, new devices are regularly being designed and existing devices are being improved. One example is the Gore HELEX® device that has been improved with a new design and construction of both the occluder device and delivery catheter, the Gore Septal Occluder® (GSO). The GSO has retained some of the features of HELEX®, such as atraumatic design and low profile with minimal atrial septal deformity, swift biological tissue response and long-term biocompatibility.

New innovations will continue to be introduced. The 'in-tunnel' devices such as FlatStent (Coherex Medical, Inc., Salt Lake City, UT) are designed to leave minimal foreign material in the PFO tunnel and on the septum with little septal distortion. Almost all of the device will be incorporated into the PFO tunnel in order to reduce the risk of device thrombosis.[35] The Spider™ occluder (Lifetech Scientific Co., Ltd., Shenzhen, China) is another example of the use of new technology with the ceramic-coated nitinol wire that is less thrombogenic than the bare nitinol material.[36] Other currently available devices, or those in development, have their innovative advantages, but are beyond the scope of our discussion.

One aspect that may help current and future research into PFO and cryptogenic stroke or PrE is to have a consensus or standardised method of stratifying patients and defining important endpoints. This may include patient classification based on: patient profile, clinical presentation, certainty of PrE, anatomy of PFO and associated structure, likelihood of recurrent PrE or CS and the presence of established cardiovascular risk factors that need to be addressed.

Recommendations are made on the standard of investigations and consensus on criteria that define CS and PrE based on current best knowledge and practice to encourage positive diagnosis rather than diagnosis by exclusion. The Risk of Paradoxical Embolism (RoPE) Study plans to derive a risk stratification model using currently available data and later validate the model based on some completed RCTs of PFO closure.[37] Such efforts may help to guide patient management in the future.

Conclusion

It seems likely that the paradigm of PFO and CS or PrE will continue in the foreseeable future. Lessons should be learned from the CLOSURE I trials. Although the risk of PFO closure should not be ignored, support should be given to on-going RCTs. Effort should come from all involved in order to improve our understanding and identify the best treatment strategy for these patients. Until then, guideline-setting organisations may lead the way towards a standardised clinical practice or structured research strategy. Innovative new technologies will continue to appear and these should be encouraged, but not at the expense of establishing the appropriate treatment strategy for the patients.

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Congenital Cardiology Solutions at the ACC's 61st Annual Scientific Session & Expo: The Evolution of Education is at ACC.12

See how the ACC is changing the learning experience. Experience cutting-edge science and innovation, and focus on lifelong learning and practice improvement. ACC.12 has everything you need to advance your knowledge — all in one place.

New this year! ACC.12 will officially kick off with the ACC.12 Opening Showcase & Late Breakers at 8 a.m. on Saturday, March 24th, and will close on Tuesday, March 27th at noon with a brand new ACC.12 Closing Session: Innovators in Cardiology, featuring top leaders in cardiology. There's so much planned for ACC.12 — you won't want to miss any of it.

ACC.12 features 16 new learning pathways, allowing the ACC to better address the needs of you, our learners. Plus, don't miss Congenital Cardiology Solutions (CCS), a featured Learning Pathway. You'll explore the latest in science and patient care across the continuum of congenital heart disease, from newborns to adults. Catch up on advances in imaging techniques, interventions and devices. Get expert advice on guiding patients through critical life changes such as pregnancy and menopause. Share ideas with colleagues on the clinical dilemmas you face every day, including when to intervene and how to minimize radiation risks. Learn about the important role general cardiologists play in managing adult patients with chronic CHD.

Go to www.accscientificsession.org/acc12 to learn more and register today!

Adult Congenital and Pediatric Cardiology Member Section at ACC.12

You are warmly invited to join the Adult Congenital and Pediatric Cardiology Section leaders for the ACPC Section meeting at ACC.12.

This forum for ACPC members and interested guests is dedicated to discussing and advancing the clinical and professional interests of pediatric and congenital heart disease specialists.

Leaders within the communities use this forum to share updates on ACPC Section priorities and activities as well as discuss activities related to education, quality, advocacy, publications and other areas. Agenda items include updates on Maintenance of Certification, ACPC's quality efforts, salient issues within the clinical practice of congenital heart disease and much more!

Interested in getting involved? Or just want to learn about what the Section is doing to support the interests of adult congenital and pediatric cardiologists, surgeons and cardiac care associates?

We welcome you to join the discussion on Saturday, March 24th from 6:00 – 8:00 p.m. at the Chicago Hilton, Continental Ballrooms A & B. Refreshments and wine will be served. Go to www.surveymonkey.com/s/KT8H39G to RSVP today or email acpcsection@acc.org.

Additionally, there will be several ACPC Section work group meetings throughout the day on Friday, March 23rd. Stay tuned for announcements through the ACPC Section list serve and relevant work group list serves. Questions, please contact Stephanie at acpcsection@acc.org.

We look forward to seeing you in Chicago for CCS.12!

ACC.12 Program Co-Chairs

Rick A. Nishimura, MD, FACC
Patrick T. O'Gara, MD, FACC

CCS.12 Topic Working Group

Arwa Saidi, MB, BCh, FACC, Topic Coordinator
Lisa Bergersen, MD, MPH, FACC, Topic Co-Coordinator
Jean A. Connor, NP
Henri Justino, MD, CM, FACC
Joshua Kanter, MD, FACC
Doff B. McElhinney, MD
Karen K. Stout, MD, FACC
Anne Marie Valente, MD, FACC

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ACC-i2 with TCT
innovation in intervention
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CCS.12
Congenital Cardiology Solutions

The Continuum of Care at CCS.12

By Arwa Saidi, MB, BCh, FACC and Lisa Bergersen, MD, MPH, FACC

For the fifth year, Congenital Cardiology Solutions (CCS) is a featured Learning Pathway at the American College of Cardiology (ACC) Annual Scientific Session in Chicago. This year's program highlights the continuum of care of the congenital heart disease (CHD) patient, from birth to adulthood. The educational sessions will underscore the importance of collaboration and deal with significant clinical issues and the questions that regularly face the cardiovascular professionals who treat patients with congenital heart disease. This year's meeting emphasizes quality of care, use of databases in developing patient care pathways and innovations in congenital cardiac care.

The ACC leadership has heard your suggestions and has responded with more CCS and pediatric cardiology sessions than ever before. Plus, as previously suggested by many attendees, the meeting starts on Saturday morning at 8 a.m. to minimize your time out of the office.

One of our goals for the CCS program this year was to achieve a balance between pediatric and adult congenital heart disease. The CCS program includes 19 total sessions: 3 in pediatric cardiology, 4 in pediatric interventional cardiology, 3 ACHD sessions, 8 sessions with both pediatric and ACHD content and 1 ABP MOC session. The sessions will be presented in a variety of formats including case-based, meet the experts and symposia with a special emphasis on minimizing the overlap of sessions with common topics of interest.

The meeting kicks off on Saturday morning with an American Board of Pediatrics (ABP) Maintenance of Certification (MOC) session, where you can earn up to 10 ABP MOC credits. ACC.12 also offers even more ABIM maintenance of certification (MOC) sessions with modules in general cardiology, interventional cardiology and — new this year — electrophysiology. Each module is worth 10 ABIM MOC points.

The CCS program begins with the symposium on Complex Issues Facing ACHD Patients which will focus on obstructive lesions. This will be followed by the Quality, Safety and Resources Enhancing Pediatric Cardiovascular Care symposium and the symposium on Updates on Care in the Congenital Heart Disease Patients. These three sessions represent the stepping stones in a four-day program that also includes the symposium regarding Women with CHD: Fertility, Pregnancy and Menopause. The popular Great Debates program will feature debates on the use of digoxin for the treatment of SVT in newborns, the timing of pulmonary valve replacement in TOF, and the use of stimulants in patients with CHD.

Four interventional sessions join the CCS and ACC-i2 with TCT Learning Pathways. These will also be of interest and relevant to the non-interventional pediatric cardiologist and include, on Sunday: two sessions on the evaluation of single ventricle patients: Pre-operative Assessment of Patients on Single Ventricle Pathway and Post-operative Glenns and Fontans: Navigating Turbulent Waters. On Monday, we will have a live case symposium — Pulmonary Artery Stenosis: Current Therapy and Future Directions — followed by a session discussing the realistic expectations of therapy for pulmonary vein stenosis.

"This year's program highlights the continuum of care of the congenital heart disease (CHD) patient, from birth to adulthood."

On Sunday, Jane Somerville, MD, FACC, will present the *Legends of Cardiovascular Medicine 2012 Dan G. McNamara Lecture* in which she plans to discuss her 50 year experience working with cardiac surgeons. She will be interviewed by Dr. Carol Warnes about her personal experience, history of CHD treatment, and thoughts on the future of congenital heart disease care. Always an interesting speaker, Dr. Somerville should offer some unique insights.

With a large number of high quality work submitted for abstract presentation, we had many excellent options to select for the oral and poster presentations. We are very fortunate to have an opportunity to include the results of excellent research that will provide evidence-based medicine for patient care as our field continues to develop. The pediatric cardiology oral abstract session on Saturday morning will focus on targeting errors, quality of care, and databases that impact clinical care and outcomes. The ACHD oral abstracts on Sunday morning will emphasize evolving therapies and the use of imaging to predict outcomes. We are also extremely fortunate to have Dr. Thomas Graham presenting an overview of the year in congenital heart disease.

We hope that we have been able to develop CCS into a meeting that appeals to all attendees. We are excited about this year's CCS program and we hope you will join us and see the evolution of education at ACC.12 and CCS in Chicago, March 24th – 27th, 2012. Go to www.accscientificsession.org/acc12 to register today!

Dr. Saidi is the topic coordinator of the Congenital Cardiology Solutions working group and a member of the ACC's Adult Congenital and Pediatric Cardiology (ACPC) Section. Dr. Bergersen is the topic co-coordinator of the Congenital Cardiology Solutions working group and is also a member of the ACC's ACPC Section. For additional information about CCS.12 and ACC.12, go to www.accscientificsession.org/acc12.

CCS LEARNING PATHWAY: SATURDAY, MARCH 24

8:00-10:00 am - [Special] - #300 **- ACC.12 Opening Showcase and Late-Breakers**
- Opening Video and National Anthem
- Welcome, Introductions and Acknowledgements
- Introduction of Keynote Lecturer: Eugene Braunwald, MD, MACC
- Legends of Cardiovascular Medicine Lecture Series: 2012 Simon Dack Lecture — The Treatment of Acute Myocardial Infarction: Into the Second Century
- ACC Presidential Address
- Late-Breaking Clinical Trial Presentations

8:00-9:30 am - [Symposium] - #202 **- Complex Issues Facing ACHD Patients: Obstructive Lesions**

10:30 am-Noon - [Orals] - #901**- From Targeting Errors to UNOS: How Quality and Databases Can Impact Clinical Care**
- Improving Survival by Targeting Errors
- Vitamin D Status in Neonates Undergoing Cardiac Operations: Relationship to Cardiopulmonary Bypass and Outcomes
- Progressive Left Ventricular Changes Predict the Likelihood of Survival in Pediatric Dilated Cardiomyopathy: Findings from the Pediatric Cardiomyopathy Registry
- Pediatric Heart Transplantation from Donors with Depressed Ventricular Function: An Analysis of the United Network of Organ Sharing Database
- Identified Mortality Risk Factors Associated with Presentation, Initial Hospitalization, and Interstage Period for the Norwood Operation: A Report from the Joint Council on Congenital Heart Disease National Quality Improvement Collaborative
- IMPACT Registry™ (IMproving Pediatric and Adult Congenital Treatment): First Data Report

2:00-3:30 pm - [Symposium] - #616 **- Quality, Safety and Resources Enhancing Pediatric Cardiovascular Care**
- Increasing Access to Care and Evaluation of Quality for Pediatric Nurse Practitioner-Managed Cardiac Clinics
- Radiation Risk for Pediatric Patients in the Catheterization Laboratory: The Evidence and Measurement of Risk
- Optimizing Growth of the Cardiovascular Infant
- Enhancing a Distraction Free Environment: The Redzone Medication Safety Initiative
- Clinical Handoffs: Models That Can Be Safely and Practically Implemented
- Quality Improvement Amongst Cardiovascular Programs in Developing Countries

4:30-6:00 pm - [Symposium] - #625 **- Updates on Care in the Congenital Heart Disease Patients**
- Newer Antiarrhythmic and Anticoagulant Therapy and Potential Applications for Adults with Congenital Heart Disease
- The Use of Leadless Subcutaneous Defibrillators in Congenital Heart Disease
- Update on the Changing Approaches and Outcomes for Immunosuppression in Heart Transplant Patients
- Outcomes after Wider Application of the Cone Reconstruction for the Tricuspid Insufficiency: What Do We Know and What Do We Need to Know?
- Ventricular Assist Device: Current Indications and Options

CCS LEARNING PATHWAY: SUNDAY, MARCH 25

8:00-9:30 am - [Symposium] - #634 **- Preoperative Assessment of Patients on the Single Ventricle Pathway: Special Problems, Creative Solutions**
- Case Presentation
- Pre-Glenn Assessment in the Current Era: Significance of the Sano and Hybrid Stage 1 Modifications
- Systemic-to-Pulmonary Arterial Collaterals: Do They Matter and What Should We Do About Them?
- Considerations in Single Ventricle Patients with Heterotaxy
- Non-Invasive PreGlenn and PreFontan Assessment: When Is Catheterization Not Indicated?

10:45 am -12:15 pm - [Symposium] - #637 **- Post-Operative Glenns and Fontans: Navigating Turbulent Waters**
- Case Presentation
- Take Action When the Post Operative Fontan Isn't What You Hoped For
- Outcomes: Update from the Pediatric Heart Network (PHN) Single Ventricle Reconstruction (SVR) Trial
- The Blue Glenn
- Role of the Catheterization Lab for the Failing Fontan

10:45 am-12:15 pm - [Orals] - #920 **- Adults with Congenital Heart Disease: Imaging Predictors, Evolving Therapies and Outcomes**
- Cancer in Adults with Congenital Heart Disease Compared to the General Population
- Echocardiographic Predictors of Outcome in Eisenmenger Syndrome
- Can Selective Pulmonary Vasodilator Therapy Be Used to Target Pulmonic Regurgitation? Results of the Pinot Noir Trial
- Is Pregnancy Associated with Adverse Right Ventricular Remodeling in Women with Repaired Tetralogy of Fallot?
- Right Atrial Size Predicts Arrhythmia and Death in Patients with Repaired Tetralogy of Fallot
- The Year in Review — Congenital Cardiology Solutions

12:30 am -1:45 pm - [Special] - #301 **- Career & Mentoring Session for Pediatric and Congenital Cardiologists**

2:00 am -3:30 pm - [Legends Lecture] - #402 **- Legends of Cardiovascular Medicine Series — 2012 Dan G. McNamara Lecture**
- Welcome and Overview of Session
- Reflecting on McNamara Lecture
- Introduction of Dr. Jane Somerville, MD, FACC
- 2012 Dan G. McNamara Lecture: Fifty Years with Cardiac Surgeons
- Panel Discussion: Lifelong Care of the CHD Patient

4:30-6:00 pm - [Symposium] - #667 **- The Great Debates**
- Digoxin Is First Line Therapy for Newborns with SVT vs. Digoxin Is Not the First Line Therapy for Newborns with SVT
- Indications for Pulmonary Valve Replacement in Tetralogy of Fallot Apply to Pulmonary Regurgitation after Balloon Valvuloplasty vs. Indications for Pulmonary Valve Replacement in Tetralogy of Fallot Do Not Apply to Pulmonary Regurgitation after Balloon Valvuloplasty
- Stimulants Can Be Used in Patients with Congenital Heart Disease vs. Stimulants Can Not Be Used in Patients with Congenital Heart Disease

4:30-6:00 pm - [Symposium] - # 668 **- ACHD for the General Cardiologist**
- The Imaging Approach to the Adult with Repaired CHD
- The Approach to Arrhythmia Management in the Adult with Repaired CHD
- Adult with TOF: Get with the Guidelines
- Management of ASDs in Adulthood

CCS LEARNING PATHWAY: MONDAY, MARCH 26

8:00-9:30 am - [Symposium] - #678 **- Pulmonary Artery Stenosis Current Therapy and Future Directions: Live Case**
- Live Case: Pulmonary Artery Stenosis
- Pulmonary Artery Rehabilitation Current State of Knowledge: What Do We Need to Know to Improve This Procedure
- Devices Studies and PMA Indications in Congenital Heart Disease: Past Failures, Successes and Future Directions

8:00-9:30 am - [Symposium] - #679 **- Women with Congenital Heart Disease: Fertility, Pregnancy and Menopause**
- Biomarkers: How They Can Be Utilized During Pregnancy
- My Cardiologist Cleared Me for Pregnancy but...
- The Menopause: Not All Palpitations Are Cardiac!
- Difficult Decisions I Have to Make in the Care of the Pregnant ACHD Patient
- Psychological Challenges of the Childbearing Years

10:30 am-Noon - [Symposium] - #692 **- Pulmonary Vein Stenosis: What Are Realistic Expectations?**
- Case Presentation
- Epidemiology and Natural History of Pulmonary Vein Stenosis: Evolution in Our Understanding
- Pathology and Pathogenesis of Pulmonary Vein Stenosis: How Well Do We Know this Enemy?
- Surgery for Pulmonary Vein Stenosis: Outcomes and Expectations in the Current Era
- Transcatheter Pulmonary Vein Interventions: Do They Help? How and When?

10:30 am-Noon - [Symposium] - #693 **- Challenging Imaging Issues in Congenital Heart Disease**
- When 3-D Imaging Can Make a Difference
- Quantification of Collateral Flow in Congenital Heart Disease: When and How
- What Stress Imaging Adds to Echocardiography in CHD
- Cardiac MRI of Complex Congenital Heart Disease: Rules to Live By

12:15-1:45pm - [International Lunch] - #506 **- Joint Session of the Egyptian Society of Cardiology and the American College of Cardiology: Adult Congenital Heart Disease: Where We Came From and Where We Are**
- Changing the Face of ACHD in Egypt
- Where We Are Now: The Epidemiology and ACHD Databases in North America
- Multimodality Non-Invasive Imaging for Assessment of Adult Congenital Heart Disease
- Cath Like an Egyptian
- Catheter Intervention in Adult Congenital Heart Disease: Cairo University Experience

2:00-3:30 pm - [Meet the Experts] - #247 **- Acquired Heart Disease in Childhood Epidemiology: Current and Future Management**

3:45-5:15 pm - [Meet the Experts] - # 252 **- Golden Moments: When Is the Right Time to Intervene in Congenital Heart Disease?**

CCS LEARNING PATHWAY: TUESDAY, MARCH 27

8:00-9:30 am - [Symposium] - #724 **- Complex Conotruncal Malformations: What the Surgeon Needs to Know and How to Get the Information**
- Complex Conotruncal Malformations: Pathologic Considerations
- Complex Conotruncal Malformations: The Whole Picture
- Double Outlet Right Ventricle with Straddling Atrioventricular Valves: Surgical Considerations
- Double Outlet Right Ventricle with Complete Atrioventricular Septal Defect: What I Need for a Two Ventricle Repair
- Transposition of the Great Arteries with Ventricular Septal Defect and Pulmonary Stenosis: Surgical Options

8:00-9:30 am - [Symposium] - #725 **- Coming of Age: The HLHS Turns 21**
- HLHS: At the Beginning....
- HLHS: What We Have Learned About the Physiology
- HLHS: How Imaging the HLH Patient Has Changed
- Surgical Evolution in the Past Two Decades: Striving for Optimal Long-Term Outcome
- Failing Fontan: Is the Hypoplastic Left Heart Patient Any Different?

9:45-11:45 am - [Special] - #309 **- ACC.12 Closing Session: Innovators in Cardiology — The closing session will feature individuals who have been most involved in new advances in the field of cardiology. Learn from them about the driving forces behind innovation and creativity. Then look to the future to see how innovation and creativity will lead to future advances in science, education and patient care.**
- Innovators in Cardiology: Regenerative Tissue Perspective
- Innovators in Cardiology: Interventional Perspective
- Innovators in Cardiology: Surgical Perspective
- Innovators in Cardiology: Imaging Perspective
- Innovators in Cardiology: Clinical and Translational Research — Application to Practice Perspective
- Innovators in Cardiology: The Future of Learning, Physician Competency Perspective

Please note the program is subject to change. Please visit www.accscientificsession.org/acc12 for the most up-to-date information on ACC.12. Search and browse sessions and faculty, and create a personalized itinerary with the Program Planner. Find it online at www.accscientificsession.org/acc12 under Plan Your ACC.12. You may also refer to the Final Program on site in Chicago.

This activity has been approved for AMA PRA Category 1 Credits™.

IMPACT Registry for CHD Patients Grows

By Gerard Martin, MD, FACC

Babies, children and adults treated for congenital heart disease (CHD) are living longer, healthier lives. But each patient experience stood alone because no national clinical registry had collected sufficient quality improvement data on CHD interventions and outcomes. The ACC's NCDR® has met this need with the IMPACT Registry™.

In 2010, the NCDR launched the IMPACT Registry (IMproving Pediatric and Adult Congenital Treatment) to provide significant contributions to the knowledge base and outcomes associated with CHD.

The IMPACT Registry assesses the prevalence, demographics, management and outcomes of pediatric and adult patients with CHD who are undergoing diagnostic catheterizations and catheter-based interventions. For more than a year, the IMPACT Registry has been collecting patient records and increasing the knowledge-base about this important patient population.

Today, with more than 50 hospitals participating, the IMPACT Registry is quickly building a reputation as the gold standard in CHD care. It was recently announced that for a second year in a row, U.S. News & World Report has recommended participation in the IMPACT Registry. As part of this recommendation, the publication proposed that IMPACT Registry participation be included on the pediatric hospital survey completed as part of the selection process for Best Children's Hospitals for Cardiology & Heart Surgery list. Looking to the future, physicians will be able to use the IMPACT Registry in their Maintenance of Certification (MOC) as a resource for quality improvement initiatives.

"This all-inclusive registry will give the interventional community the opportunity to share experiences, understand institutional variation, and compare outcomes. Ultimately, this will improve the care we provide in the catheterization lab."

"The ACC, by supporting the IMPACT Registry, is making an enormous contribution to the community caring for patients with congenital heart disease" said Lisa Bergersen, MD, MPH. "This all-inclusive registry will give the interventional community the opportunity to share experiences, understand institutional variation, and compare outcomes. Ultimately, this will improve the care we provide in the catheterization lab."

To request more information about the IMPACT Registry, please visit www.ncdr.com/chd. Plus, to hear more about the IMPACT Registry data reports, register for ACC.12 and attend Oral Session #901 on Saturday, March 24, 2012.

Dr. Martin is Chair of the IMPACT Registry Steering Committee, the immediate past Chair of the Adult Congenital and Pediatric Cardiology Section, and serves on the ACC's Board of Trustees.

SCAI Monthly Column:

By Eric Grammer

The Society for Cardiovascular Angiography and Interventions (SCAI) recently announced the schedule for SCAI 2012 Scientific Sessions, including the continuation of an expanded Congenital Heart Disease (CHD) Symposium introduced last year. Taking place May 9-12, 2012 at the Mirage in Las Vegas, the meeting will celebrate 35 years of the best of the best in interventional and invasive cardiology.

"The CHD Symposium will still feature uninterrupted, focused programming on interventional therapies for congenital and structural heart disease… only more of it."

In addition to old favorites, CHD Symposium Chair Daniel Levi, MD FSCAI and CHD Symposium Co-Chair Thomas Fagan, MD, FSCAI will be introducing several new sessions in May, each with an eye on creating a bridge between pediatric and adult interventionalists. One of these that promises to be practice-changing is the "Round Peg in a Square Hole" Session. Moderated by Frank F. Ing, MD, FSCAI and Zahid Amin, MD, FSCAI this session will focus on the overlooked role of congenital interventionalist as innovator and how each attendee can be better at thinking outside of the box in applying existing devices to each individual's care.

Speaking of innovation, SCAI is tremendously proud to announce that Julio C. Palmaz, MD will be delivering the Mullins Lecture providing a historical perspective on stent technology and how it has revolutionized care in both pediatric and adult congenital heart disease. This will be immediately followed by another new session, "Adult Congenital Interventions," featuring a panel of Zahid Amin, MD, FSCAI; Daniel Levi, MD, FSCAI; Larry Latson, MD, FSCAI; John W. Moore, MD, FSCAI; and Carlos Ruiz, MD, PhD, FSCAI.

Dr. Palmaz will also be presenting on "Surface Nanotechnology and Endothelial Function for Vascular Implants" in yet another exciting addition, "New Gadgets and Technology," moderated by Ziyad M. Hijazi, MD, MPH, FSCAI, and Abraham Rothman, MD, FSCAI. The session will examine emerging devices.

Need more reasons to attend? The schedule also includes the introduction of the "Imaging Safely" Session. Specifically designed to impact YOUR practice, attendees will come away with methods that they can employ to immediately minimize radiation exposure for patients and the care team.

We are excited to announce that SCAI 2012 Scientific Sessions will again feature an expanded Congenital Heart Disease (CHD) Symposium introduced last year. The CHD Symposium will still feature uninterrupted, focused programming on interventional therapies for congenital and structural heart disease…only more of it.

There are many more additions that we just don't have space to mention. To access the full schedule and to register, please visit www.scai.org/SCAI2012.

Of course, the CHD Symposium will also include your tried-and-true favorites. We'll be bringing back the enormously popular "Brain Scratchers" session to challenge you to solve hemodynamic, angiographic or interventional mysteries, and to provide solutions for less than routine cases in the congenital catheterization laboratory. The "I Blew It" sessions will also return to educate, entertain, and shock, with all the ways interventional cases can go awry, and with the creative ways that our colleagues manage these complications. The Great Debates Session will feature an enthralling debate on pre-mounted stents for pulmonary arteries.

We hope to see you in Las Vegas!

CCT

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Medical News, Products and Information

Berlin Heart's EXCOR® Pediatric Ventricular Assist Device (VAD) Receives FDA Approval

In December, the Berlin Heart Group www.berlinheart.com announced that the FDA has granted "Humanitarian Device Exemption" (HDE) approval of the Berlin Heart EXCOR® Pediatric Ventricular Assist Device (VAD).

The Berlin Heart EXCOR® Pediatric VAD is a mechanical cardiac support system for critically ill pediatric patients suffering from severe heart failure. The system is designed to support pediatric patients of all age groups, from newborns to teenagers, and is intended to bridge patients awaiting heart transplantation from days up to several months, until a donor heart becomes available. The Berlin Heart EXCOR® Pediatric VAD, which has previously been approved for use in Europe and Canada, is now the only Ventricular Assist Device that is designed specifically for the pediatric population to be approved in the United States.

The National Principal Investigator for the Berlin Heart EXCOR® Pediatric VAD study, Charles D. Fraser, Jr., MD, Surgeon-In-Chief and Head of the Division of Congenital Heart Surgery at Texas Children's Hospital and Professor of Surgery and Pediatrics, Baylor College of Medicine in Houston, Texas, said, "On behalf of the many investigators, coordinators, and administrative personnel involved in the study, I am extremely gratified by the news that the EXCOR® Pediatric VAD has achieved an HDE approval by the FDA. This is a landmark event for children suffering from terminal heart failure. The medical community is now able to offer this lifesaving device to support desperate children who would not otherwise survive while awaiting a heart transplant. This ushers in a new era for children with heart disease. The study involved an incredible effort from 15 centers across North American with extensive experience in pediatric heart failure and transplantation and should serve as a model for future collaborative device investigations involving children, industry, medicine, and the FDA."

Dr. Stefan Thamasett, Chairman of the Board of Berlin Heart, said, "This milestone marks the closure of a long process, and we are very happy that we were able to achieve this for the Berlin Heart Group. Our special thanks goes to all of the participating clinics and their doctors as well as our countless patients and their relatives; and, of course, we would like to thank our employees, because without their tireless commitment we would not have been able to reach this goal. We are looking forward to a new and exciting chapter in the history of Berlin Heart."

Bob Kroslowitz, President & CEO of Berlin Heart's North American operations, added, "Being granted HDE approval is an outstanding achievement for the whole Berlin Heart team. The FDA worked effectively with Berlin Heart to refine the design of the clinical trial that resulted in a meaningful study with useful conclusions. With the approval, we are now able to more readily offer this important lifesaving technology to this most important patient population. We are grateful and need to especially thank our study sites, our investigators and most importantly, the families of the children that participated in the study. Additionally, without the support of my colleagues in Berlin and the Berlin Heart team in the US, especially Mary Beth Kepler, VP of Regulatory Affairs, the approval could have never been achieved."

The EXCOR® Pediatric VAD clinical study, which enrolled the first patient in November 2007, is the first prospective clinical trial ever conducted to investigate the safety and benefit of a Ventricular Assist Device in the pediatric population. Full enrollment of the trial took approximately 33 months. The following US centers participated in the IDE study: Arkansas Children's Hospital (AR), Boston Children's Hospital (MA), Children's Healthcare of Atlanta (GA), Children's Hospital of Wisconsin (WI), The Children's Hospital of Denver (CO), Lucille Packard Children's Hospital at Stanford (CA), Mott Children's Hospital (MI), Mount Sinai Hospital (NY), Pittsburgh Children's Hospital (PA), Riley Children's Hospital (IN), Seattle Children's Hospital (WA), St. Louis Children's Hospital (MO), Texas Children's Hospital (TX), Children's Hospital at the University of Alabama at Birmingham (AL), and the University of Minnesota at Fairview (MN).

Nationwide Children's Hospital Selected a 2011 Leapfrog Top Children's Hospital

The Leapfrog Group's annual class of top hospitals -- 65 from a field of nearly 1200 -- was announced in December in Washington, DC, and included Nationwide Children's Hospital on the list, one of only ten children's hospitals.

"There are too few sources of information on the safety and quality of children's hospitals," said Leah Binder, CEO, The Leapfrog Group. "The Leapfrog Group is proud to be one of the only national sources of information that families can turn to when they are faced with the tough decision of which hospital is best for their child. Leapfrog's safety and quality measures allow families to compare hospitals on things like preventing infections and putting practices in place that are known to reduce medical errors. We are honored to recognize Nationwide Children's Hospital as a Leapfrog Top Hospital. Nationwide has out-performed other hospitals across the country and we congratulate them on their continued excellence and commitment to transparency."

While numerous agencies and organizations collect and publicize hospital quality data, the Leapfrog Hospital Survey is the toughest standard-bearer and provides the most complete picture of a hospital's quality and

safety. The 2011 list includes university and other teaching hospitals, children's hospitals and community hospitals in rural, suburban and urban settings. The selection is based on the results of the Leapfrog Group's national survey that measures hospitals' performance in crucial areas of patient safety and quality. The results of the survey are posted on a website (www.leapfroggroup.org) open to patients and families, the public, employers and other purchasers of health care. It is the most complete picture available of a hospital's quality and safety.

"The Leapfrog Top Children's Hospital designation is an affirmation that our Zero Hero quality and safety initiative is creating a culture in which every single employee recognizes and accepts a duty and responsibility to provide a safe day every day for every patient and family we serve," said Steve Allen, MD, Nationwide Children's CEO. "We are gratified to be on this list and it strengthens our resolve to provide quality care while ensuring the safest possible experience for our patients."

Nationwide Children's Zero Hero project was launched in July of 2009 and is designed to emphasize the safety role of every Nationwide Children's Hospital employee. By striving to zero, the program seeks to eliminate preventable harm by 2013. The program teaches staff to incorporate behaviors into their everyday clinical activities that have been shown to reduce the likelihood of committing an error.

The Leapfrog survey focuses on four critical areas of patient safety: the use of computer physician order entry (CPOE) to prevent medication errors; standards for doing high-risk procedures such as heart surgery; protocols and policies to reduce medical errors and other safe practices recommended by the National Quality Forum; and adequate nurse and physician staffing. In addition, hospitals are measured on their progress in preventing infections and other hospital-acquired conditions and adopting policies on the handling of serious medical errors, among other things.

The Winner of the CONGENITAL CARDIOLOGY TODAY's GO GREEN Drawing of the Echo Smart Pen is:

Gary M. Satou, MD, FASE
Director, Pediatric Echocardiography
Co-Director, Fetal Cardiology Program
Mattel Children's Hospital UCLA
Associate Clinical Professor
David Geffen School of Medicine at UCLA

Dr. Satou's name was drawn on January 10, 2011, and the Pen has been sent to him

Congratulations from
CONGENITAL CARDIOLOGY TODAY

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