

CONGENITAL CARDIOLOGY TODAY

News and Information for Pediatric and Congenital Cardiovascular Physicians and Surgeons

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Focus on the PFO

By John W. Moore, MD; Medical Editor/
Congenital Cardiology Today

This Issue of Congenital Cardiology Today focuses on the PFO (Patent Foramen Ovale). Dramatic advances in device technologies have made it possible to close PFO's with little morbidity and essentially no mortality. This issue is devoted to those technologies and to the surrounding issues.

There is no doubt that some ischemic strokes are caused by paradoxical embolism of venous emboli into the arterial circulation: Thrombus has been observed in and traversing PFOs both during open heart surgery and during echocardiography. However, the larger question is whether some, most, or all of the 40% of acute ischemic strokes with no clearly defined etiology can be attributed to this mechanism.

There is much data suggesting that the PFO has a role in most cryptogenic strokes. For example, a meta-analysis of case-control studies found that 55% of patients having cryptogenic stroke had PFO's, whereas only 17% of patients with known cause of their strokes and only 17% of control patients without stroke had PFO's[1]. In addition, pooled analyses of 46 retrospective studies describing almost five thousand patients have shown statistically significant reductions in recurrent episodes of stroke and transient ischemic attacks after device closure of PFO in comparison to patients who had medical therapy but no device closure[2,3]. It is fair to say that many practitioners are already convinced by the existing data, and they are advocating and

performing PFO closures to prevent recurrent neurological events.

On the other hand, there is data which suggests that the PFO may have a less significant role. For example, a prospective study suggested that there is not a significant difference in the incidence of stroke in 5-year follow-up between patients who have or do not have PFO[4], and the well constructed PFO in Cryptogenic Stroke Study (PICSS) showed that the incidence of death or recurrent stroke was not statistically different between the groups of patients with or without PFO who were treated medically[5]. Such studies create a lack of clarity in the medical literature, and are the basis for the statement by The American Academy of Neurology describing the evidence to evaluate the efficacy of PFO closure for prevention of stroke as insufficient[6]. Fortunately, prospective randomized studies are underway; these hopefully will provide the needed clarity.

In addition to its role in the pathogenesis of cryptogenic stroke, the PFO is thought to have an important role in the pathogenesis of migraine headache, deep-sea diver's decompression sickness, and the syndrome of platypnea-orthodeoxia. Decompression illness and platypnea-orthodeoxia are boutique issues. But, migraine is a major public health problem and like cryptogenic stroke, needs to be evaluated critically. Existing migraine data largely parallels the cryptogenic stroke data. There is an increased incidence of PFO in patients with migraine versus controls, and pooled retrospective data suggests more than 40% of migraine patients have complete resolution or significant improvement of their headaches after PFO closure[7,8]. Larger randomized studies in migraine patients are

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* J of Neuroimaging, Vol 14, No 4, Oct 2004.

underway, which hopefully will also better define the role of PFO closure in migraine headaches.

Percutaneous PFO closure has been widely performed for cryptogenic stroke and migraine for several years. In the United States, however, The Food and Drug Administration withdrew previously granted Humanitarian Device Exemption (HDE) status from both the CardioSeal (NMT) and the Amplatzer PFO (AGA Medical) devices in August 2006. Thus, in the States, these devices are currently only available for use in one of the FDA randomized trials or registries enrolling patients with recurrent cryptogenic stroke, PFO, and failure of medical therapy. Outside the United States, of course, these devices are widely available for PFO closure. Additional devices, available in the

United States and elsewhere, which have been used "off label" for PFO closures include the Helix Device (Gore Medical), the VSD Device (NMT), the Amplatzer Septal and Cribriform Septal Occluders (both AGA Medical).

Beyond the existing devices, a number of new devices are being developed. There are also new technologies such as bioabsorbable, stitch-mediated, and stent-based devices, as well as non-device technologies like tissue welding under development.

In this Issue, Congenital Cardiology Today hopes to raise awareness of PFO-mediated pathologies, the role of interventional PFO closure in their treatments, as well as the technologies available and under development designed to close the PFO.

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The cardiology division is in a state of rapid growth, with construction of a dedicated Congenital Heart Center within Cardinal Glennon Children's Medical Center projected to begin in 2008. An active congenital heart surgery program exists, and a new addition to the hospital recently opened housing state-of-the-art operating rooms and a new 60-bed neonatal intensive care unit. A new 10-story tower that will serve as the Health Sciences Center Research Building will be completed in 2007.

Interested candidates must submit a cover letter, application, and current CV to <http://jobs.slu.edu>. Other correspondence regarding this position can be sent to Kenneth O. Schowengerdt, MD, Wieck-Sullivan Professor and Director of Pediatric Cardiology, Saint Louis University School of Medicine, 1465 South Grand Blvd, St. Louis, MO 63104. Telephone: (314)-577-5633; Fax: (314)-268-4035; email: schowko@slu.edu.

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The Use of TCD Power M-Mode Technology in Conjunction with Ultrasound as a Diagnostic Tool For PFO Closures

By J. Shari Snyder RT(R)

There are many ways of using today's technology for detecting shunts at the atrial level. As a technologist in pediatric cardiology, you quickly learn that all congenital defects have different locations, sizes and shapes. There are many factors that can effect the medical management of each patient's shunt. For the sake of this article, I will limit the different types of shunting at the atrial level to only Patent Foramen Ovale (PFO).

One in every four people has a PFO and does not know it. It is a very common hole that does not close after birth in adults. Usually, people with this defect can lead normal lives until symptoms present. A PFO is a tunnel-like hole in the septum between the right atrium and left atrium. Upon exertion or physical activity, the flap may open allowing venous blood to flow across the tunnel and mix with the arterial blood. This shunting of blood can often cause micro embolisms, and/or broken plaque deposits that flow across to the atrial level, up the carotid vasculature, thru the Circle of Willis, and end up blocking flow to a section of the brain that causes stroke. This can also be called a Transient Ischemic Attack (TIA). There are also research studies that are focused on studying the patient population that have frequent migraines with aura. These groups of people are tested for a PFO. The positive population is randomized into a drug treatment method of therapy vs. complete closure.

Transthoracic echocardiography (TTE), Transesophageal echocardiography (TEE), Intercardiac echocardiography (ICE),

“One in every four people has a PFO and does not know it. It is a very common hole that does not close after birth in adults. Usually, people with this defect can lead normal lives until symptoms present.”



Figure 1. ICE image confirming PFO.

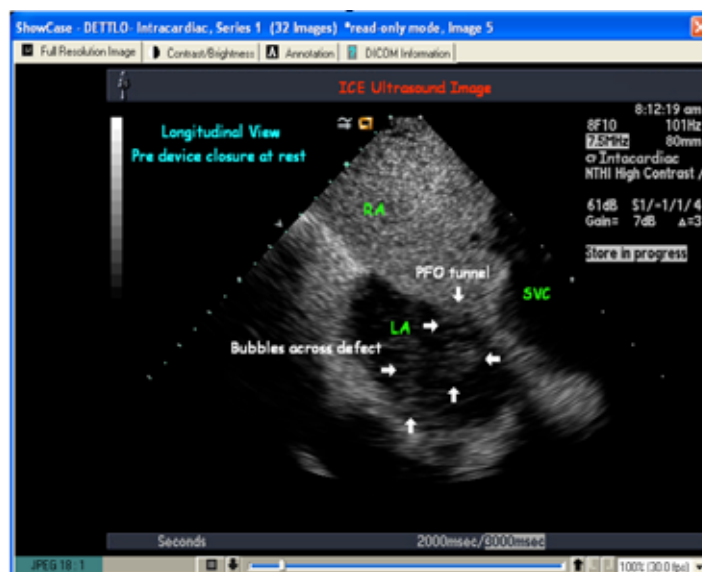


Figure 2. ICE injection at rest showing R-L shunt

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and power M-mode Transcranial Doppler (TCD) monitoring are all ultrasound techniques used to evaluate and diagnose PFOs. Working with Dr. Ziyad Hijazi at The Rush Center for Congenital and Structural Heart Disease, we have developed a standard protocol for our patients that utilizes TCD M-mode technology in conjunction with ICE for the catheterization and TCD monitoring along with TEE for follow-up. After device

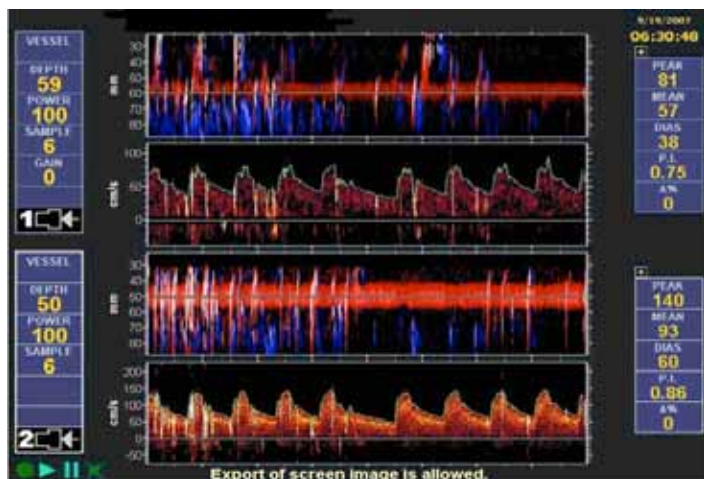


Figure 3. TCD showing multiple hits at rest.

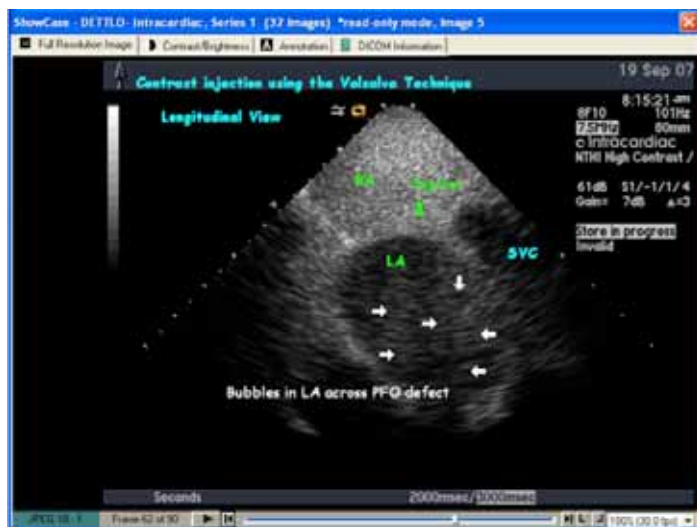


Figure 4. ICE image of the injection pre device with the Valsalva technique showing severe shunting across PFO.

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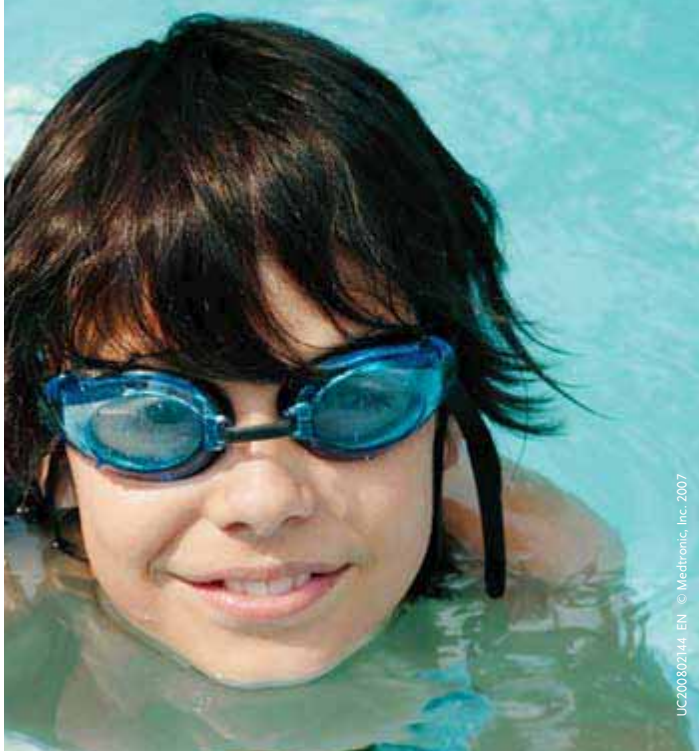


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implantation this process is done on every catheterization patient repeatedly until there is a negative (Grade 1/5 based on the scale created by Dr. Spencer) result.

Most patients come to Dr. Hijazi with a copy of their TEE/TTE and a diagnosis of Patent Foramen Ovale from the referring

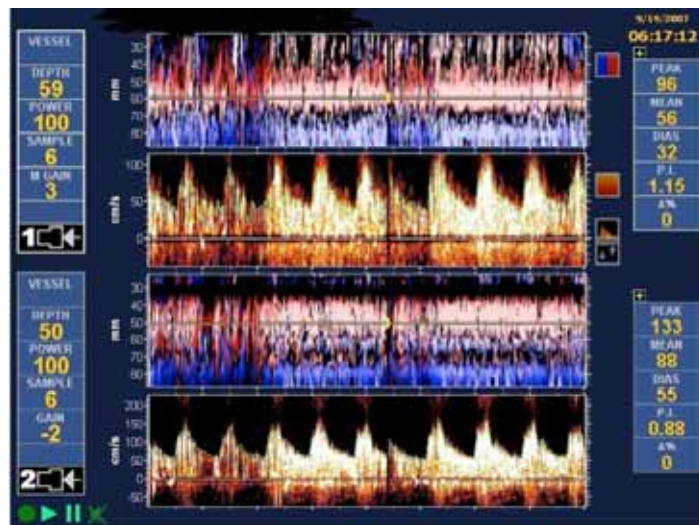


Figure 5. TCD pre-device image showing significant amount of hits when the Valsalva technique is used.



Figure 6. Immediate post device closure ICE image of the injection, showing minimal shunting across device.



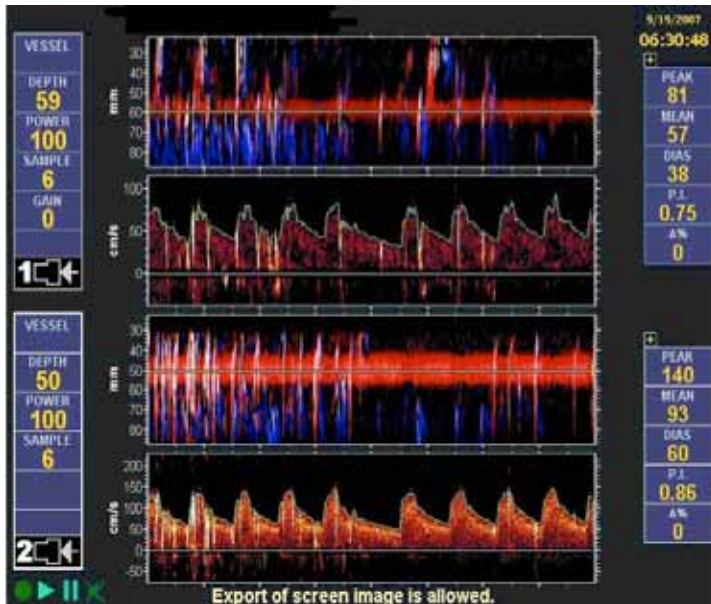
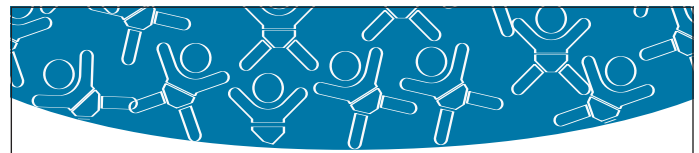


Figure 7. TCD immediately post device closure using the Valsalva Technique confirming shunting is still present.



Figure 8. 24-hour post closure TTE showing no bubbles across device.



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A team of nine pediatric intensivists and eleven pediatric cardiologists cover the congenital heart surgery unit. A dedicated 10-bed pediatric cardiovascular intensive care unit opened in 2004. Construction has begun on a newer unit with a completion date in late 2008.

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Figure 9. Injection image using the Valsalva technique, taken 24-hours post-device implantation, showing no bubbles across septum and complete closure.

physician. Dr. Hijazi reviews the cardiac catheterization procedure for closure of PFO with a device with the patient. Once the patient makes a decision, a cardiac catheterization is scheduled and instructions are given to the patient. The standard is for the patient to have a current ECHO, 24-hour holter monitor, and an EKG the day of their clinic visit. The clinic data is reviewed by Dr. Hijazi before the catheterization as a baseline reference.

The patient arrives for the catheterization, consent is obtained. The patient is placed under conscious sedation. The technologist places on the power M-mode TCD helmet and transducers. The probe on the transducers are lined up through the temporal window and manipulated correctly until adequate signals of the right and left MCA, ACA, and PCA are obtained and seen on the M-mode and spectrogram screen bilaterally. The groins are prepped and draped in a sterile fashion. Venous access is obtained percutaneously and two 8 French Cordis Sheaths are placed in the right femoral vein. A standard hemodynamic catheterization is performed. An ICE catheter is inserted and imaging is obtained. After confirmation of PFO by ICE imaging (Figure 1), a contrast bubble study is done. Utilizing fluoroscopy, ICE and TCD monitoring two injections are done thru a catheter placed in the IVC. The first injection is done with the patient at rest (Figures 2 & 3). Both injections confirm the R to L shunt.

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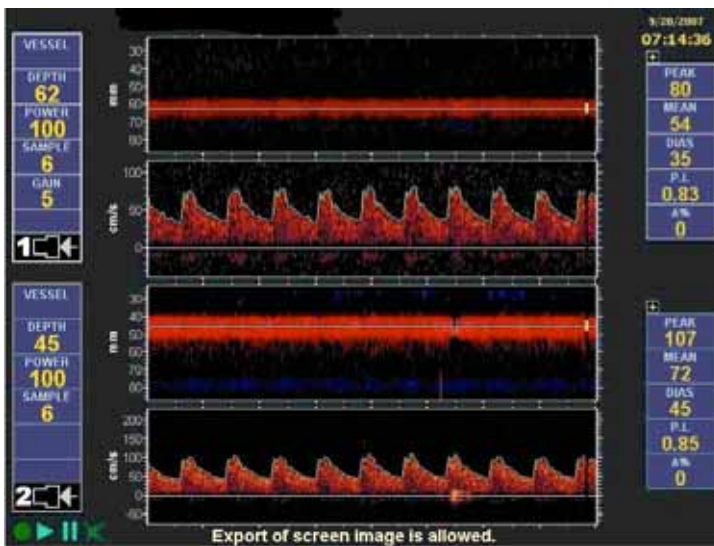


Figure 10. Post device 24-hour f/u TCD at rest showing no hits and confirming complete closure of defect.

A second injection is given with the Valsalva technique. This is when a patient bares down as if they are tightening their stomach muscles. In a PFO case, this is helpful. Because PFO's are often a tunnel or flap-like defect, this straining technique can often open the flap, and provide information about what may have happened while the patient was lifting or exercising. It also can be a sign of how significant the shunt is to the patient, and what risk factors are involved. (See Figures 4 & 5).

After careful review of the imaging, a device is chosen. In this case, a 25mm ASD Cribribriform device is placed into the defect. The device is released; ICE imaging is obtained and reviewed by the physicians. A final Bubble study is done with the Valsalva maneuver. An ACT is drawn for clot response. Usually the patient will still be therapeutic, so a follow-up TTE and TCD are scheduled for the next day. The patient is discharged from the lab (See Figures 6 & 7). Just post device closure, it is evident how much less shunting there is both on ICE and TCD monitoring.

The next day, before the patient is discharged, a repeat injection is done on the floor, bedside, using the same IV. A good view of the device on profile is performed using TTE by the sonographer, and two syringes are prepared. A syringe with a 1cc of air, and another with 9cc of saline is attached to the stopcock. Two injections are repeated with TCD monitoring and TTE (Figures 8-11). The patient has now returned to baseline clot time. It is clear by both TTE and TCD monitoring there is no residual shunting. This allows the treating



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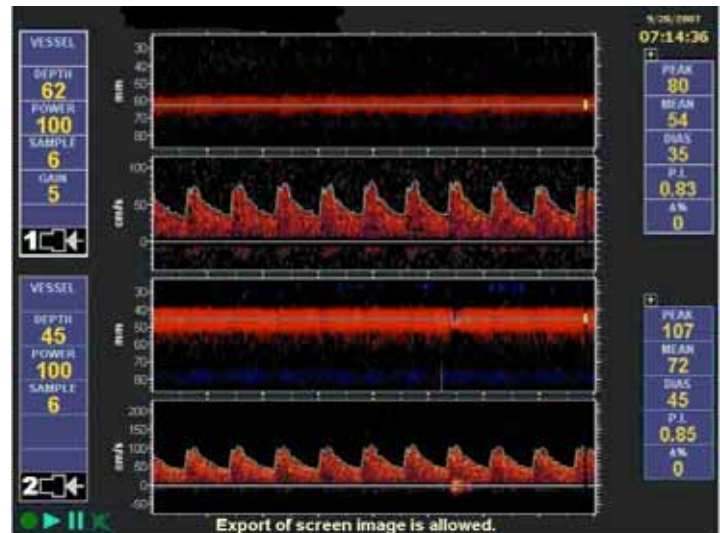


Figure 11. Post device 24-hour f/uTCD with the Valsalva technique showing no shunt detected and confirming completed closure of defect.

physician to absolutely determine complete closure of the PFO. TCD monitoring is the most sensitive tool for verifying complete closure.

In conclusion, the use of TCD, TTE, TEE, and ICD with TCD aids in the complete closure of PFO. It is an essential combination of each of these tools used in a specific protocol that allow our patients the peace of mind that they have no more hole that can lead to complications later in life. Utilizing all of the available technology is essential for patient satisfaction and accurate treatment.

CCT

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Case History: Cryptogenic Stroke and PFO

By Jennifer Franke, MD; Stephan Staubach, MD and Horst Sievert, MD

Introduction

A patent foramen ovale (PFO) is an opening connecting the right atrium with the left atrium; it is common and usually without medical relevance. A PFO is a remnant of the fetal circulation which generally seals itself within a few months after birth. In about 20-30% of the population it does not close completely, and under certain conditions blood can pass directly between the right and left atria [1,2]. The PFO has been identified as a contributing cause of cryptogenic stroke, chronic migraine, decompression sickness, and obstructive sleep apnea [3-11]. A PFO may contribute to these conditions by providing a pathway for emboli in the venous system to reach the arterial system directly by passing from the right atrium to the left atrium [12]. Since the initial description of an atrial septal defect occluding device in the mid 1970s by King and Mills [13], a number of devices have been developed [14]. To date, various transcatheter devices and methods to close congenital heart defects are currently available commercially or within clinical trials.

Case History

We report the case of a 27-year old woman who was admitted to the neurological department of her nearest hospital in April 2007 due to a sudden weakness of the right arm and dysarthria shortly after travelling on a transatlantic flight. Cranial MRI detected an infarction of the left hemisphere, as well as few older lesions occipital and in the right hemisphere. Her risk factors included smoking and oral contraceptives. Familial neurological history or other previous illnesses were negative. Initial diagnostic examinations included a duplex scan of the supraaortic arteries, a transcranial Doppler examination (TCD), transthoracic echocardiography (TTE), 24-hour ECG as well as thrombophilia lab testing. All tests were without pathological findings except the transcranial Doppler examination which detected a right to left shunt. To determine the exact type of right-to-left shunt a transesophageal echocardiography (TEE)



Figure 1. 90° long axis view.

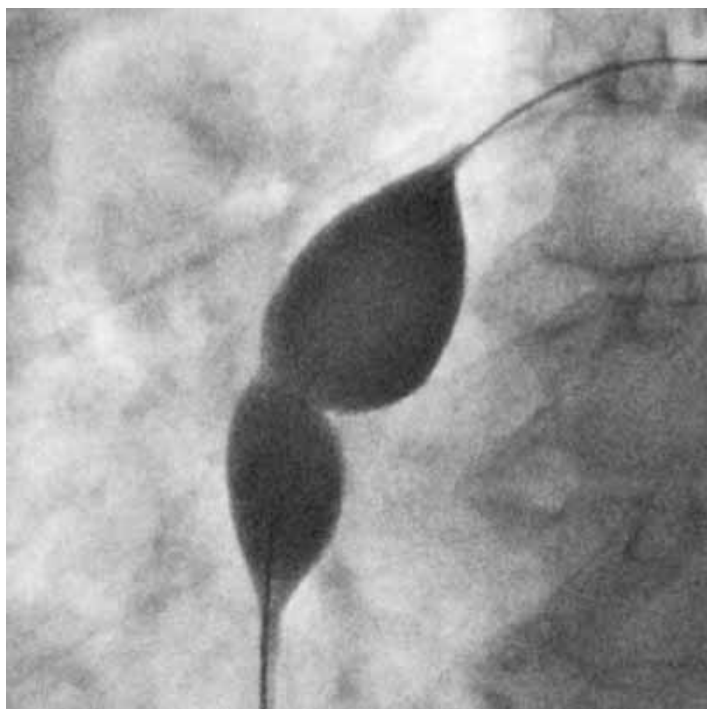


Figure 2. Balloon sizing.



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Figure 3. Fluoro of the PFxTM Closure System.

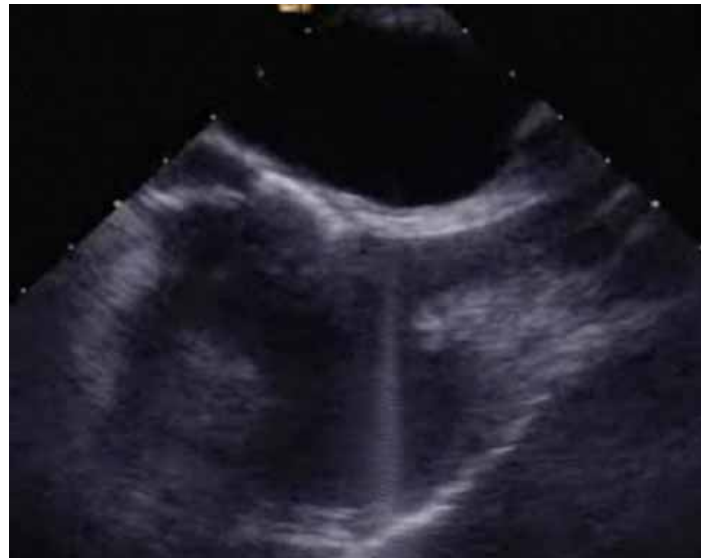


Figure 4. Applying energy by the PFxTM Closure System.

was performed thereafter. TEE revealed a patent foramen ovale with right-to-left shunt during Valsalva maneuver (Figure 1). After informing the patient about different treatment modalities, she was started on coumadin treatment and was referred to our center for interventional PFO closure. The woman was discharged seven days after the initial event with mild fine motor dysfunction of the left hand as well mild residual dysarthria.

In May 2007 the woman was admitted to our center for interventional PFO closure. Coumadin therapy had been replaced by low-molecular-weight heparin five days before. Three hundred mg aspirin were administered before the intervention. Peri-interventional TEE confirmed the diagnosis of a PFO. Balloon sizing (Figure 2) measured 14 mm, therefore, we used a new technique (Figure 3, 4), the PFxTM Closure System (Cierra Inc., Redwood City, CA, USA). Post-closure fluoro (Figure 5) confirmed complete closure. Examinations before discharge included an ECG and a TTE exam which showed normal findings. The patient was informed about follow-up procedures and was put on clopidogrel 75 mg and aspirin 100 mg for three months. She was discharged the day after the procedure with no complications.

Device Information

The PFxTM Closure System is a percutaneous system that employs monopolar radiofrequency energy to effect closure of a PFO by welding the tissues of the septum primum and septum secundum together. The procedure is performed from the right atrial side of the septum, reducing the potential complications associated with left atrial catheterization. Welding and PFO closure is achieved via application of a few minutes of energy delivered at levels below those employed in many cardiac ablation procedures. There are several PFx Catheter models which may be used. Models vary by the electrode size (15, 19 or 23mm) and electrode segments (1 or 3), which can be activated separately. The model is selected by the physician during the procedure based on the size of the PFO, the septal plane angles and morphology of the subject's right atrium. Currently ongoing clinical trials include The Paradigm IV Trial "PFxTM Closure System in Subjects with Cryptogenic Stroke, Transient Ischemic Attack, Migraine or Decompression Illness." The closure system has still not received U.S. Food and Drug Administration (FDA) and European CE Mark approvals.

Discussion

Interventional closure of a PFO is an alternative to prophylactic anticoagulation especially in young patients who have suffered paradox embolism/cryptogenic stroke, who wish to avoid a life-long medical therapy. Procedure duration is less than an hour and can be performed as an ambulant treatment. Clinical data

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Figure 5. Post-closure contrast injection.

so far has shown that PFO closure is a safe and effective technique to prevent paradox embolism/cryptogenic stroke [15-31].

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DIVISION OF PEDIATRIC CARDIOLOGY



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The Division of Pediatric Cardiology at OHSU Doernbecher Children's Hospital has a faculty position available at the assistant or associate professor level. The position requires excellent clinical skills in general pediatric cardiology. Subspecialty interest or training in heart failure, pulmonary hypertension and the care of cardiac transplant patients (currently performed elsewhere) is required. The candidate needs to be BE/BC in pediatric cardiology. In addition, the candidate should have excellent clinical judgment, a good work ethic, and the ability to collaborate with staff. This position will include ample opportunities for teaching and time to perform clinically focused research.

OHSU is located in Portland, Oregon, and is the state's only medical school. Doernbecher Children's Hospital is part of OHSU and includes 12 (soon to be 16) intensive care beds, 48 general pediatric beds, 12 (soon to be 24) oncology beds, and 48 neonatal intensive care beds. A well-established pediatric residency and pediatric cardiology fellowship program also exist. Portland is the largest city in Oregon and provides wonderful access to the Pacific Northwest.

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Candidates are encouraged to submit their curriculum vitae to:

John Kovalchin, MD,
Director of Echocardiography and Non-Invasive Imaging
ED628
700 Children's Drive
Columbus, OH 43205
PH 614:722-2530 or
John.Kovalchin@nationwidechildrens.org

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Opportunity for Adult Congenital Heart Disease Cardiologist

The Heart Center at Nationwide Children's Hospital (NCH, formerly Columbus Children's) and the Ohio State University Medical Center (OSUMC) is seeking a third adult congenital heart disease (ACHD) specialist at the assistant or associate professor level to join our active established program. Candidates with pediatric and/or adult cardiology training who demonstrate proficiency in the medical management of the ACHD patient will be considered. Candidates would be expected to provide consultation to in-patient services at both NCH and the OSUMC campuses as well as to conduct regular ACHD clinics. The ability to perform independent and collaborative laboratory or clinical research in this field is expected. Our ACHD program includes two dually trained & board certified pediatric and adult cardiology physicians, ACHD nurse practitioners, nurse clinicians, research nurse and dedicated technical staff. Additionally, we have an accredited ACHD five-year fellowship program currently with three fellows in training. Our program actively manages nearly 2000 ACHD patients and has an emerging transitional ACHD program. State of the art imaging, interventional catheterization & surgery, electrophysiology, intensive care, CHF and heart, heart-lung and lung transplant programs are integrated with the ACHD program.

Candidates may submit their curriculum vitae to:

Curt Daniels, MD,
Nationwide Children's Hospital
700 Children's Drive
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or via e-mail to
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Initial Experience with the Cardia Intrasept™ Device for Percutaneous Occlusion of the Patent Foramen Ovale

By Jean Marcelo F. da Silva, MD; Simone F. Pedra, MD; and Carlos A.C. Pedra, MD

INTRODUCTION

Percutaneous occlusion of the patent foramen ovale (PFO) has become a frequently employed therapeutic option for prevention of recurrent cerebrovascular events and improvement in the severity and/or frequency of migraine symptoms [1-8]. Longitudinal and case-control studies in which a variety of devices have been used have shown the safety and efficacy of this therapeutic modality [1-8]. The Intrasept™ is the latest generation of Cardia devices (Cardia, Inc., Burnsville, MN, USA) designed for PFO closure. The previous generation devices have been used with good clinical results [9]. The purpose of this study was to report the initial experience with the Intrasept for percutaneous PFO closure.

METHODS

Patient Selection

Inclusion/exclusion criteria: Patients with (1) one or more previous cryptogenic cerebral vascular accident (CVA) and/or (2) recurrent migraine attacks with aura despite aggressive medical treatment conducted by a neurologist (3) associated with transesophageal echocardiographic (TEE) evidence of a PFO with right-to-left (R-L) shunt were included in this study. The diagnosis of R-L shunt was also made by Transcranial Doppler (TCD) in some patients. The magnitude of R-L shunting, either by TEE and/or TCD, was assessed using previous reported protocols [10,11]. A high risk PFO was defined as one with a higher likelihood for recurrences with > 1 of the following characteristics: a > 4 mm hole; spontaneous R-L shunt; severe R-L shunt after Valsalva maneuver; association with an aneurysm (ASA) of the interatrial septum (IAS) and/or prominent Eustachian valve. Patients with other causes of stroke; with no femoral access or with active infectious diseases were excluded. Informed consent for the procedure was obtained from patients.

Characteristics of the Device

The PFO-star was the first generation of the Cardia devices developed to close PFOs [12]. It has undergone several modi-

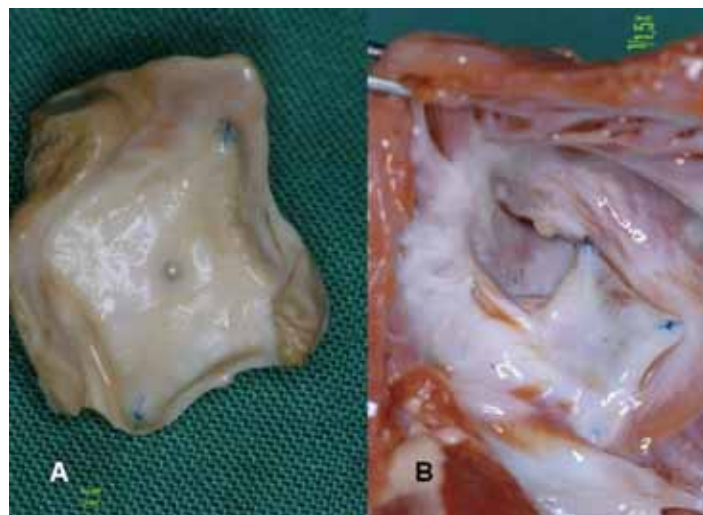


Figure 1. PFO-star appearance 137 days after percutaneous implantation in lamb hearts. (A): Right atrial view after explantation. (B): Left atrial view.

fications since its introduction in 1998, resulting in the Intrasept, which is the 4th generation of this device. Experimental studies with the PFO-star showed satisfactory endothelialization of both discs 4 months after implantation [12] (Figure 1). The Intrasept is a low profile double-umbrella type of device with two polyvinyl-alcohol (Ivalon) sails connected in its central portion by a 3 mm bi-articulated center post made of titanium, which is encircled by an Ivalon ring (Figure 2). The Ivalon sails are mounted on a Nitinol frame with six arms on each side, with each arm made of a 19 stranded Nitinol wire. The Ivalon on the left side sail is attached on the outside of the frame in order to eliminate exposure of metallic material in the left atrium (Figure 1A). The bi-articulated central post allows for some independent movement of each sail resulting in some disc asymmetry if needed, which is important for optimal apposition and better conformation to different anatomies of the IAS (Figure 2 B and C). The device is delivered through a tranvenous sheath by means of pushing a modified biopsy forceps. The jaws of the forceps are connected to a rounded pin on the right disc and secured with a reliable locking mechanism (Figure 3 A and B). The sails open with a spring back mechanism. The device is fully retrievable before and after deployment of the 2 discs and repositionable. The length of each Nitinol arm



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corresponds to the size of the device. They are available in 20, 25, 30 and 35 mm sizes (Figure 2A). The devices are delivered through a 12 Fr (for 20, 25, and 30 mm devices) or a 13 Fr (for 35 mm devices) long sheaths positioned in the left atrium. Prior to delivery, the Intrasept should be loaded in a short 12 or 13 Fr sheath with the aid of a plastic loader.

Technique of Implantation

On the day before the procedure, patients were started on aspirin (100 mg) and clopidogrel (loading dose: 300 mg). The procedures were performed under endotracheal general anesthesia and TEE monitoring. After establishment of right venous femoral access, heparin sulfate (5,000 IU) and cefazolin were given. Standard right heart catheterization was carried out and an angiogram was obtained in a hepatoclavicular view using a 7 Fr NIH catheter positioned within the PFO (Figure 4A). Stretched diameter of the PFO was not determined for the sake of device selection. In this study, the 30

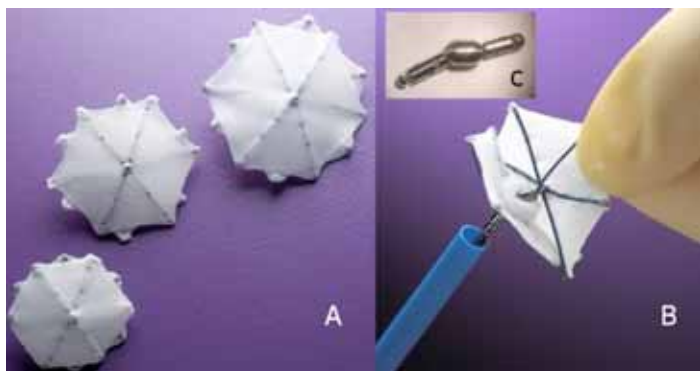


Figure 2. The Cardia Intrasept device. (A): Three of the four available sizes are displayed from the left atrial perspective. (B): Independent movements of each sail are allowed by the biarticulated central post, which is covered by foam. (C): Zoom of the biarticulated central post.

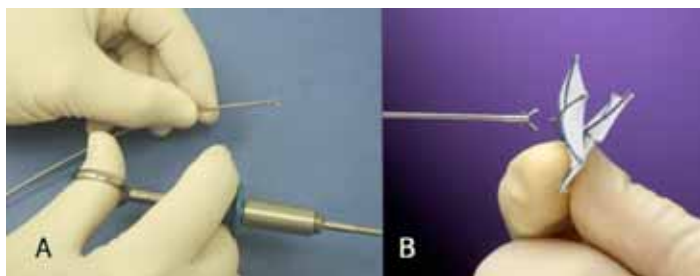


Figure 3. (A): Biopptome forceps. (B): Connection with the device.

CHICAGO - Rush University Medical Center

The Department of Pediatrics in conjunction with the Center for Congenital and Structural Heart Disease at Rush University Medical Center, located in downtown Chicago, is seeking to recruit mid-senior level candidates for the following positions:

Electrophysiology: We are seeking a cardiologist with fellowship training in pediatric and congenital/structural electrophysiology. The candidate should have expertise in invasive and non-invasive electrophysiology and skills and expertise in diagnosis and management of complex arrhythmias.

Director of Echocardiography for the Center: We are seeking board certified physician candidates with experience in advanced echocardiography. Additional experience in other non-invasive imaging modalities would be advantageous to the candidate's application.

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Pediatric Cardiologist: Board eligible/certified in pediatric cardiology with interest in outpatient and inpatient aspects of their field, including attending satellite clinics in the Chicago metro area. For this position recent fellowship graduates are encouraged to apply.

These recruitments are part of a key strategic growth initiative in a multidisciplinary advanced congenital/structural cardiology program with state of the art mechanical support and clinical trials. Experience in clinical research is desirable. Candidates should be eligible for faculty appointment at the Associate Professor or Professor level. Rush is home to one of the first medical colleges in the Midwest and one of the nation's top-ranked nursing colleges, as well as graduate programs in allied health, health systems management and biomedical research. Rush is an Equal Opportunity Employer.

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The Division of Pediatric Cardiology seeks interested faculty candidates for:

Pediatric Electrophysiology – responsibilities would include directing and developing the Pediatric Electrophysiology Program at UHMC / Rainbow Babies and Children's Hospital. This person would be expected to foster and develop an invasive EP program in the northeast Ohio region. Clinical and academic collaboration with two busy affiliated adult EP divisions is available and encouraged.

Non-invasive Cardiology / ECHO Lab Director – cardiologist with imaging interest and expertise to help develop comprehensive imaging services to include fetal, MRI, TEE, 3-D, and regional telemedicine program. Would join three other full time non-invasive cardiologists in providing clinical services at Rainbow Babies and affiliated institutions.

Critical Care Cardiology / Director – responsibilities will include establishing, developing, and directing cardiovascular critical care services in collaboration with the Divisions of Cardiothoracic Surgery / Cardiology and Pediatric Intensive Care.

The Pediatric Cardiovascular Program at UHMC/ Rainbow's is provides full-service congenital cardiovascular care to the Northeast Ohio region, and currently consists of 6 full time cardiologists, 2 cardiothoracic surgeons, 3 certified NPs, 2 full-time investigators and comprehensive subspecialty and fellowship programs. We are academically affiliated with Case Western Reserve University, and interest in clinical and/or basic research is encouraged. Rainbow Babies and Children's Hospital is consistently ranked among the top children's hospitals nationally.

Interested applicants should forward cover letter and CV to:

Ernest S. Siwik, MD

Interim Director, Pediatric Cardiology

RBC 380C – 11100 Euclid Avenue, Cleveland, OH 44106

ernest.siwik@uhhospitals.org

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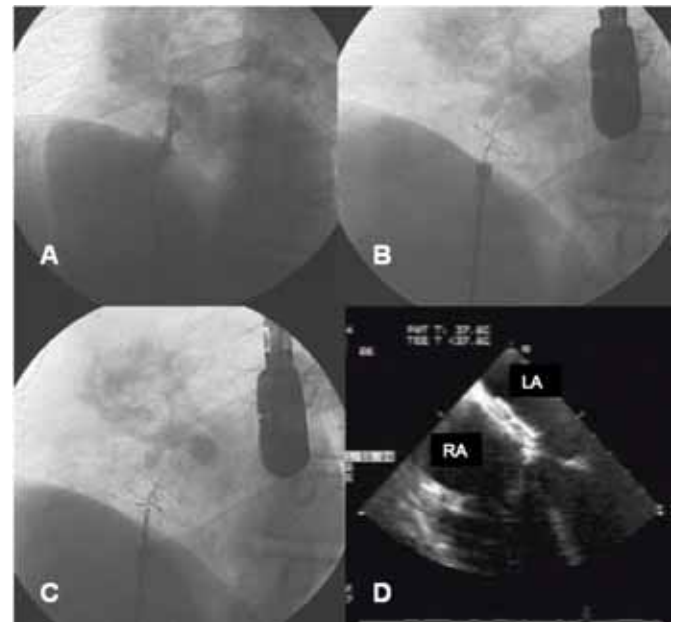


Figure 4. Technique of implantation. (A): Initial angiogram within the PFO in hepatoclavicular view showing the classic tunnel like defect. (B): Still fluoroscopy frame showing the left atrial disc deployed in the left atrium and apposed against the interatrial septum (C): Still fluoroscopy frame showing the deployment of the right disc, which is still attached to the forceps (D): Transesophageal echocardiogram in 4 chamber view showing excellent position and the low profile of the device. PFO: patent foramen ovale; LA: left atrium; RA: right atrium.

mm devices were used for PFOs associated with ASA and the 25 mm devices were used for PFOs without ASA. The PFO was crossed with an end hole catheter (multipurpose or right coronary Judkins) and a long 12 Fr Mullins (Cook) sheath was positioned in the mouth of the left upper pulmonary vein after catheter/wires exchanges. The technique of implantation of the Cardia device has been described previously [12]. In short, the loaded device was transferred to the long sheath by pushing the bioprote. The right disc was delivered in the left atrium by retracting the sheath and pushing the bioprote. The whole system (sheath + bioprote) was brought back as a unit towards the IAS until some resistance was felt by the operator (Figure 4B). At this point the left disc displayed some concave configuration on fluoroscopy in hepatoclavicular view. TEE confirmed a good position on the the IAS. While some gentle tension was applied to the bioprote, the long sheath was retracted to deliver the right disc (Figure 4C). Device release was carried out after satisfactory device position was confirmed by TEE using multiple views. (Figure 4D). Hemostasis was achieved



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The appointment will be non-tenure-accruing. This position will remain open until an appropriate candidate is selected.

Applicants should send a letter of application, a C.V., and three letters of recommendation referencing LP#00017673 to:

Barry J. Byrne, M.D., Ph.D.
The Congenital Heart Center
University of Florida
College of Medicine
P.O. Box 100296
Gainesville, FL 32610-0296

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Faculty Member for the Congenital Heart Center at the University of Florida

The Congenital Heart Center at the University of Florida is recruiting a Board Certified Pediatric Cardiologist with fourth year interventional catheterization training for faculty position of Pediatric Interventional Cardiologist. This position will assist with coordinating all aspects of pediatric interventional cardiac catheterization services and provide general pediatric cardiology care. This role includes teaching of residents, fellows, medical students and other health care professionals and participation in a strong clinical research program and excellent clinical practice.

The appointment will be at the non-tenure accruing level of Clinical Assistant/Associate Professor based upon experience. This position will remain open until an appropriate candidate is selected.

Applicants should send letter of application, C.V., and three letters of recommendation referencing LP# 00023005 to:

Randal M. Bryant, M.D.
Search Committee Chair
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Faculty Member for the Congenital Heart Center at the University of Florida

The Congenital Heart Center at the University of Florida is recruiting a Board Certified Pediatric Cardiologist for the faculty position of Director, Non-invasive Imaging. This position will lead a cohesive unit for advancing research and clinical care in congenital heart disease imaging through coordination of echocardiography, MRI and CT angiography. The position will also provide general pediatric cardiology services and includes teaching residents, fellows, medical students and other health care professionals.

The appointment will be at the non-tenure or tenure accruing level of Associate Professor or Professor based upon experience. This position will remain open until an appropriate candidate is selected.

Applicants should send letter of application, C.V., and three letters of recommendation referencing LP# 00023002 to:

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by manual compression of the groin. Patients were awakened in the catheterization laboratory and transferred to the recovery room for routine monitoring. They were discharged home the following day on aspirin (100 mg/day) for a year and clopidogrel (75 mg/day) for a month. Endocarditis prophylaxis was recommended for 6 months.

Follow-up

Patients returned for clinical and transthoracic (TTE) assessment after 1, 3, 6 and 12 months, and yearly thereafter. A TCD and/or a TTE was performed at the 6 month visit to determine the presence of R-L shunt.

Safety and Efficacy

Safety was assessed by the prevalence and severity of periprocedural and/or follow-up complications. Major complications were defined as those that resulted in surgery (embolization without percutaneous retrieval; perforation/erosion; device thrombosis), death or neurological sequelae. Local vascular complications and non sustained arrhythmias were considered minor complications. Efficacy was defined by the absence of R-L shunt by TEE and/or TCD and absence of recurrent events.

Statistical Analysis

Values were expressed as frequencies and percentages, and mean and standard deviation or median and ranges where applicable.

RESULTS

Population

From March 2006 to September 2007, 17 patients (10 female) underwent the procedure at a median age of 30 years (15 – 64) and with a mean weight of 69 ± 12 kgs. Fifteen patients had previous episodes of CVAs with or without sequelae and 4 patients had migraines with aura, with 2 having it as the sole indication for PFO closure. Three patients had ASA and none had a tunnel longer than 10 mm. Six patients had high risk PFOs as defined above.

Immediate results

The 25 mm device was employed in 14 patients and the 30 mm device in the 3 patients with ASA. Adequate implantation was achieved in all patients without any complications. The median procedure time was 60 minutes (50-120) and all patients were discharged the following day with good device position on TTE.

Follow-up Results

Clinical follow-up time was a mean of 7 ± 4 months (median 7 months). Twelve had more than 6 months of follow-up with all having complete closure without R-L shunting on TCD and/or TEE. None of the patients had recurrences of the CVAs during the short follow up period. Three of the 4 patients with migraine had significant improvement in the frequency and severity of the episodes (subjective evaluation). One patient had a femoral vein aneurysm that was managed clinically by manual compression at the 3 month follow-up visit.

DISCUSSION

Percutaneous occlusion of the PFO has been employed as a safe and effective method to prevent recurrences of cryptogenic CVAs and to improve the frequency and severity of migraine symptoms [1-8]. However, no randomized, multicenter, prospective study with large number of patients comparing the clinical and percutaneous approaches for secondary prophylaxis of recurrent cryptogenic CVAs has been published yet. In the observational longitudinal studies, it seems that the percutaneous approach is at least as effective as the clinical management and probably more effective in those patients with more than one previous CVA episode and in those in whom complete closure is achieved [13]. It also seems reasonable to offer the percutaneous procedure to those patients who had recurrences on medical treatment. We believe that the indication for closure must be customized and stratified taking into account several aspects such as the functional and anatomical characteristics of the PFO, which can increase the likelihood of recurrences, contra-indications for medical treatment, adherence to the use of antiplatelets/anticoagulation agents, option of the patient and institutional experience with the percutaneous procedure.

Although there has been no data in regards to comparison of results among the different devices available for the interventionalist, a recent study showed satisfactory outcomes after PFO closure with the previous generations of the Intrasept device [9]. The new Intrasept® has some general advantageous characteristics such as ease of handling (“user friendly”), full capability for retrieval and repositioning, low profile, limited amount of metal exposed in the left atrium and good conformity to different septal anatomies. However, it needs large profile sheaths for implantation, which probably resulted in a femoral vein aneurysm in this early experience. In addition, it has been suggested that the prevalence of thrombus may be higher in double-umbrella type of devices 9, such as the Intrasept. In this regard, thrombus formation has not been observed as yet within the Intrasept (Eustaquio Onorato, personal communication), probably due to the location of the metallic arms, hidden under the Ivalon fabric. Even so, an optimized regimen with aspirin + clopidogrel should be recommended as part of the antiplatelet protocol for the first month after implantation.

Although in this small study there was no need to retrieve a fully deployed device, recapturing the right disc into the sheath is generally not possible if the device is straddling the IAS. This is due to the way the right disc opens up with a spring back mechanism after the sheath is retracted. Pulling the bioprobe would exert forces to the right disc in the opposite direction it had been deployed, bringing the IAS with it. Therefore, in order to retrieve a fully deployed device, it is recommended that the whole device should be advanced towards the left atrium (with the right disc folding over itself and slipping through the PFO) prior to pulling the bioprobe to recapture the device. Further modifications on the opening mechanism of the right disc have been made by the manufacturer [14] to facilitate recapturing the device.

In this study with limited number of patients and length of follow up, we showed that percutaneous occlusion of the PFO with or without aneurysm using the Intrasept device was feasible, safe and effective. Schrader et al [9] had limited complications and a rate of complete closure of 89.2% in 403 pa-

tients who underwent PFO closure with the first three generations of the Cardia devices. In this same study, the recurrence rate of CVAs was 2% per year. In a recent study with 371 patients, the presence of a residual R-L shunt was the sole risk factor for recurrences (HR of 6.9; $p < 0.003$) [15]. In this regard, there was a high rate of elimination of R-L shunting at 6 month follow-up using TEE and/or TCD in this initial experience. Although our initial results are encouraging, more patients and longer follow up are obviously required to draw stronger conclusions.

CONCLUSIONS

The Intrasept® device seems to be an attractive alternative in the armamentarium of the interventionalist for percutaneous occlusion of the PFO.

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DISCLOSURE

Dr. Carlos AC Pedra is a consultant for Neomex Hospitalar LTDA (Cardia representative in Brazil) and a proctor for Cardia (USA) in Brazil.

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Medical News, Products and Information

FDA Approves GORE HELEX Septal Occluder for Treatment of Atrial Septal Defect

On October 3, 2007 W. L. Gore & Associates (Gore) announced that the US Food & Drug Administration (FDA) granted approval for the GORE HELEX Septal Occluder with modified catheter delivery system indicated for the transcatheter closure of atrial septal defect (ASD). An ASD is a congenital heart defect that affects thousands of patients every year. The GORE HELEX Septal Occluder is a permanently implanted prosthesis and the first device of its kind to use ePTFE, a biocompatible material that allows tissue ingrowth, to seal the defect. The recently approved catheter-based delivery system allows for easier device deployment via standard femoral venous access, bringing the GORE HELEX Septal Occluder to the forefront of non-surgical ASD repair.

An ASD is an abnormal hole in the wall between the upper chambers of the heart, which allows blood to improperly flow from the left side of the heart to the right, forcing the right side of the heart and lungs to overexert to compensate for the problem. Left untreated, an ASD can cause the heart to enlarge, or weaken, leaving the patient at risk for serious conditions like atrial fibrillation, pulmonary hypertension, heart failure or stroke. The defect is most often treated in pediatric patients.

"In treating such a delicate area of the heart, particularly in small children, interventional cardiologists need to be confident that treatment will be effective for the long term," said Dr. Alexander Javois, The Heart Institute for Children, Advocate Hope Children's Hospital, Oak Lawn, Illinois. "Percutaneous ASD closure is successful in the very young patient using the GORE HELEX Septal Occluder. Its design and conformity allows tissue to incorporate the device easily so that it becomes part of the heart's anatomy, sealing the ASD successfully and improving, even normalizing, the patient's heart function without open heart surgery."

The GORE HELEX Septal Occluder is composed of ePTFE patch material supported by a single Nitinol wire frame that bridges and eventually occludes the septal defect to stop the shunting of blood between the atria. Over the course of several weeks to months, cells begin to infiltrate and grow over the ePTFE membrane, resulting in successful closure of the defect.

Products listed may not be available in all markets pending regulatory clearance. GORE and HELEX are trademarks of W. L. Gore & Associates. For more information:
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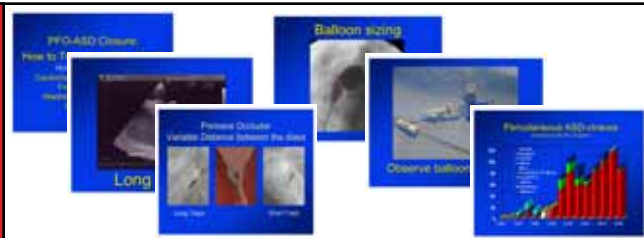
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The Division of Pediatric Cardiology at the University of Utah School of Medicine and Primary Children's Medical Center is recruiting 3 Pediatric Cardiologists with expertise in the following areas to join a 20-member division. All candidates should have a strong clinical background in all areas of pediatric cardiology, must be BE/BC in pediatric cardiology, and eligible for licensure in the State of Utah.

Noninvasive Imaging: The candidate should have expertise in echocardiography (TTE and TEE). The candidate should also have expertise in fetal echo and/or cardiac MRI.

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The successful candidates will receive faculty appointments at the University of Utah. These positions may be at the rank of Instructor through Associate Professor. For all positions, there will be protected time for clinical research with mentoring available within the Division. The Division has a very active clinical research program and is one of the participating centers in the Pediatric Heart Network funded by the NIH.

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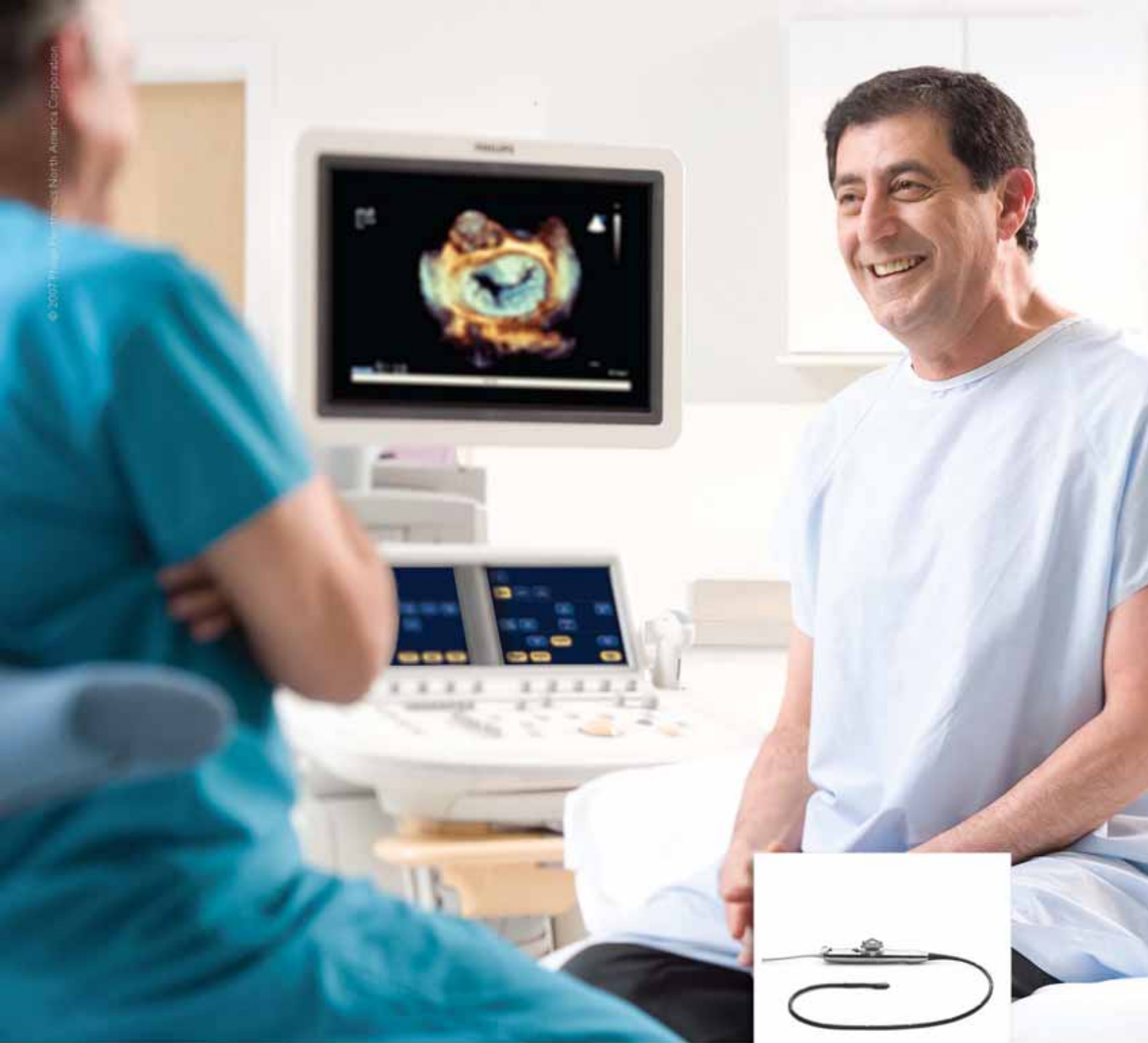
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