

CONGENITAL CARDIOLOGY TODAY

News and Information for Pediatric and Congenital Cardiovascular Physicians and Surgeons

Volume 5 / Issue 11
November 2007
International Edition

Focus on the PFO

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

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CONGENITAL CARDIOLOGY TODAY

Editorial and Subscription Offices
16 Cove Rd, Ste. 200
Westerly, RI 02891 USA

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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 con-

vinced 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

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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 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

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.

“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.”

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

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“PFO-ASD Closure
How to Treat and with What”
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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), Interatrial echocardiography (ICE), and power M-mode Transcranial Doppler (TCD) monitoring are all

“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.

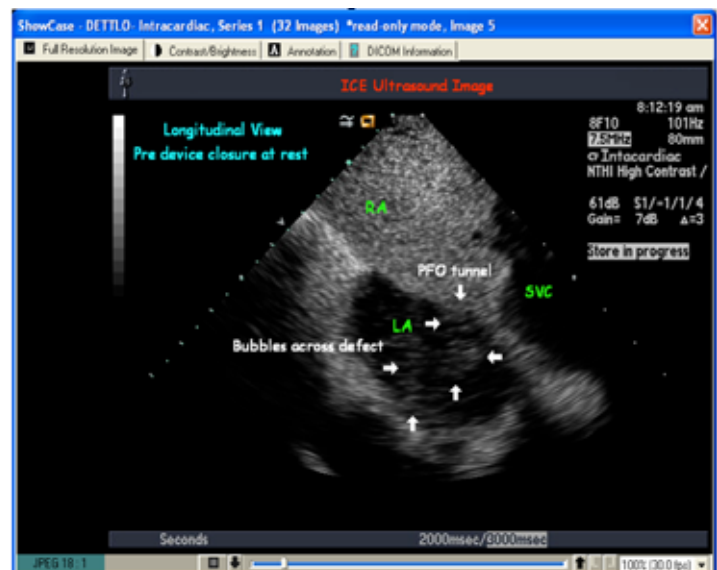


Figure 2. ICE injection at rest showing R-L shunt



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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 implantation this process is done on every catheterization patient repeatedly until there is a

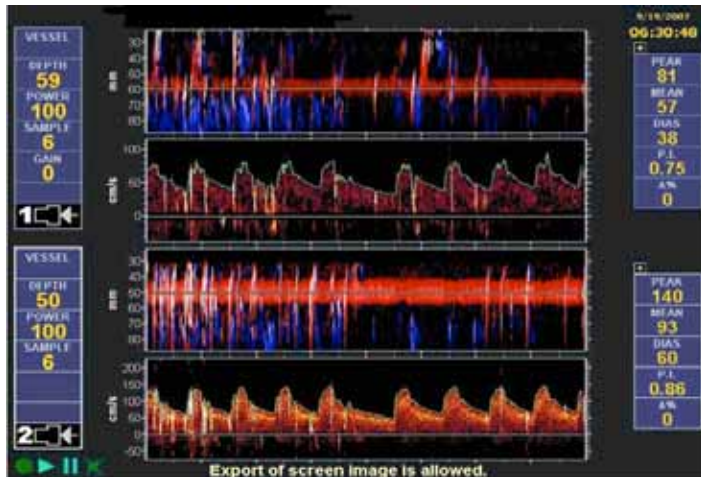


Figure 3. TCD showing multiple hits at rest.



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

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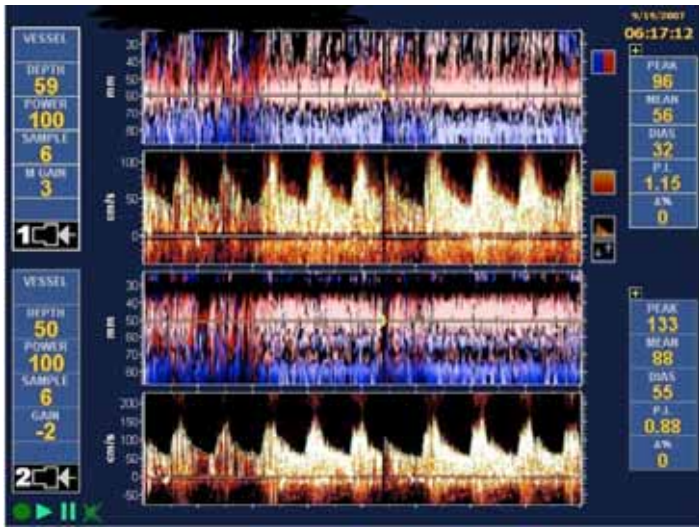


Figure 5. TCD pre-device image showing significant amount of hits when the Valsalva technique is used.

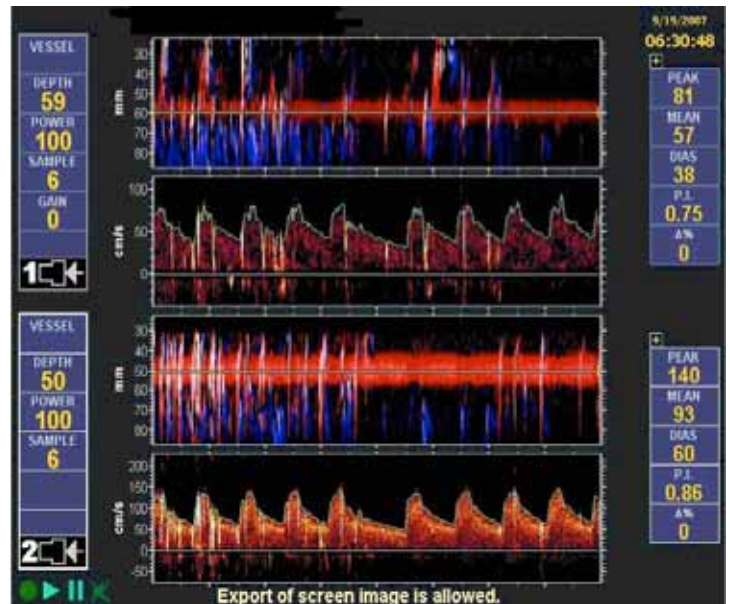


Figure 7. TCD immediately post device closure using the Valsalva Technique confirming shunting is still present.



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

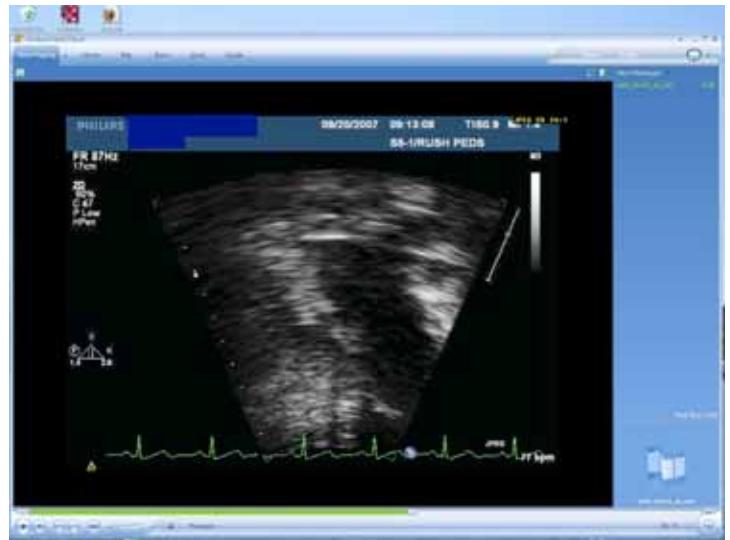




Figure 8. 24-hour post closure TTE showing no bubbles across device.

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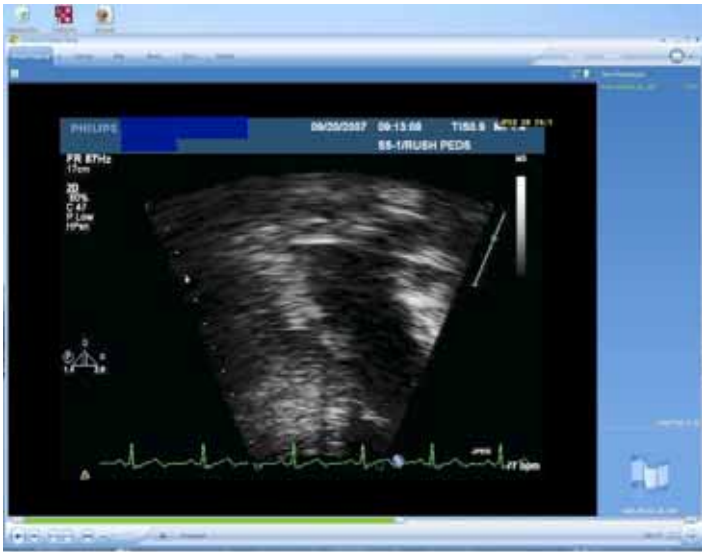


Figure 9. Injection image using the Valsalva technique, taken 24-hours post-device implantation, showing no bubbles across septum and complete closure.

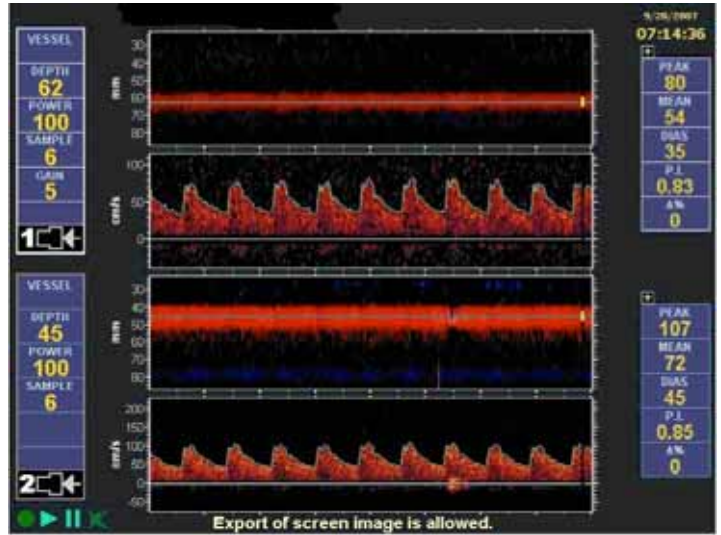


Figure 11. Post device 24-hour f/uTCD with the Valsalva technique showing no shunt detected and confirming completed closure of defect.

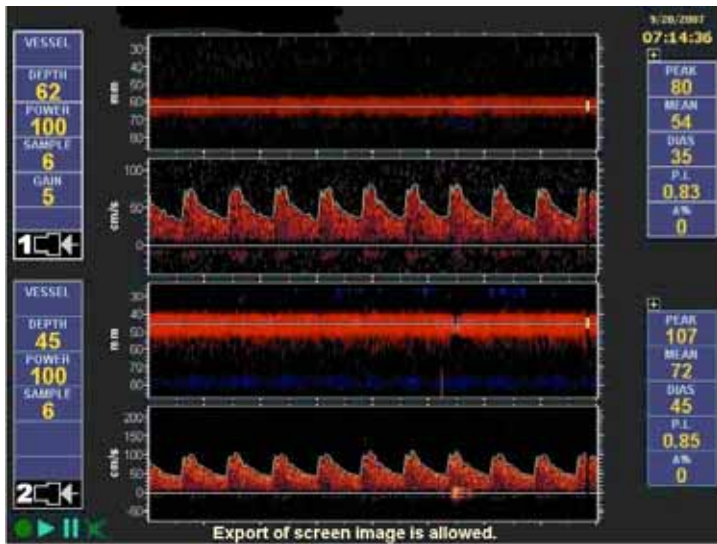


Figure 10. Post device 24-hour f/u TCD at rest showing no hits and confirming complete closure of defect.

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 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

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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.

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 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.

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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 supraaortal 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 exami-



Figure 1. 90° long axis view.

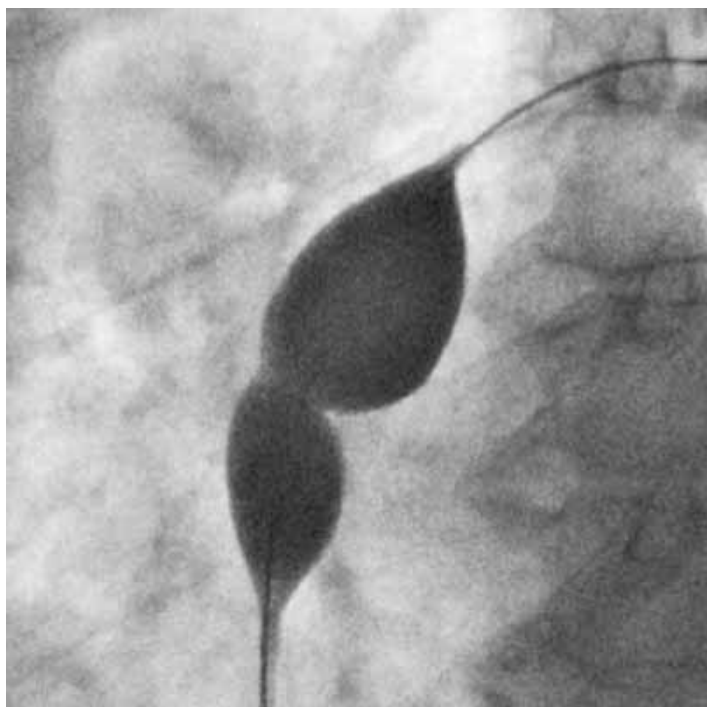


Figure 2. Balloon sizing.

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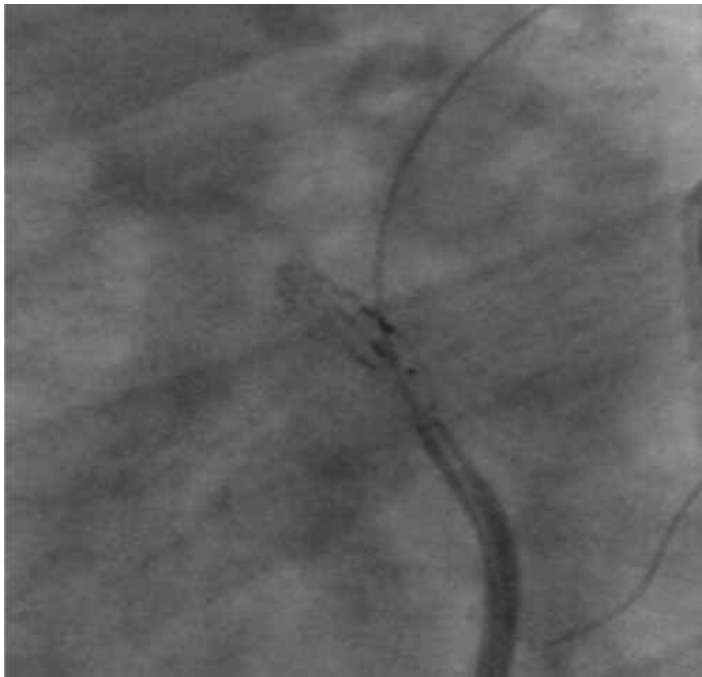


Figure 3. Fluoro of the PFX™ Closure System.



Figure 4. Applying energy by the PFX™ Closure System.

nation which detected a right to left shunt. To determine the exact type of right-to-left shunt a transesophageal echocardiography (TEE) 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 PFX™ 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 PFX™ 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 "PFX™ 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 suf-

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Figure 5. Post-closure contrast injection.

ferred paradox embolism/cryptogenic stroke, who wish to avoid a lifelong medical therapy. Procedure duration is less than an hour and can be performed as an ambulant treatment. Clinical data 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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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 modifications 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

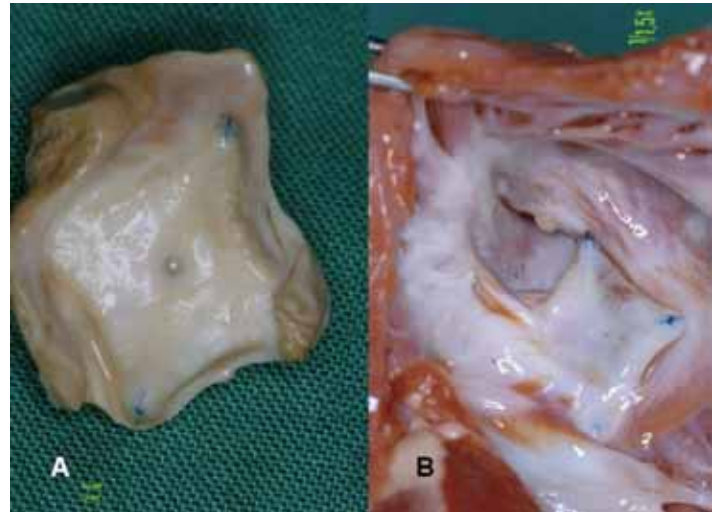


Figure 1. PFO-star appearance 137 days after percutaneous implantation in lamb hearts. (A): Right atrial view after explantation. (B): Left atrial view.

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 transvenous 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 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 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 bioptome. The right disc was delivered in the left atrium by retracting the sheath and pushing the bioptome. The whole system (sheath + bioptome) 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 bioptome, 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 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 peri-procedural 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

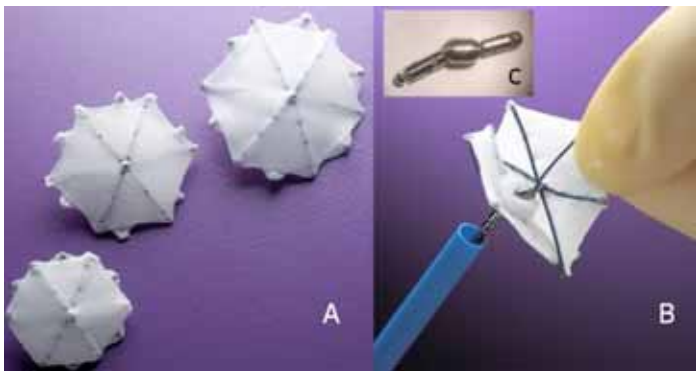


Figure 2. The Cardia Intrasept device. (A): Three of the four available sizes are displayed from the left atrial perspective. (B): Independent movements of each sail are allowed by the biarticulated central post, which is covered by foam. (C): Zoom of the biarticulated central post.

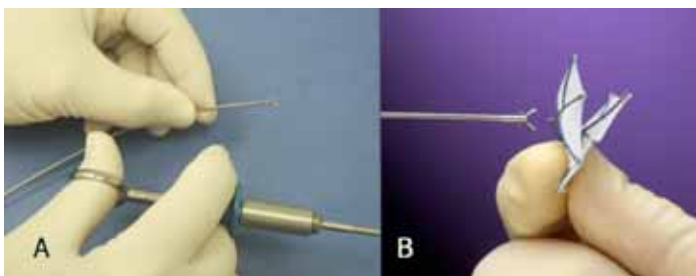


Figure 3. (A): Bioptome forceps. (B): Connection with the device.



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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.

“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.”

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

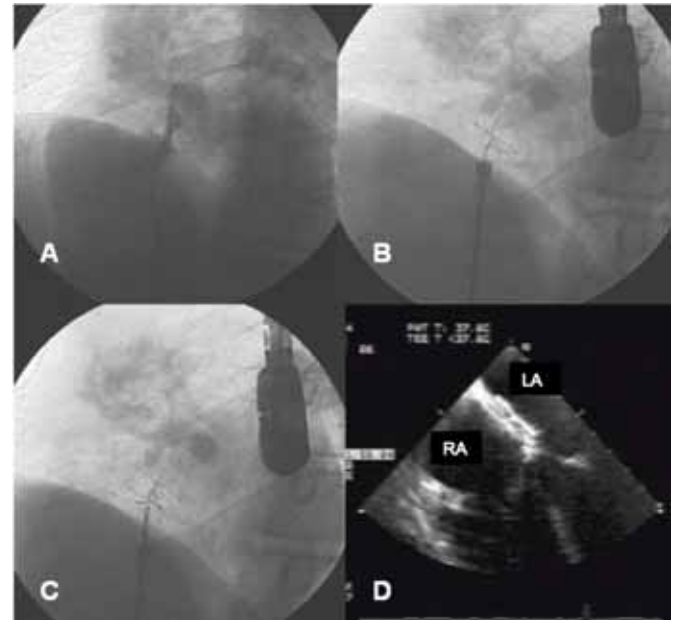



Figure 4. Technique of implantation. (A): Initial angiogram within the PFO in hepatoclavicular view showing the classic tunnel like defect. (B): Still fluoroscopy frame showing the left atrial disc deployed in the left atrium and apposed against the interatrial septum (C): Still fluoroscopy frame showing 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.

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 biopptome would exert forces to the right disc in the opposite direction it



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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 bioptome 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 patients 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.

ACKNOWLEDGMENTS

We would like to thank Dr. Eustaquio Onorato for his technical assistance during the first 2 cases in this experience. We are also grateful to Mr. Pete Buonomo and Mr. Fabio Sabbione from Cardia (USA) and to Neomex Hospitalar LTDA (Brazil) for the continuous support.

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.

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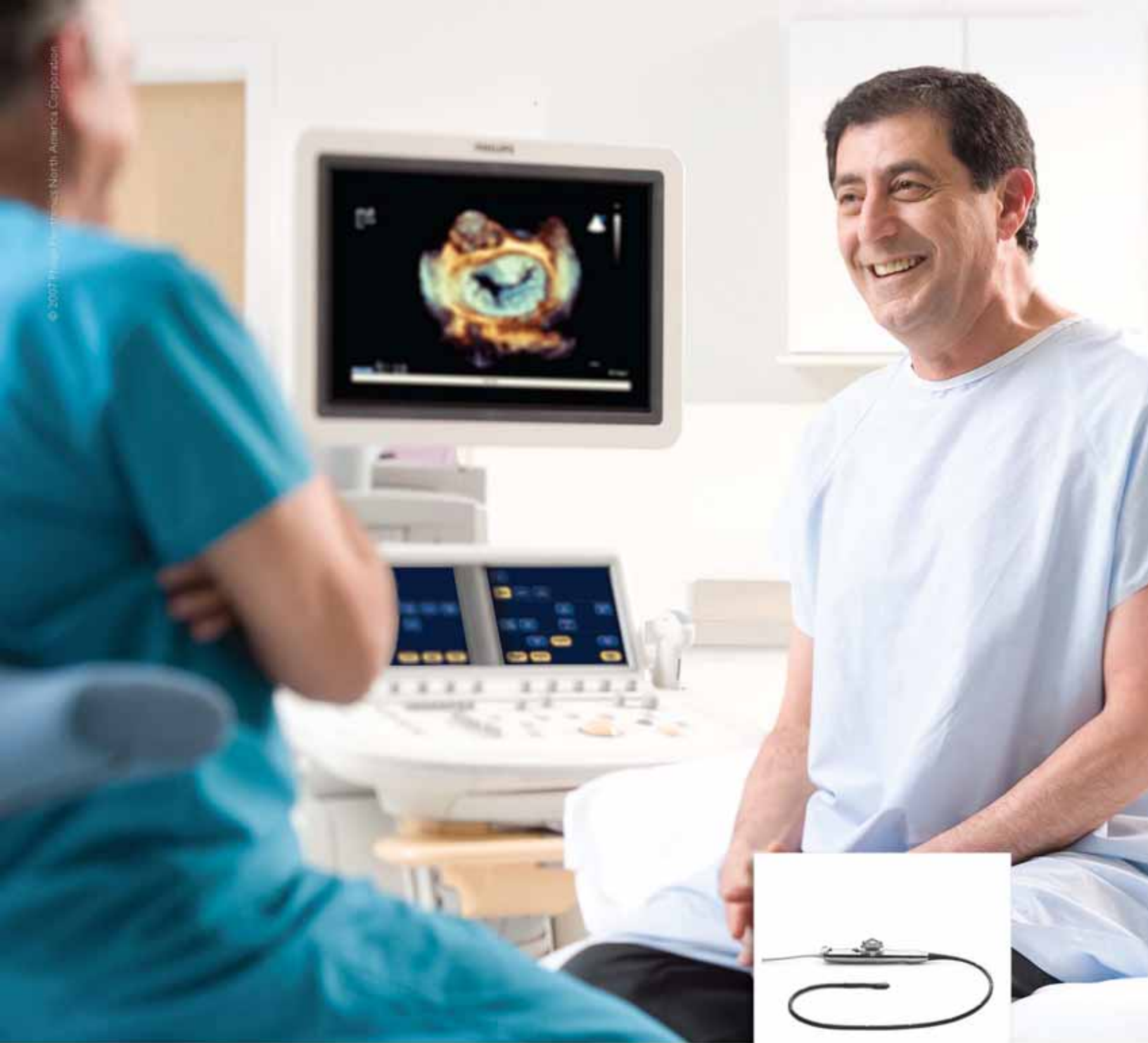
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