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IN THIS ISSUE

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See website for additional meetings

23rd Annual Conference of the Western Society of Pediatric Cardiology
June 8-10, '12; Skamania Lodge, WA USA

CARDIOSTIM 2012 - Cardiac Electrophysiology & Cardiac Techniques
June 13-16, 2012; Nice, France
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GORE® Septal Occluder: Early Clinical Results

By Gianfranco Butera, MD; Paolo Danna, MD; Carmine Musto, MD; Cosimo Sacra, MD; Roberto Violini, MD; Maurizio Viecca, MD; Kia Vaziri Farahani, MD; Massimo Chessa, MD; Mario Carminati, MD

Abstract

Background: Transcatheter closure of patent foramen ovale (PFO) is a widespread procedure. However, the "quest" for the ideal device is still ongoing. Here we present the procedural and early results of transcatheter closure of PFO with the GORE® Septal Occluder (GSO).

Methods: Four Italian centers participated in a multicentric registry and collected data from 25 patients undergoing PFO closure by using the GSO device. The indication for closure was previous stroke in 15 subjects and previous transcient ischemic attack (TIA) in 10.

Results: The procedure was successful in all of the patients. The PFO closure procedure was performed with local anaesthesia, fluoroscopic and intracardiac echocardiographic imaging in 12 subjects; the procedure was also performed under general anaesthesia, fluoroscopic and trans-esophageal echocardiographic imaging in 13 subjects. Twenty-three patients received a 25 mm device, two received a 30 mm device. Procedure and fluoroscopy times were 47±12 and 6±2 minutes, respectively. Residual shunting at procedure was absent in all subjects when performed at the basal status, while a mild shunt was present in 3 subjects at Valsalva Manoeuvre. Two subjects (8%) experienced vascular complications. At one month follow-up one subject experienced atrial fibrillation. All subjects showed a well-positioned device with no signs of complications. No neurological recurrences occurred. No significant residual shunting was found.

Conclusion: In our experience GORE® Septal Occluder in our experience is an easy, safe and effective device for use in closing patent foramen ovale.

Introduction

Transcatheter closure of patent foramen ovale is a widespread procedure and many devices have been used in clinical practice.[1,2] However, different problems have been encountered with the devices used[1-3] including thrombus formation, arrhythmias, atrial perforation, cardiac tamponade, device malposition or embolization, and residual shunting.

Here we report on the initial Italian experience with PFO closure using the GORE® Septal Occluder device in 25 adults with previous cerebral ischemia.

Methods

Four Italian centers participated in a registry where data from patients undergoing PFO closure using the GORE® Septal Occluder were collected. Data from 25 subjects were obtained. All subjects had experienced previous cerebral stroke or transient ischemic attacks and were taking acetilsalicilic acid. All subjects underwent

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

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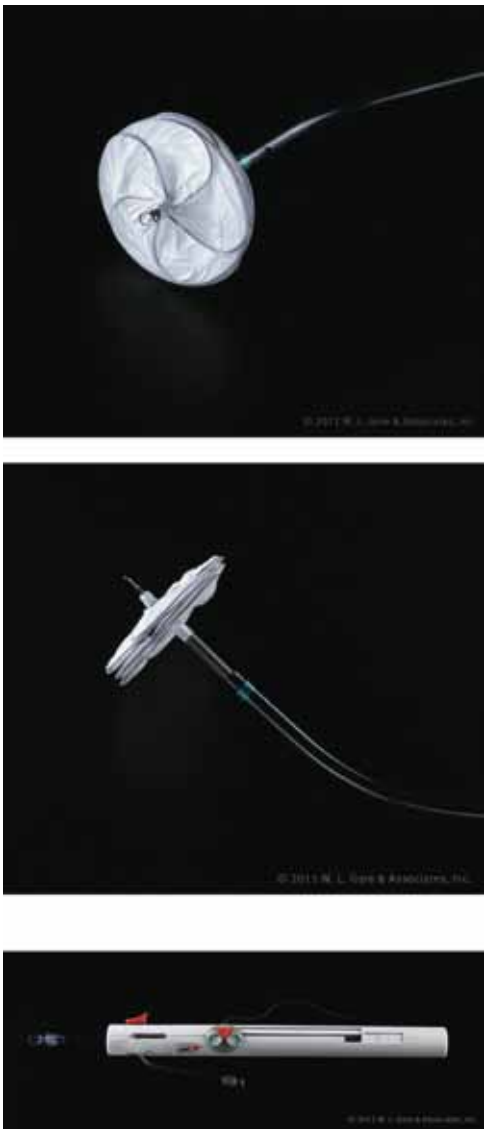

Figure 1. Gore Septal Occluder. Upper and middle: occluder in frontal and lateral views; Bottom: handle. See text for description.

complete evaluation in order to rule out other causes of cerebral ischemia. Written informed consent was obtained from all patients enrolled in the study.

Device Description and Implantation Technique

The GORE® Septal Occluder consists of an implantable occluder and a delivery system (Figure 1). The occluder is comprised of a platinum-filled nickel-titanium (Nitinol) wire frame covered with expanded polytetrafluoroethylene (ePTFE). The wire frame is formed from five wires, shaped into the right and left atrial discs, the eyelets and the lock loop. The five-wire design provides conformability, allowing each individual wire within a right or left atrial disc to conform to the heart anatomy. Wire dimensions are proportional to the occluder nominal diameter, which optimizes septal apposition and conformability across all occluder sizes. The ePTFE includes a hydrophilic surface treatment to facilitate echocardiographic imaging of the occluder and surrounding tissue during implantation. The delivery system consists of a 75 cm working length 10 Fr outer diameter delivery catheter, a control catheter, and a mandrel coupled to a handle. The handle facilitates loading, deployment, and locking of the occluder. The handle also allows repositioning and retrieval of the occluder via the retrieval cord, if necessary. The occluder is available in sizes of 15, 20, 25, and 30 mm. The occluder is delivered using conventional catheter delivery techniques and may be delivered with the aid of a 0.035" guide wire if desired.

Echocardiography Protocols

Transesophageal echocardiography was conducted using with bubble test and Valsalva Manoeuvre under general anesthesia and oro-tracheal intubation. Local anesthesia was used in subjects undergoing the procedure by ICE monitoring. The 8 Mhz ACUNAV ultrasound catheter (Biosense Webster, Johnson & Jonshon, CA USA) was used. In these subjects a second 8 Fr femoral venous access was obtained. Measurement of the diameters of the fossa ovalis, the entire atrial septum length and rims was obtained with electronic caliper edge-to-edge on the aortic valve plane and the four-chamber plane. PFO tunnel length was measured. Presence of multiple fenestrations, redundant Chiari network or Eustachian valve were assessed. ICE monitoring of the implantation procedure was conducted in the four-chamber and long and short axis planes. Care was taken to choose a device with an entire left disk diameter that did not exceed the entire atrial septum length on ICE measurements. ASAs were classified as reported in literature.[1,2]

Follow-Up Protocol

At one month, subjects underwent trans-thoracic echocardiography, associated or not associated with echocontrastography. Any residual shunt was graded as trivial, small, moderate, or severe as previously described.[1,2] Clinical examination was scheduled at the

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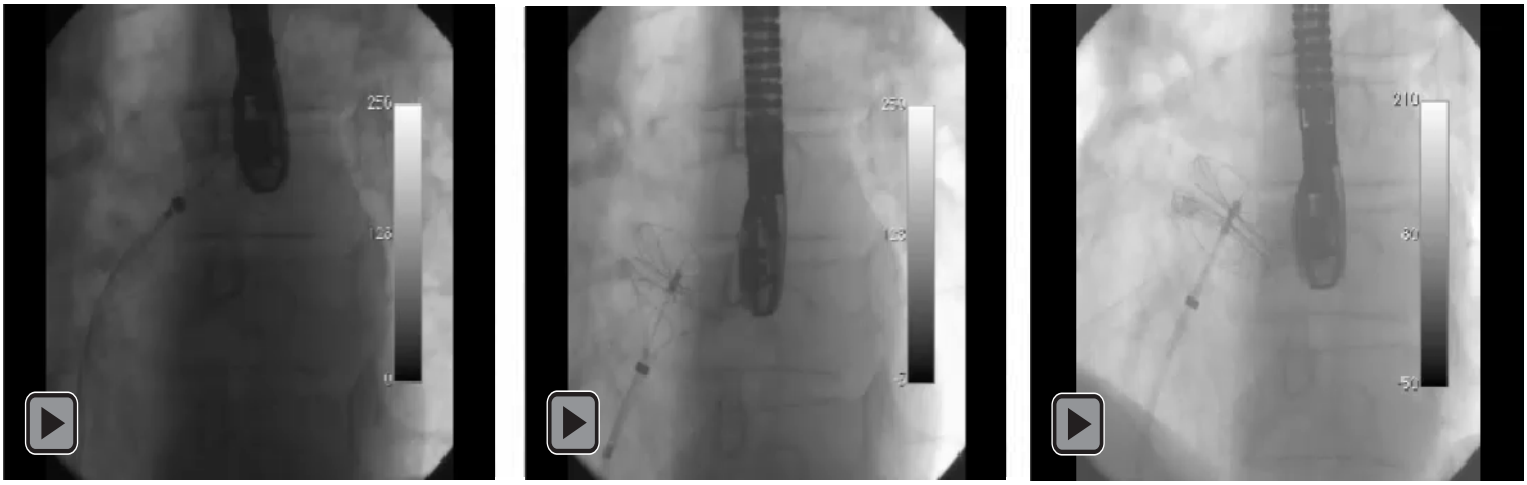

Figure 2. Fluoroscopic views in left anterior oblique. Procedure is performed under fluoroscopic and intracardiac echocardiographic views. Left: left atrial disc is opened; Middle: Left and right discs are opened and placed across the septum; Right: occluder is released and properly placed.

Table 1. Patients' characteristics	
Number of patients	25
Sex F/M	12/13
Median age (range) years	45 (30-65)
Comorbidities	14 pts (56%)
Previous neurological history Stroke Transient ischemic attack	 15 pts 10 pts
Diagnosis of right-to-left shunting TEE alone TEE with TCD TTE and TEE TCD alone	 14 pts 8 pts 2 pts 1 pt
Table legend: TEE trans-esophageal echocardiography; TCD trans-cranial doppler; TTE: Trans-thoracic echocardiography	

same time. Telephonic contact with the patients is performed at three months follow-up. Further evaluations are planned at 6 and 12 months and then yearly after the procedure.

Definition

The patients were discharged the day after the procedure and placed on anti-platelet therapy, according to each center's policy. Success was defined as the ability to release the device in a stable position under fluoroscopy and ICE or TEE guidance with no more than a trivial shunt.

Immediate complications included any degree of groin hematoma, atrial wall perforation, pericardial effusion, entrapment of device or sheath or ICE equipment through venous valves or embryonic remnants, and air embolism. Pre-discharge occlusion rate was defined as a percentage of complete occlusion (no shunt on TEE and Transcranial Doppler). Aortic or atrial wall erosion, new onset or increase of previous atrio-ventricular valves insufficiency, and device removal were included in the early-term complication rate.

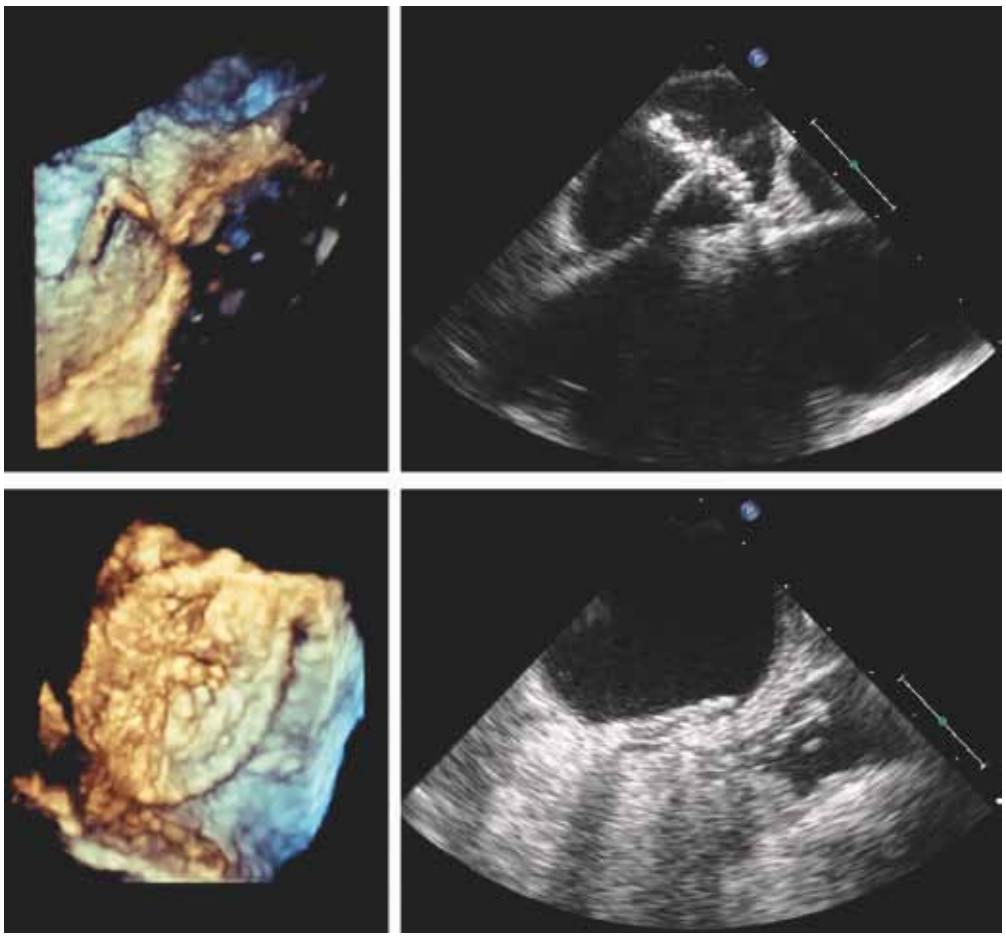

Figure 3. Echocardiographic views. Left upper: Three-D Echocardiography showing the guidewire passing through the PFO; Right upper: Two-D Echocardiography showing the left atrial disc opened; Left Bottom: Three-D Echocardiography showing the left atrial disc placed on the left atrial aspect of the interatrial septum; Right bottom: Two-D Echocardiography with contrast injection showing a properly placed device and no residual shunting.

Results

Baseline Characteristics

Patients' characteristics are reported in Table 1. Twenty subjects received pre-procedural therapy with 100 mg acetilsalicilic acid. Migraine history was found in two subjects experiencing stroke. Pre-procedural neuro-radiologic imaging showed ischemic lesions in 22 cases. Coagulation abnormalities were found in two subjects with Leiden factor V mutation.

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Basal shunting was graded as absent in 5, mild in 17 and severe in 3 subjects. Shunting at Valsalva maneuvres was graded as moderate in 9 patients and severe in 16 subjects.

Procedure

The procedure was performed with local anaesthesia, fluoroscopic and intracardiac echocardiographic control in 12 subjects while it was performed under general anaesthesia, fluoroscopic and trans-esophageal echocardiographic control in 13 subjects.

Atrial septal aneurysm was present in 6 subjects, while none showed rigid tunnel PFO, multiple fenestrations, or redundant chiari network or Eustachian valve. Balloon sizing was performed in only three subjects. The procedure was successful in all of the patients. Twenty-three patients had a 25 mm device while 2 received a 30 mm device. Procedure and fluoroscopy times were 47±12 and 6±2 minutes, respectively (Figures 2 and 3). Residual shunting at procedure was absent in all subjects when performed at the basal status;a mild shunting was present in 3 subjects at Valsalva Manoeuvre.

Complications occurred in 2 subjects (8%). A 53-year-old lady who experienced retroperitoneal hematoma needing blood transfusion. A 53-year-old-men showed an arterovenous femoral fistula the day after the procedure and needed vascular surgical treatment. No early release, device malposition, embolization or other technical problems occurred.

Median hospital stay was 3 days (range 2-19 days). Patients were discharged home with a planned treatment with aspirin for 6 months in 17 subjects, or with 3 months double anti-platelet agents (aspirin +clopidrogel) followed by 9 months aspirin alone in 8 patients.

Follow-up

All subjects underwent one month follow-up evaluation. One patient experienced atrial fibrillation and was treated medically. All subjects showed a well-positioned device with no signs of complications. No neurological recurrences occurred. At transthoracic echocardiography and contrast bubble study no patients exhibited residual shunting.

At three months, 16 patients were contacted by phone and reported no complications.

Rates of early procedural success, occlusion, and complication were: 100%, 88% and 12%, respectively. In all cases complications were transient and not directly related to the device implantation.

Discussion

Percutaneous patent foramen ovale closure is an effective, safe, and commonly employed procedure.[1,2,4-6] It is used to prevent paradoxical embolism in patients who have had recurrent cryptogenic cerebrovascular events (CVA) and transient cerebral ischemia (TIA), prevent decompression and high altitude illness, and to treat patients with hypoxemia due to right to left shunting.[4-6] A number of different devices have been used to close PFO via a percutaneous technique, each with unique advantages and disadvantages.[1-4]

The "ideal" device for percutaneous transcatheter PFO closure should be easily implanted, with low profile, easy retrievability.

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Furthermore, it should achieve safe, complete foramen closure and rapid healing. Finally, it should adapt to anatomic variability in the effective size or opening of the foramen, including: the compliance and mobility of the septal tissue, the thickness of the superior limbus of the atrial septum, and the accessory fenestrations avoiding interference with other important adjacent cardiac structures.

The previous generation GORE® HELEX® Septal Occluder achieved some of the "ideal" device characteristics being a soft device adapting easily to heart anatomy however it had several drawbacks. In fact implantation needed several steps that had to be performed gently. This prevented an easy and friendly use of the device and increased the fluoroscopic exposure of both patient and operator. Furthermore, because of its softness and release mechanism several authors reported unexpected release of the locking loop with device mal-position. Device retrieval was needed in these cases and a second device had to be implanted. Billinger et al[7] reported this event in 4%, Latson et al[8] in 5.8%, Taeffe et al[2] in 3%. Embolization was quite rare and reported in 3 out of 220 subjects (1.4%) by Taeffe and in 2 out of 119 subjects (1.7%). In our experience we had no ma-lposition, embolization or other problems related to GSO implantation. Furthermore, implantation was easy and with very short procedure and fluoroscopy times

Another relevant issue associated with the use of the GORE® HELEX® Septal Occluder is the occurrence of residual shunting at procedure and at follow-up. Latson et al[8] reported that a significant leak at one year after implantation occurred in 2.6% of subjects. In the series published by Sorensen[9] it occurred in 23 out of 315 (7%) at 3 months after the procedure, while Thaman[10] showed it in 58 % at 6 months. Van Banderleben et al[11] studied 357 patients closed by using three different devices: the Amplatzer PFO device (n=199), Starflex device (n=48) and GORE® HELEX® Septal Occluder device (n=110). The closure time curves between the three devices were significantly different (p=0.0072). Devices of 25 mm or less had a better occlusion rate. The difference between the closure time curves of PFO and PFO+ASA concerning each device type was significant for GORE® HELEX® Septal Occluder (p=0.006) and Starflex (p=0.030). When using larger devices, the GORE® HELEX® Septal Occluderequired more time to achieve total occlusion than did the Amplatzer and Starflex devices (p=0.0029). In our report on GORE® Septal Occluder all subjects except two had complete closure at procedure, while closure was 100% at early follow-up. Complications occurred in 8% of subjects. A 53-year-old lady experienced retroperitoneal hematoma needing blood transfusion while a 53-year-old man showed an arterovenous femoral fistula the day after the procedure and needed vascular surgical treatment. In both cases they were related to vascular access and not to device performance. At one-month follow-up, one patient experienced atrial fibrillation and was treated medically. Complications occurrence was very similar to those reported in literature with the devices available.[1-4]

Limitations

Our experience has several limitations. First of all, the number of subjects treated is not large enough to draw general conclusions. Furthermore, follow-up is too short.

However, early device performance in terms of friendly implantation, safe positioning, complete closure is very good and highly promising for the future.

Pediatric Cardiologists

The Division of Pediatric Cardiology at the University of Utah School of Medicine and based at Primary Children's Medical Center is recruiting board eligible/board certified pediatric cardiologists with major interests in 1) Heart Transplant/Heart Failure and 2) Adult Congenital Heart Disease. The Pediatric Cardiologists will join a 25-member division and established Heart Transplant and Adult Congenital Heart Disease Programs. There will be protected time and mentoring available within the Division for clinical research. The Division has a very active clinical research program and is one of the participating centers in the Pediatric Heart Disease Clinical Research Network funded by the NIH.

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Conclusions

In our experience, GORE® Septal Occluder is an easy, safe and effective device for use in closing PFO. We think that it achieves several steps forward to the "ideal" device.

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www.congenitalcardiologytoday.com/Articles/June2012/index.html

Video 1 - Left anterior oblique view showing opening of the left disc of the Gore® Septal Occluder

Video 2 - Left anterior oblique view showing opening of the right disc of the Gore® Septal Occluder

Video 3 - Left anterior oblique view showing release of the device

Video 4 - Left anterior oblique view . The device is released and angiography in the right atrium shows no residual shunting.

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Highlights from the Congress of Congenital Heart Disease: "Atrial Septal Defect from A to Z" - HCMC Pediatric Cardiology and Congenital Heart Disease Society 1st Annual Meeting January 12-13, 2012, Ho Chi Minh City, Vietnam

By Casey B. Culbertson MD; Do Nguyen Tin, MD; Trong-Phi Le, MD; Nguyen Lan Hieu, MD; Vu Minh Phuc, MD

Introduction

On January 12-13, 2012, the 1st Annual Meeting sponsored by the Ho Chi Minh City (HCMC) Pediatric Cardiology and Congenital Heart Disease Society titled "*The Congress of Congenital Heart Disease: Atrial Septal Defects (ASD) from A to Z*" took place at the historic Rex Hotel in HCMC, Vietnam. ASD lesions worldwide represent approximately 10% of all congenital heart disease (CHD) lesions and at least until recently had only been treated surgically in Vietnam. The goal of this meeting was to review the embryology and morphology of various types of ASD's, echocardiographic evaluation of ASD's, hemodynamic considerations of ASD's and treatment options for ASD's focusing on demonstrating and discussing transcather techniques for ASD closure.

The "All Star" Faculty Band: Drs. Qureshi, Galal, Sukman, Wunderlich, Benson and Brahat.

The two-day meeting was a combination of didactic sessions and live interactive cases broadcast to the meeting site from the Nhi Dong (Children's Hospital) #1 (ND #1) catheterization laboratory. The organizing committee assembled an excellent international panel of experts in morphology, echocardiography, and interventional cardiology from

"The goal of this meeting was to review the embryology and morphology of various types of ASD's, echocardiographic evaluation of ASD's, hemodynamic considerations of ASD's and treatment options for ASD's focusing on demonstrating and discussing transcather techniques for ASD closure."

Canada, Germany, India, Indonesia, Japan, Korea, Malaysia, Saudi Arabia, Taiwan, Thailand, the United Kingdom, the United States, and Vietnam. Guest operators from many of these countries worked with their Vietnamese colleagues in the catheterization lab at ND #1 to transmit live transcather ASD closure cases with various clinical manifestations (large ASD, fenestrated ASD, ASD with deficient rims, etc.) to the meeting site. This format (which has been previously used successfully at PICS/AICS meetings) was well received by the approximately 250 international attendees (primarily from Asia and Southeast Asia), resulted in excellent discussions and interactions between attendees and guest faculty and was felt by all to be an excellent educational experience.

Meeting

Day #1

The Congress opened with a welcome from Drs. Hoang Trong Kim and Trong-Phi Le of the Vietnamese organizing committee. The first morning session was labeled "Basic considerations of ASD's and PFO's" and was chaired by Drs. Shakeel Qureshi (UK), Neil Wilson (UK), Akaji Teiji (Japan) and Trong-Phi Le (Germany). Lectures during the morning session included embryology of the atrial septum by Dr. Hara Hidehiko (Japan), morphology of the atrial septum by Dr. Andrew Cook (UK), hemodynamics of ASD's by Dr. Toshio Nakanishi (Japan) and echocardiographic evaluation of ASD's by Dr. Nina Wunderlich (Germany). All the lectures were of excellent quality and the video clips of ASD cardiac specimens shown by Dr. Cook and the 2D and 3D echocardiograms shown by Dr. Wunderlich enhanced the participants' understanding of the live cases that were transmitted from the ND #1 cath lab during the morning session.

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Congress Faculty and Participants

The first live case transmitted (Transcather closure of a "straightforward" ASD) had Dr. Nguyen Lan Hieu (Vietnam) as the guest operator and Drs. Haifa Latiff (Malaysia) and Phan Tien Loi (Vietnam) performing the transesophageal echocardiogram (TEE) for the procedure. Initial TEE, however, showed more significant deficiencies of the aortic and AV valve portions of the atrial septum and that generated much discussion between participants, panelists and the operators at ND #1. After much discussion, the device was successfully deployed and post procedure TEE showed good position of the device with no residual shunt.

The second live case (Transcatheter closure of an ASD without fluoroscopy) is a technique that has been used in multiple cases at ND #1 and whose TEE imaging techniques for successful device deployment have been developed by Dr. Loi at ND #1. In this case, both Drs. Loi and Latiff were the echocardiographers and Dr. Worakan Promphan (Thailand) was the guest operator. This technique generated much discussion between participants and panelists, and a poll of the participants demonstrated no other participants at the Congress were performing ASD closures without fluoroscopy. Indeed, the prevailing question from the participants was "Why do it this way?" The device was successfully deployed in this case, but the participants in general still felt fluoroscopy should be utilized at the time of device placement and release.

The second morning session titled "Transcather ASD closure" was again chaired by Drs. Qureshi and Wilson and they were joined by Dr. Bharat Dalvi (India) and Dr. Jae Young Choi (Korea). Lectures presented in this session were by Dr. Pham Nguyen Vinh (ACC/AHA guidelines for ASD/PFO closure-what's new in 2011); Dr. Pornthep Lertsacharoen (Special considerations in ASD closure for small patients); Dr. Geetha Kandavello (Special considerations in ASD closure in the elderly) and by Dr. Qureshi (Closure of ASD's with pulmonary hypertension). All the lectures were again of excellent quality and very relevant for all the participants.

The third live case of the morning (Transcatheter closure in a small patient) had Dr. Mazeni Alwi (Malaysia) as the guest operator and Dr. Nguyen Ba Trieu performing the TEE for the procedure. The patient weighed 8.3Kg and the ASD measured 7mm with minimal enlargement of

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Transplant Cardiologist

Assistant or Associate Professor
(In Residence, Adjunct, or Clinical)

THE UNIVERSITY OF CALIFORNIA, SAN DIEGO, DEPARTMENT OF PEDIATRICS (http://www-pediatrics.ucsd.edu) AND CHILDREN'S SPECIALISTS OF SAN DIEGO (http://childrensspecialists.com) are committed to academic excellent and diversity within the faculty, staff, and student body and are jointly recruiting a Medical Director of Cardiac Transplantation for the unified Division of Pediatric Cardiology at Rady Children's Hospital, San Diego. This 220-bed facility serves as a major regional tertiary care hospital for children and is the major teaching facility for the Department of Pediatrics of the UCSD School of Medicine.

The Director position is a unique opportunity to develop an exceptional Cardiac Transplantation Program in San Diego. The successful candidate must have training and experience in a UNOS certified pediatric cardiac transplant center and should possess the qualifications for academic appointment at the rank of Assistant or Associate Professor. The academic series will be determined based on the background and qualifications of the successful candidates. Candidates must be Board Certified in Pediatric Cardiology and licensed or licensable to practice medicine in the State of California. This appointment will require demonstrated administrative capabilities, excellent skills in clinical care and teaching, and research accomplishment.

The Division provides a full range of Pediatric Cardiology services. It currently has six pediatric cardiologists, two cardiothoracic surgeons, and an ACGME approved fellowship program. The Division supports a program with approximately 400 surgical procedures yearly. Extensive opportunities to perform clinical, epidemiologic or basic science research exist at UCSD and Children's Hospital, San Diego.

Salary commensurate with qualifications and based on University of California pay scales.

Applications received by July 1, 2011 or until the position is filled, will receive full consideration.

Please send Curriculum Vitae, the names and e-mail addresses for three references, and a personal statement summarizing your demonstrable commitment to promoting and enhancing diversity and equality, or your potential to make contributions in the field.

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Catheterization Laboratory at Nhi Dong #1 (Children's) Hospital, Ho Chi Minh City, Vietnam

the right ventricle. This was easily closed, but did raise some discussion by the participants about the indication for closure of the ASD in this patient.

The "breakout" lunch sessions provided participants an opportunity to hear lectures and have discussions with faculty in smaller venues than the general session. Two parallel lunch sessions were held on Day #1. The first session was titled "Echocardiography as it is related to ASD morphology and closure" and was chaired by Dr. Casey Culbertson (USA). Excellent short presentations included the following topics: Dr. Latiff (TTE and TEE in difficult cases: how to get the best images for evaluation and closure of ASDs/PFO's); Dr. Nina Wunderlich (Advantages of 3D TEE in ASD closure) and Dr. Lee Benson (ICE in ASD closure). The second parallel lunch session was chaired by Drs. Wang (Taiwan) and Huan (Vietnam) and was titled "Special techniques for the interventionalist." This session featured presentations from by Dr. Quereshi (Pulmonary vein approach: when and how?); Dr. Dalvi (Balloon assisted technique: Scope and limitations); Dr. Worakan Promphan (Techniques for overcoming disc prolapsed) and Dr. Yat-Yin Lam (Steerable sheath techniques). These sessions proved to be quite popular immediately. However, it was felt by participants in both sessions that the 15-20 minutes allotted for each presentation followed by a question/answer period was too short.

The afternoon session titled "Techniques in transcather ASD closure" was chaired by Drs. Omar Galal (Saudi Arabia), Jou-Kou Wang ((Taiwan), Do Quang Huan and Nguyen Lan Hieu (Vietnam) and later by Dr. Lee Benson. Lectures included Dr. Benson (Procedural steps of transcatheter ASD closure), Dr. Wilson (Selection of devices for ASD closure), Dr. Qureshi (Closure of anatomically difficult ASD's), Dr. Galal (Balloon sizing every case (?) and slight modification of ASD closure with deficient aortic rim), Dr. Dalvi (Adult with ASD and severe PHTN-Assessment and selection for intervention), Dr. Choi (transcatheter closure of ASD: does age matter?), and Dr. Hieu (Fluoroscopic evaluation for the appropriate position of ASD device) The faculty is to be commended not only for very educational presentations but also for

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their flexibility in presenting their talks while occasionally being interrupted by the live case demonstrations.

Concurrent with the afternoon sessions, two more "live" cases were transmitted. The first case (Transcatheter ASD closure of a large ASD) had Dr. Pornthep Lertsacheron and Dr. Le Hong Quan as the guest operators. They expertly demonstrated techniques for closure of a large (24mm) ASD which was successfully closed without difficulty. Dr. Trieu (Vietnam) provided the TEE guidance for the procedure. The second and final case of the day (Transcather ASD closure of a fenestrated defect) had Dr. Hasri Samion (Malaysia) as the guest operator. This proved to be a more challenging case as multiple defects (more than originally suggested by TTE) were demonstrated by Drs. Wunderlich and Loi by TEE. After much discussion between participants and the operators in terms of positioning of the device and the use of balloon sizing of the defects, two different sizing balloons were used before final device selection. An appropriate device was then selected based on balloon sizing and successfully placed, which by TEE showed no residual ASD shunting and good position.

On the first evening of the Congress, participants were treated to a Gala Dinner on the roof of the Rex Hotel. They enjoyed excellent Vietnamese food as well as music and dancing from both Vietnam and all over Southeast Asia. The Gala was very well attended and the participants also had excellent views of the streets of Ho Chi Minh City below with the outstanding light and floral arrangements which were on display in anticipation of the Vietnamese TET holiday.

Day #2

The morning sessions was again chaired by Drs. Qureshi and Wilson, with the addition of Drs. Samion, Pornthep Lertcharoen and later Drs. Martine Schneider (Germany) and Sukman Putra (Indonesia). The theme of this session was "Special Considerations in ASD closure" and included presentations by Dr. Reiner Figulla (ASD closure with deficient rim and future developments of ASD closure devices), Dr. Schneider (ASD closure with floppy rims), Dr. Akagi (ASD closure with malalignment of the atrial septum), Dr. Samion (Fenestrated ASD closure), Dr. Dalvi (Closure of large ASD's in small children), Dr. Choi (Closure of complex or large ASD's), and Dr. Qureshi (ASD closure without fluoroscopy: scope and limitations). The final presentation by Dr. Mazeni Alwi of Malaysia (When should we stop the procedure?) while unknown at the time, proved to be very timely for the first live case of the morning.

The first transmitted case of the morning (ASD closure with an abnormal (interrupted) IVC with azygous vein connection) had Drs. Galal and Phi as the guest operators and Drs. Latiff and Loi doing the TEE. Their TEE demonstrated the ASD to be in a very difficult position to approach. The operators tried from both femoral venous and internal jugular vein approaches. However, good position of the ASD device could never be demonstrated and resulted in much discussion between the operators, participants and the faculty. While a transhepatic approach was suggested, with no onsite blood bank at ND #1, it was not felt that this approach was prudent if there was a complication. It was agreed at that point by all participants to stop the case and send the child for surgical repair in the future.

The second transmitted case of the morning (child with floppy ASD rim) had Dr. Benson as guest operator and Dr. Wunderlich as echocardiographer. The ASD was rapidly and successfully closed with both Drs. Benson and

UC San Diego SCHOOL OF MEDICINE | Children's Specialists

Assistant Professor - Electrophysiologist (Cardiology)

THE UNIVERSITY OF CALIFORNIA, SAN DIEGO, DEPARTMENT OF PEDIATRICS (http://www-pediatrics.ucsd.edu) AND CHILDREN'S SPECIALISTS OF SAN DIEGO (http://childrensspecialists.com) are committed to academic excellent and diversity within the faculty, staff, and student body and are jointly recruiting a Pediatric Electrophysiologist for the unified Division of Pediatric Cardiology at Rady Children's Hospital, San Diego. This 442-bed facility serves as a major regional tertiary care hospital for children and is the major teaching facility for the Department of Pediatrics of the UCSD School of Medicine.

The Electrophysiologist position is a unique opportunity to join an exceptional Electrophysiology, Pacing and Adult Congenital Electrophysiology in San Diego. The successful candidate must have specific training and experience in pediatric cardiac electrophysiology and should possess the qualifications for academic appointment at the rank of Assistant Professor. The academic series will be determined based on the background and qualifications of the successful candidates. Candidates must be Board Certified or eligible in Pediatric Cardiology and licensed or licensable to practice medicine in the State of California. This appointment will require administrative capabilities, excellent skills in clinical care and teaching, and clinical research development and accomplishment. Preference will be given to candidates with experience in equity and diversity with respect to teaching, mentoring, research, life experiences, or service towards building an equitable and diverse scholarly environment.

The Division provides a full range of Pediatric Cardiology services. It currently has ten pediatric cardiologists, three cardiothoracic surgeons, and an ACGME approved fellowship program. The Division supports a program with more 400 surgical procedures yearly and 100 electrophysiology procedures. Extensive opportunities to perform clinical, epidemiologic or basic science research exist at UCSD and Children's Hospital, San Diego.

Salary will be commensurate with qualifications and based on University of California pay scales.

Review of applications will begin July 1, 2012 and continued until the position is filled.

Please apply via http://apol-recruit.ucsd.edu/ to the following job opening:

PEDIATRICS - Assistant Professor (RCHSD Cardiology) (10-387)

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- a statement of teaching experience,
- the names and email addresses of 3-5 references, and
- a separate personal statement summarizing past or potential contributions to diversity (see http://facultyequity.ucsd.edu/Faculty-Applicant-C2D-Info.asp for further information).

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The second day lunch sessions were, again, parallel sessions similair to those held on Day #1. The first parallel session was "Congenital and structural heart disease images" and was chaired by Dr. Culbertson. Presentations were given by Dr. Cook (Morphology of atrio-ventricular septal defects–AVSD), Dr. Wunderlich (What the echocardiographer needs from the interventionalists), Dr. Wilson (What the interventionalist needs from the echocardiographer) and also by Dr. Latiff (TEE evaluation for device: release or not release). The second parallel session was titled "Special Cases," and was chaired by Drs. Wang, Samion, Putra and Le. The presenters included Dr. Prachasilchai (My first ASD closure case), Dr. Djer (My most interesting case), Dr. Thien (My mystery case), Dr. Sakidjan (My most challenging case) and Dr. Promphan (My nightmare case). Again, both lunch sessions were very well-attended and felt by all participants to be very educational and need to be expanded in upcoming meetings.

The afternoon sessions were chaired by Drs. Benson, Figulla, Le, Schneider and Wunderlich and focused on "Lessons learned from Complications and Failures" and "Follow-up after ASD/PFO Closure." Presentations included Dr. Alwi (Complications and how to deal with them), Dr. Schneider (Retrieval of embolized devices), Dr. Nakanishi (Japan experience of perforation), Dr. Benson (Arrhythmias after ASD closure: device related or genetic), Dr. Wilson (Problems on long-term follow-up), Dr. Galal (How to deal with a residual shunt), Dr. Wunderlich (Echocardiography for follow-up of ASD closure: what to look for), Dr. Putra (Problems and Outcomes of Transcatheter Closure of ASD in the limited resource Pediatric Heart Center), Dr. Promphan (Different devices make different results?) and Dr. Wang (Rho Kinase (ROCK) activity before and after ASD closure). Again, all these presentations were of excellent quality and well-received.

There were three afternoon cases transmitted. The first case (ASD with deficient rim) had Dr. Figulla and Thien as the guest operators. TEE showed the IVC rim to be quite deficient, but it was quickly and successfully closed with the TEE showing the device to be in good position with no residual leak. The second case (ASD closure in a 'smaller' patient) had Drs. Qureshi, and Choi as the guest operators. The patient in this case weighed 14Kg with the ASD measuring 8-9mm. As there was right ventricular enlargement, the participants felt it was prudent to close this ASD. Post device placement TEE demonstrated a well-positioned device with no residual shunt. The final transmitted case of the Congress (Fenestrated ASD) was performed by guest operators Drs. Dalvi and Tin. TEE done by Dr. Latiff showed the ASD to be larger than expected so again, a sizing balloon was used. There was some concern by participants that the sizing balloon could potentially lacerate the tissue between the ASD's. However, after discussion, the sizing balloon was utilized and the device was successfully placed with no residual shunt.

The final evening of the Congress was also quite special as faculty and special guests were treated to a Vietnamese "Cultural Night" at the Binh Quoi Village outside of Ho Chi Minh City. This included a cruise by speed boat up the Saigon River, an excellent Vietnamese dinner as well as Vietnamese music and dance and an impromptu 'all-star' faculty band playing traditional Vietnamese instruments. For those faculty and participants who stayed on following the Congress, the next day the Vietnamese organizing committee arranged for a special city tour of HCMC.

Summary

The organizers would like to thank all the attendees who came from many countries to participate in this inaugural Congress in HCMC as well as the International faculty who took time off from their schedules to travel to Vietnam and were instrumental in making this Congress a success. The organizers would also like to recognize and thank the exhibitors/industry sponsors whose support of this Congress was also instrumental in making it a success. Finally, the organizers would also like to recognize the Vietnamese Scientific Committee members (Drs. Kim, Vinh, Liem, Phu, Thuong, Viet, Phuc, Huan, Hieu and Tin) who organized this Congress, and whose hard work turned an 'idea' into a successful Congress for all those who participated.

Follow-Up

Of note, while this article was in preparation, Dr. Phan Tien Loi (ND #1) kindly supplied the authors data from ECHO and ECG studies he performed on all "live" cases; both one day following their procedures and at their two month follow-up. Evaluation of all "live" cases (at both visits) demonstrated no residual shunts, good device position and no arrhythmias.

Future

By overwhelming demand of the 2012 Congress participants, plans are already underway for the *2nd Congress of Congenital Heart Disease* to be held in Hanoi, Vietnam in early 2013. The proposed topic will be "VSD from A to Z." This Congress will again include didactic sessions, as well as controversy sessions (VSD-surgical vs. interventional treatment), hybrid approaches, treatment in older CHD cases as well as live interventional cases. There will be more 'breakout' sessions which have a more intimate environment for teaching, and question and answer periods with the faculty. Please look for further information and announcements in the near future in *Congenital Cardiology Today*.

The Congress organizers would like to thank, *Congenital Cardiology Today* in advance, (www.CongenitalCardiologyToday.com) for their support of the 2013 Congress.

CCT

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CONGENITAL CARDIOLOGY TODAY

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

Letter To The Editor - June 2012

By Jacqueline Kreutzer, MD and Sara M. Trucco, MD

Dear *Congenital Cardiology Today*:

We thank Dr. Slack for his insightful comments on our article "Expanding the Role of Percutaneous Pulmonary Valve Implantation" in the April 2012 edition of *Congenital Cardiology Today* (CCT). In his Letter to the Editor (May 2012 edition of CCT) he raises two important points. In particular, it is correct that the Sapien™ valve from Edwards Lifesciences was approved by the FDA through a full Premarket Approval Application (PMA) process and not a Humanitarian Device Exemption (HDE) one. As stated by Dr. Slack, there are significant differences between both approval pathways. A device with a PMA is approved for marketing based on valid scientific evidence and reasonable assurance that the device is safe and effective for its intended use. A device with an approved HDE, such as the Melody Valve™, is approved for marketing, but the approval is based on evidence of safety and probable benefit. Humanitarian use devices (HUDs) are exempt from the requirement to establish a reasonable assurance of effectiveness. The HUD is only intended for use in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

The second point Dr. Slack makes regarding the off label use of the Melody Valve™ is also of utmost importance, particularly for practitioners within the United States. It was not our intention to encourage off label use of the Melody Valve™. We concur that it is of critical importance to follow accepted regulatory pathways at all times, as has been our practice at Children's Hospital of Pittsburgh of UPMC. As stated in the "Guidance for HDE holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff Humanitarian Device Exemption Regulation: Questions and Answers," issued on July 8, 2010 (www.fda.gov/downloads/MedicalDevices/Device%20Regulation%20andGuidance/Guidance%20Documents/ucm110203.pdf), when facing the potential use of a HUD outside its approved indication, physicians should be cognizant that the FDA has made a determination of safety and probable benefit for use of the HUD only within its approved indication(s). Prior to use of a HUD outside its approved indication(s), the FDA recommends that the physician obtain informed consent from the patient (or parent or legal guardian) and ensure that reasonable patient protection measures are followed, such as devising schedules to monitor the patient, taking into consideration the patient's specific needs and the limited information available about the risks and benefits of the device. The FDA further recommends that the physician first contact the specific IRB before such use to review any institutional policy and submit a follow-up report on the patient's condition to the HDE holder. However, the FDA indicates that the extent of IRB oversight in these circumstances is up to the specific IRB. In addition, physicians who want to study the use a HUD for a new indication must submit an Investigation Device Exemption (IDE) application to the FDA if the device is classified as a significant risk device.

Sincerely,

Jacqueline Kreutzer, MD, FACC, FSCAI
Sara M. Trucco, MD

CCT

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Letters to the Editor

Congenital Cardiology Today welcomes and encourages Letters to the Editor. If you have comments or topics you would like to address, please send an email to: LTE@CCT.bz, and let us know if you would like your comment published or not. Those wishing to have their LTE published will be sent a preproduction draft to review.

CALL FOR CASES AND OTHER ORIGINAL ARTICLES

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- Title page should contain a brief title and full names of all authors, their professional degrees, and their institutional affiliations. The principal author should be identified as the first author. Contact information for the principal author including phone number, fax number, email address, and mailing address should be included.
- No abstract should be submitted.
- The main text of the article should be written in informal style using correct English. The final manuscript may be between 400-4,000 words, and contain pictures, graphs, charts and tables. Accepted manuscripts will be published within 1-3 months of receipt. Abbreviations which are commonplace in pediatric cardiology or in the lay literature may be used.
- Comprehensive references are not required. We recommend that you provide only the most important and relevant references using the standard format.
- Figures should be submitted separately as individual separate electronic files. Numbered figure captions should be included in the main Word file after the references. Captions should be brief.
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Medical News Products and Information

New Data on EDWARDS INTUITY Valve System Demonstrate Promise of Rapid Deployment Platform

(Marketwire) - Edwards Lifesciences Corporation, a global leader in the science of heart valves and hemodynamic monitoring, announced that new data from the European multi-center TRITON trial studying the EDWARDS INTUITY valve system highlights the promise of several important benefits, including the facilitation of small-incision surgery for aortic valve replacement (AVR), a high procedural success rate, and consistent and sustained hemodynamic valve performance at one year. The data was presented in May during the *Emerging Technologies and Techniques Forum at the American Association for Thoracic Surgery's 92nd Annual Meeting* in San Francisco.

The EDWARDS INTUITY valve system leverages a proven valve platform and features an innovative balloon-expandable frame for rapid deployment. Rapid deployment AVR may benefit patients by enabling small-incision surgical approaches and reduced operative times, leading to potentially reduced morbidity and faster recovery.

In the prospective, single-arm TRITON trial, six European centers treated 152 consecutive patients in need of surgical AVR; the rate of procedural success for patients receiving the EDWARDS INTUITY valve was 97.3%. Surgeons performed 86 isolated AVR procedures, with about half of these cases using small-incision approaches. The EDWARDS INTUITY valve system also showed single-digit mean gradients at one year in all valve sizes, and a low incidence of paravalvular leaks -- a small pressure gradient across the aortic valve is normal and indicative of good hemodynamic performance. Valve-related mortality rates were low; the survival in this group of patients was 98.6% at 30 days and, at one year, the Kaplan-Meier curve demonstrated 94% freedom from death.

The data also demonstrated shortened procedures, as characterized by reductions in cross-clamp times and the time patients spent on cardiopulmonary bypass. For isolated AVR cases, mean aortic cross-clamp times were reduced by 48%, and mean bypass times by 39%, compared to times noted in the Society of Thoracic Surgeons' (STS) Adult Cardiac Database. Several published studies indicate that a shorter duration of aortic cross-clamping is associated with a reduction in mortality and morbidity after AVR.

"In addition to establishing low rates of mortality and morbidity and a reproducible valve replacement procedure with the EDWARDS INTUITY valve system, the study gives us confidence in the opportunity to use this system with less-invasive surgical approaches. We also see promise in the performance of the EDWARDS INTUITY valve system due to the early, excellent hemodynamic results and the design inspired by the proven platform of Edwards' family of surgical valves," said Günther Laufer, MD, Chair and Professor, Cardiac Surgery, Medical University of Vienna.

The EDWARDS INTUITY valve system received CE Mark in Europe in February 2012. It and GLX are investigational, and not currently available for sale or use in the US.

Cincinnati Children's Heart Institute First in Nation To Receive Pediatric Accreditation

The Heart Institute at Cincinnati Children's Hospital Medical Center has been named the first accredited Pediatric Heart Failure Institute in the US.

The Healthcare Accreditation Colloquium's designation recognized the Cincinnati Children's Heart Institute for seeking "pre-eminence in heart care."

"The work being done at Cincinnati Children's will set the tone for a new collaborative paradigm melding the worlds of pediatric and adult heart failure and will profoundly affect the way we view and treat heart failure in the not too distant future," says Frank Smart, MD, chairperson of the Colloquium. "We are delighted that Cincinnati Children's is our first accredited pediatric heart failure institute and will soon invite other forward thinking organizations to join in this groundbreaking effort."

The Heart Institute was founded in 2008 to transform pediatric cardiovascular medicine with clinical programs driven by scientific discovery. The infrastructure now in place includes the innovative Advanced Cardiomyopathy/Heart Failure Service, which includes a large inpatient and outpatient program. The Advanced Cardiomyopathy/ Heart Failure Clinic is one of the largest in the nation, with a highly specialized, multidisciplinary team serving more than 600 patients with cardiomyopathies (heart muscle disease) a year.

What sets the clinic apart from others is its combination of cardiovascular genetics and cardiovascular genetic counseling, working in tandem to diagnose and treat cardiomyopathy and complex forms of heart muscle disease. Families of children are counseled regarding the underlying genetic basis of their disease and associated inheritance patterns. Patients also receive diagnostic genetic screening. The team includes five pediatric cardiologists, two clinical cardiovascular geneticists, three cardiovascular genetic counselors, an electrophysiologist and a diagnostics laboratory that analyzes underlying genetic causes of disease and viruses in the heart to detect and treat myocarditis (heart inflammation).

"Cincinnati Children's is one of the few places in the world that offers state-of-the-art viral PCR (polymerase chain reaction) analysis and genetic testing for cardiac disease, combined with expert clinical insight and patient management," says John Lynn Jefferies, MD, Director of the Cardiomyopathy/Heart Failure Service. "The diagnostic lab is also a key part of our 'soup-to-nuts' approach to pediatric cardiovascular disease management. The integration leads to rapid new advances in therapies and care protocols."

"Because of this marriage," adds Jeffrey Robbins, PhD, Co-Director of the Heart Institute, we now have the ability to know the exact gene – the exact mutation – that's causing disease, and we have the doctors who can stratify the risk and, at some point in the future, cure it."

Studies have shown that the largest heart failure burden comes from children born with congenital malformations. It has been estimated that 15% to 25% of children who have structural heart disease develop heart failure. Although cardiomyopathy is relatively rare, approximately 40% of patients who

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experience cardiomyopathy develop heart failure of such severity that it leads to transplantation or death.

The Healthcare Accreditation Colloquium's rigorous accreditation process is modeled after process improvement methods and includes a study of current practices, a gap analysis (a technique to get to a desired future state), in-depth interviews, clinical process mapping, an onsite review and a comprehensive milestone report with specific action steps. Benefits include:

- an integration of care from early diagnosis to advanced care
- streamlined processes across the entire continuum of care
- enabling caregivers to provide greater care at home and less hospitalization
- collaboration with other Colloquium member hospitals across the country.

"When we started the process of establishing the Heart Institute, the leadership at Cincinnati Children's asked us to shake the trees, shoot for the moon – which turned out to be a watch-what-you-wish-for scenario, because we do," says Jeffrey Towbin, MD, Chief of Cardiology and Co-Director of the Heart Institute, along with with Dr. Robbins. "The Colloquium likewise approaches accreditation as an opportunity for improvement. Shooting for the moon can be uncomfortable, but we have to challenge the paradigms, no matter what they are."

High Blood Pressure Often Missed in Children and Adolescents, U-M Experts Say

Newswise - High blood pressure in children and adolescents is a growing health problem that is often overlooked by physicians, according to a University of Michigan Health System article published in *American Family Physician* that offers doctors a guide to catching and treating hypertension early.

A child's blood pressure reading may appear normal, but when it's factored in with the patient's age, sex and height, that same value could actually reflect hypertension, the authors warn.

"When it comes to young people's blood pressure, we can't use a flat number value for what's normal or abnormal like we do in adults. They may have a reading of 80/40, which sounds good, but that may actually be high," says lead author Margaret Riley, MD, Assistant Professor of Family Medicine at the U-M Medical School. "This is becoming a much greater concern in society because of the obesity epidemic we're seeing that's contributing to high blood pressure among kids.

The paper reminds physicians that they must check the blood pressure values for patients ages three to 18 years against charts that factor in age, sex and height to accurately determine if the blood pressure is normal.

These charts are available online from the National Institutes of Health and through applications for handheld devices that allow physicians to quickly determine if the patient's blood pressure is within normal range.

"Despite the high prevalence and potential risks of hypertension in children, physicians often don't recognize the condition in this population," Riley says. "High blood pressure may start causing problems even in childhood, including changes to the structure of the heart that damage blood vessels, and can also be associated with high cholesterol, diabetes and other health issues."

While the issue of weight loss can be a sensitive one to broach with parents, high blood pressure may be a strong motivating factor to drive family lifestyle changes, such as increasing physical activity and incorporating healthier foods into diets, Riley says.
Other highlights from the article for physicians:

- If high blood pressure is detected, further tests should be done to determine whether a patient has primary hypertension or secondary hypertension, which can be caused by an underlying medical condition like kidney disease, heart problems, thyroid abnormalities, or obstructive sleep apnea.
- Blood pressure should be recorded at every visit starting at age three, not just annual check-ups.
- Using the wrong size of blood pressure cuff is a common cause of inaccurate readings. Physicians who see children and adolescents should have cuffs of varying sizes.
- Lifestyle changes including eating a healthy diet and getting regular exercise are first line treatments for high blood pressure in children. Children with secondary hypertension or primary hypertension that doesn't improve with lifestyle changes may need medication to lower blood pressure.

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Advocate Medical Group (AMG), a physician-led multi-specialty team of over 900 physicians, seeks an experienced board certified/board eligible Pediatric Cardiac Critical Care specialist to join The Heart Institute for Children at Advocate Hope Children's Hospital. Located in suburban Chicago this unique, thriving, dynamic clinical practice includes 16 Pediatric Cardiologists.

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The Heart Institute for Children
Advocate Hope Children's Hospital

Additional Authors: Brian Bluhm, MD, Integrated Healthcare Associates, Ann Arbor. Bluhm was completing a fellowship at U-M at the time the article was written. Citation: "High Blood Pressure in Children and Adolescents,"Am Fam Physician. 2012; 85 (7): 000-000.

The Heart Institute at Cincinnati Children's Hospital Medical Center Offers Excellent Teaching and Learning Material about ACHD

The material was recorded at the 2011 ACHD Program in Cincinnati. It will be of value to: physicians and others with an interest in ACHD, adult and pediatric cardiology trainees who need more exposure to ACHD, and teachers who need educational material for rounds or other teaching. The two major types of resources are: "Topic-based Learning" and "Case-based Learning."

Topic-based Learning: ACHD echocardiography symposium, Aortic root symposium, Aortic valve symposium, The future of ACHD care symposium, Advances in ACHD arrhythmia management, ACHD imaging, Special lectures, Challenges in ACHD surgery, Fontan symposium, This I believe presentations, Pregnancy and heart disease, Contraception and heart disease, Pulmonary arterial hypertension symposium, Varied topics, Imaging and CHD, Surgery and CHD, EP/ arrhythmias and CHD, and Interventional cardiology and CHD.

Case-based Learning: Case presentations and discussion were presented from the following International teams: Amsterdam, Columbus, London, Montréal, Mayo Clinic, and Toronto.

While there was some technical difficulties with some of the video clips, the information is invaluable.

Cincinnati Children's Hospital Medical Center (CCHMC) would be grateful for feedback from each user as to how valuable each presentation was to them. It is a five-star scoring system. There is also an opportunity to communicate with CCHMC if any of users are having problems with the website. Users will also note a help button to teach them how best to use the various controls on the website.

With the assistance of colleagues and other institutions, CCHMC plans to add other teaching material to create an ACHD learning site. Use what they now have, and remain alert to finding additional material in the future. Please feel free to offer your suggestions as to what material you would like to see on the site, or suggest where CCHMC may find material that you already know about that could be put on the ACHD learning site.

For more information visit the website, https://cincinnatiachdcourse.org, or contact: Gary Webb, MD; Cincinnati Adolescent and Adult Congenital Heart Disease Program; The Heart Institute at Cincinnati Children's Hospital Medical Center; Gary.Webb@cchmc.org; Phone: 513-803-1777; Mobile: 215-313-8058; Fax: 513-803-1778.

Rigorous Trial Design and Monitoring Provides New Insight to Outcomes for Men and Women with Aortic Stenosis

Medtronic, Inc. announced at May *EuroPCR 2012* in Paris new results from the Medtronic CoreValve ADVANCE Study, which found that women and men benefitted similarly from the Medtronic CoreValve®

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System. The study evaluated patients who were at high-risk for surgical aortic valve replacement. The Medtronic CoreValve System is currently limited to investigational use in the United States.

The gender analysis, a secondary-endpoint evaluation in the real-world CoreValve ADVANCE Study, found that survival rates were nearly identical between genders, with no statistical differences in 30-day and 6-month all-cause mortality, cardiovascular mortality or the 30-day MACCE endpoint (Major Adverse Cardiac & Cerebrovascular Events, a composite of all-cause mortality, myocardial infarction, emergent cardiac surgery or percutaneous re-intervention, and stroke).

Overall, patients experienced low 30-day stroke rates (2.9% overall), with the combined stroke rates of major and minor strokes being very low (major 1.2%, and minor 1.7%). However, female patients experienced a statistically higher rate of strokes (4.4% vs. 1.4%; p-value <0.01), major vascular complications (14.1% vs. 7.1%; p-value <0.01) and major bleeding (5.0% vs. 3.1%; p-value <0.01). For minor strokes between genders, and for major strokes between genders, differences were not significant, though there was a trend for women to have more minor strokes than men.

"This study is an important contribution to the growing base of research on TAVI, and sheds light on the unique needs for managing severe aortic stenosis in women," said Patrizia Presbitero, MD, Director of Interventional Cardiology at Hospital Humanitas Rozzano in Milan and an investigator in the CoreValve ADVANCE Study, and a professional development co-chair and member of the Leadership Council of WIN (Women in Innovations/Society for Cardiovascular Angiography and Interventions, SCAI). "We need to know more about gender differences to effectively treat patients with heart disease in a more specific way, taking into account those differences that can affect treatment."

Women and men benefited similarly from the CoreValve System even though women (51% of patients) and men (49% of patients) had different risk profiles. Specifically, at the time of enrollment, women as compared to men were:

- Older than males (82.2 years vs. 79.9 years; p-value <0.001);
- Had higher average gradients (47.6 vs. 43.5 mmHg; p-value <0.001) and peak gradients (79.0 vs. 72.5 mmHg; p-value <0.001), a measure of blood flow across the valve;
- Had less coronary artery disease (46% vs. 70%; p-value <0.001); and
- Were prescribed fewer cardiovascular medications, including cholesterol-lowering medications (p-value 0.002) and statins (p-value 0.013).

"The robust ADVANCE trial provides a compelling discovery that the CoreValve System is an excellent therapeutic option for both men and women, and it helps us begin to consider how men and women present differently prior to implant and might be managed accordingly," said Axel Linke, MD, Professor of Medicine at Universitat Leipzig Herzzentrum in Leipzig, Germany and principal investigator of the ADVANCE clinical trial. "An important next step will be to further evaluate why stroke events were more common for women, including the possible role of medications which were prescribed less frequently for women in this study."

The ADVANCE study is one of the largest multicenter transcatheter aortic valve implantation (TAVI) trials to date, with 1,015 patients consecutively treated at 44 experienced TAVI centers in 12 countries. Clinical endpoints were calculated according to Valve Academic

Pediatric Cardiology Division Chief

The Department of Pediatrics at the Wake Forest University School of Medicine (WFUSM) in Winston Salem, North Carolina, is recruiting a full-time section head (chief) for the division of Pediatric Cardiology. The ideal candidate will be a board certified cardiologist with training and experience in providing leadership, as well as clinical, academic and service excellence. The candidate should have already achieved the rank of associate or full professor, or be qualified for promotion to the rank of associate professor in the department of Pediatrics. In addition to proven leadership abilities, a strong record of research or academic success is required.

The Children's Heart Program at Brenner Children's Hospital functions as a service-line enterprise with support from the hospital administration. The chief of cardiology will be responsible for providing clinical oversight and supporting the academic growth of the current faculty of eight and will also function in collaboration with the director of the Children's Heart Program (one of the two CT surgeons, who is ABTS certified in congenital heart surgery), the vice-president of Brenner Children's Hospital, and the chair of the department of Pediatrics, to formulate the strategic vision for growth of the program. This is a major leadership position for our Children's Hospital and consequently, the successful candidate will receive appropriate support, including an opportunity to recruit other essential team members as needed and develop required programs. We want this important recruit to be successful in helping us achieve our strategic goals of becoming the recognized center of excellence for congenital heart care in Western North Carolina, as well as their own goals to be recognized as a successful leader in academic pediatric cardiology. An interest in and track record of teaching medical students, residents and fellows is required. We are in the process of submitting our PIF for a pediatric cardiology fellowship.

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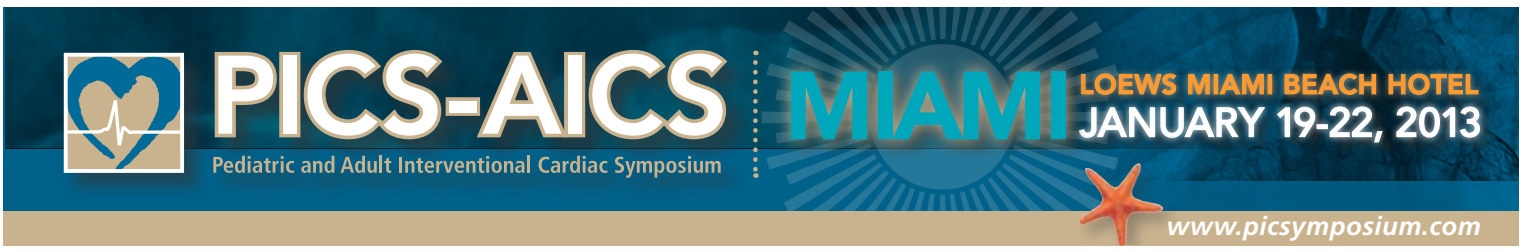

Research Consortium (VARC) standardized definitions. All data were independently monitored, all adverse events related to the primary endpoints were adjudicated by an independent Clinical Events Committee (CEC) consisting of experienced cardiac surgeons and interventional cardiologists, and all cerebrovascular events (including stroke and other events) were adjudicated by an independent neurologist using neuroimaging and systematic NIH Stroke Scale assessments.

The Medtronic CoreValve System received the CE (Conformite Europeenne) Mark in 2007 for the treatment of patients deemed at high or extreme risk for surgery. Since then, it has been implanted in more than 27,000 people in more than 50 countries outside the US. The CoreValve System is available in three sizes (26mm, 29mm and 31mm), and is the only transcatheter aortic valve implantation system approved for direct aortic or subclavian access.

Worldwide, approximately 300,000 people have been diagnosed with symptomatic, severe aortic stenosis, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery [*Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? Bernard Iung et al. Eur Heart J (December 2005) 26(24): 2714-2720.*].

For additional information www.medtronic.com.

Children's National Disappointed in Gov. Bob McDonnell's Veto of Newborn Heart Disease Screening Legislation

On April 10th Governor Bob McDonnell of Virginia vetoed legislation that would have taken the first step toward saving the lives of newborn Virginia babies who die each year from heart disease.

The legislation, HB 399, would have fast-tracked implementation of screening in all Virginia hospitals to ensure that every child would have access to a simple, yet vital, screening test for Critical congenital heart disease (CCHD).

"While we commend the Governor for acknowledging CCHD screening is an issue that deserves attention, we respectfully disagree that convening a no cost, public-private stakeholders group to ensure that all hospitals in Virginia – both urban and rural – have the necessary tools to implement a newborn screening program is unnecessary," said Jacqueline D. Bowens, Executive VP & Chief Government Affairs Officer at Children's National. "It is the role and responsibility of state government to establish uniform standards for statewide newborn screening. As such, to replace the pathway established in HB 399, we urge Governor McDonnell to formally direct the Department of Health to convene experts and stakeholders to establish a plan for implementation of statewide CCHD screening this year."

"Screening for critical types of congenital heart disease using pulse oximetry is simple, non-invasive, inexpensive, and helps to identify newborns with congenital heart disease so they can get early care," said Gerard Martin, MD, Senior VP, the Center for Heart, Lung and Kidney Disease at Children's National. "Doctors and nurses can perform this simple test just after birth to help detect a life-threatening condition when we do other routine tests. We are deeply troubled by the Governor's veto of a bill that could bring such dramatic benefit to newborns."

"If serious forms of congenital heart disease are missed, lifelong health problems or death may result. Some hospitals in Virginia, but not all, are already screening newborns for CCHD and this bill would have guaranteed smart and cost effective care to all children in Virginia, regardless of where they live," said Martin.

Gov. McDonnell's veto of this legislation could also hurt Virginia's chances of receiving $1 million in badly needed federal funding to help address this public health issue, said one of the bill's supporters, Cathleen Smith Grzesiek, Senior Director of Government Relations for the American Heart Association.

"This legislation would have shown the federal government that Virginia is serious about saving the lives of newborns with heart disease, increasing our chances to get financial support to make progress on this issue and make a difference for more Virginia families," said Grzesiek.

House Bill 399 would have established a process for statewide implementation of newborn screening for CCHD. This type of screening is endorsed by The American Academy of Pediatrics, American College of Cardiology, the American Heart Association, and the US Department of Health and Human and Human Services.

Coming in the July issue

Biodegradable Devices for the Treatment of Congenital Cardiovascular Disease, by Daniel S. Levy, MD and Andrew L. Cheng, MD

Coming in the August issue:

FDA Clearance of Cardiac Devices for Children: A Primer and Call to Action, by Robert H. Beekman, III, MD

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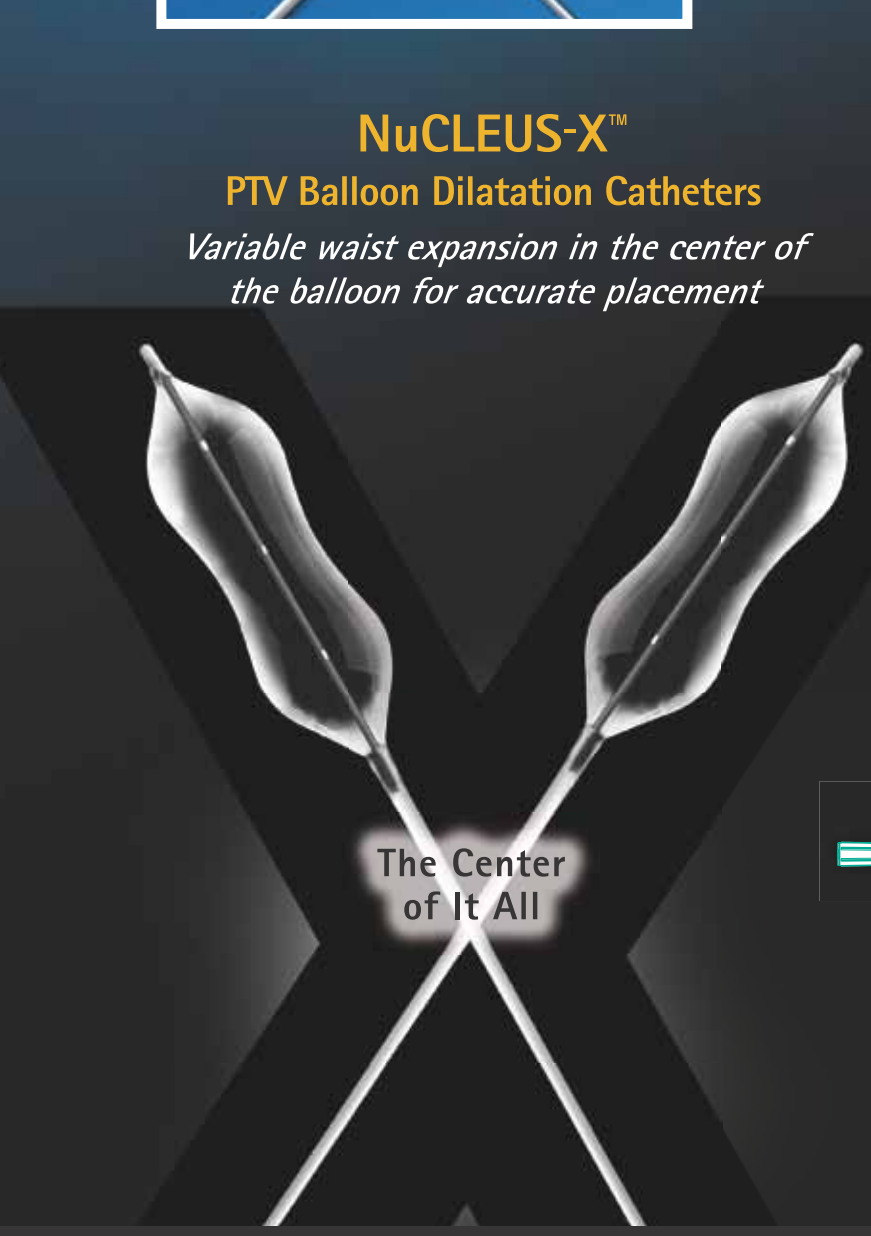

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