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Focus on the PFO in 2008

By John W. Moore, MD

With respect to Patent Foramen Oval (PFO), the state of our knowledge and practice in 2008 is not significantly different than it was one year ago.

There is no doubt that many ischemic strokes are caused by paradoxical embolism. However, the big questions remain about whether most or all of the 40% of acute ischemic strokes with no clearly defined etiology can be attributed to this mechanism, and whether interventional closure of PFO is preferable to medical therapy for prevention of such strokes. These questions continue to be controversial, but probably less so than a year ago.

This issue of *Congenital Cardiology Today* once again focuses on the PFO (Patent Foramen Ovale). Dramatic advances in device technologies not only have made it possible to close PFO's with little morbidity and essentially no mortality, but also have provided an array of devices available for PFO closures.

Clearly, there is data pointing to the role of the PFO in cryptogenic stroke including the meta-analysis of case-control studies finding 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]. There is also data suggesting that PFO closure by a device is superior to medical treatment in preventing recurrent strokes, such as the pooled analysis of 46 retrospective studies describing almost five thousand patients

showing 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]. These and similar retrospective data, however, have not reached the standard of "evidence based" medicine.

Fortunately, prospective randomized controlled trials of PFO closure versus drug therapy for reducing the risk of recurrent stroke and TIA continue to progress. These studies promise to provide high quality data, and are powered sufficiently to set the standard of care. The CLOSURE I Trial of NMT Medical's STARFlex device has already completed enrollment. Whereas, the AGA Medical's trial of the Amplatzer PFO device (RESPECT) continues to enroll patients, and its enrollment status is closely held by the company. Gore Medical has also received US FDA approval for a study of the HELIX device dubbed the REDUCE Clinical Study. This study will be unique because the FDA will allow participation of sites outside the United States.

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. Current operators in the United States have the opportunity to enroll patients in one of the prospective studies or to perform PFO closure "off label," using a number of available devices. Outside the US, a larger number of devices are available and already approved for this indication.

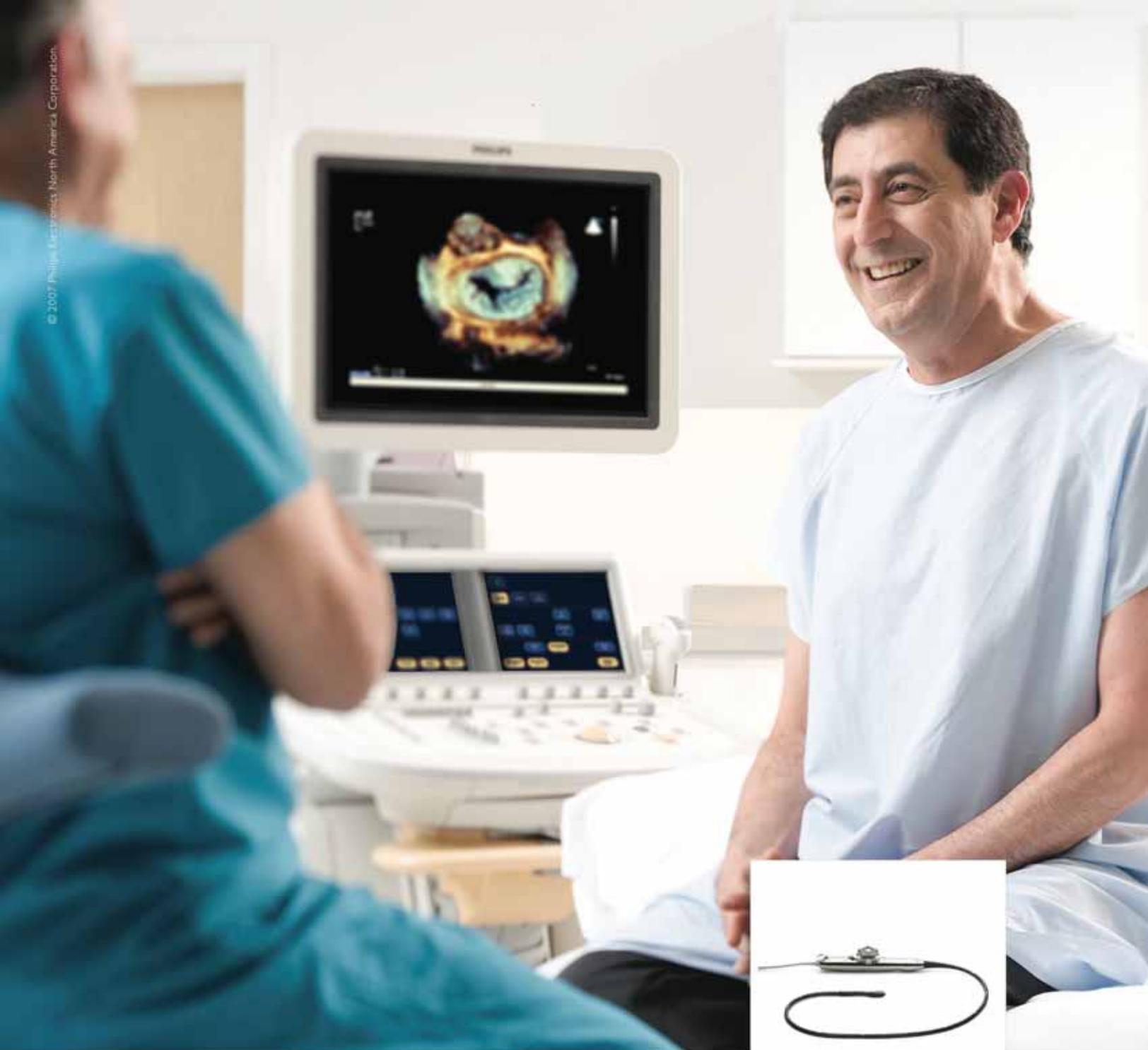
In addition to its role in the pathogenesis of cryptogenic stroke, the PFO has a role in the



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pathogenesis of migraine headache. Prospective studies of the Amplatzer device in migraine patients are underway in the United States (Premium Trial) and in Canada and Europe (Prima Trial). NMT also has sponsored studies of the STARFlex device (MIST trial). These studies promise to provide improved data which may eventually guide clinical practice.

Finally, patients with deep-sea divers decompression sickness or the syndrome of Platypnea-Orthodeoxia are often noted to have PFO. These applications for PFO closure technology will remain boutique indications, as the patient populations are too limited to allow well-designed studies.

In this Issue, *Congenital Cardiology Today* hopes to raise awareness of PFO-related pathologies, the role of interventional PFO closure in their treatments, and the technologies available to close the PFO.

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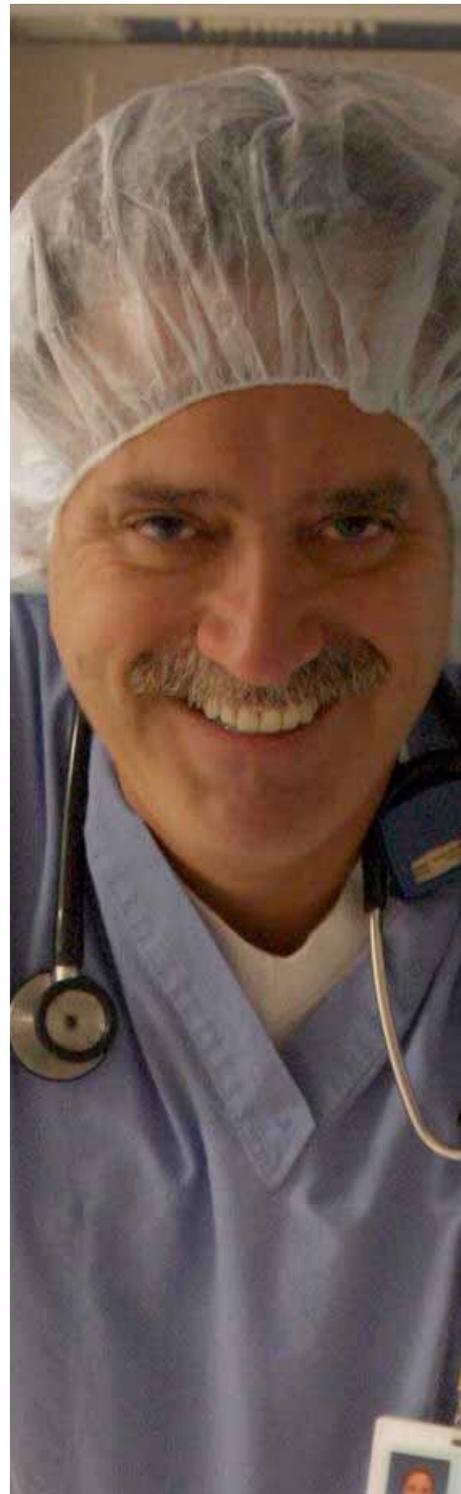
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Working Together to Develop a Better Tomorrow

Case Report: Patent Foramen Ovale and Atrial Septal Aneurysm

By Kristina Renkhoff, Nina Wunderlich, MD and Horst Sievert, MD

Introduction

A patent foramen ovale (PFO) is a persisting embryonic defect in the interatrial septum that is present in up to 27% of the general population [1]. Multiple studies have shown an association between PFO and cryptogenic stroke, chronic migraine and decompression sickness [2-6]. It may provide a pathway for paradoxical embolism, which is the passage of a clot or other embolic particle from the venous system to the arterial circulation through a right-to-left shunt [2]. However, PFO alone is not a predictor for stroke and may be found in the healthy population as well [7]. Therefore indication for closure is only given as secondary prevention, after a neurologic event has occurred. The American Heart Association (AHA) even suggests PFO closure only with recurrent neurological event despite medical therapy [1] a statement which is controversially discussed between professionals. Particularly in patients with cryptogenic stroke who are younger than 50 years, PFO is three times more common than in matched controls [8]. Therefore, although randomized trials are still ongoing many believe that if other stroke causes can be excluded, the PFO should be closed. The combination of a PFO and an atrial septal aneurysm is especially associated with a higher risk of stroke than PFO alone, as it may alter the flow through the PFO or serve as a nidus for thrombus formation [2]. An atrial septal aneurysm is defined as a hypermobile septum primum that bulges 10 mm or more into the left and/or into the right atrium depending on the phase of the cardiac cycle [2].

Transcatheter closure of PFO has become a safe standard procedure today, since side effects are minimal compared to surgery. A variety of occluders exist that can be implanted percutaneously [6,9]. Most of them have the shape of two discs attached in the middle to encompass the interatrial septum from both sides. The implantation is usually guided by fluoroscopy and transesophageal echocardiography, but also newer techniques like the intracardiac echocardiography are getting more popular. After venous access is obtained, a right heart catheterization is typically performed to measure the defect size: First, the defect is crossed using a curved catheter and semistiff wire, then a soft, pliable balloon is inserted and carefully inflated checking the pressure in the balloon (Figure 2). The device size is selected according to the "waist" in fluoroscopy or in echocardiography. Echocardiography is also used to image the interatrial septum and assess morphologic particularities. After choosing and inserting a device into the delivery catheter, it can be released under fluoroscopic and echocardiographic guidance - reinsuring optimal placement. The procedure usually takes less than 30 minutes, and the patient can be discharged the same day, or the day after with the same post-procedural limitations as after a diagnostic heart catheterization.

Case History

Our patient is a 47 year old female who has had a minor stroke without other known causes in January 2008. She was admitted to the neurological department with paraesthesia and analgesia of the left hand, blurred speech and walking insecurity. Symptoms lasted approximately 2 1/2 hours and disappeared sponta-

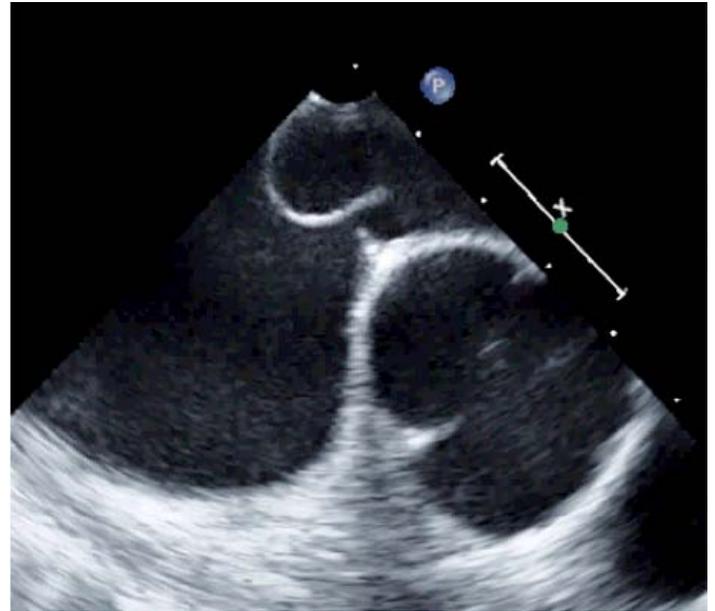


Figure 1. TEE short axis view of PFO and atrial septal aneurysm.

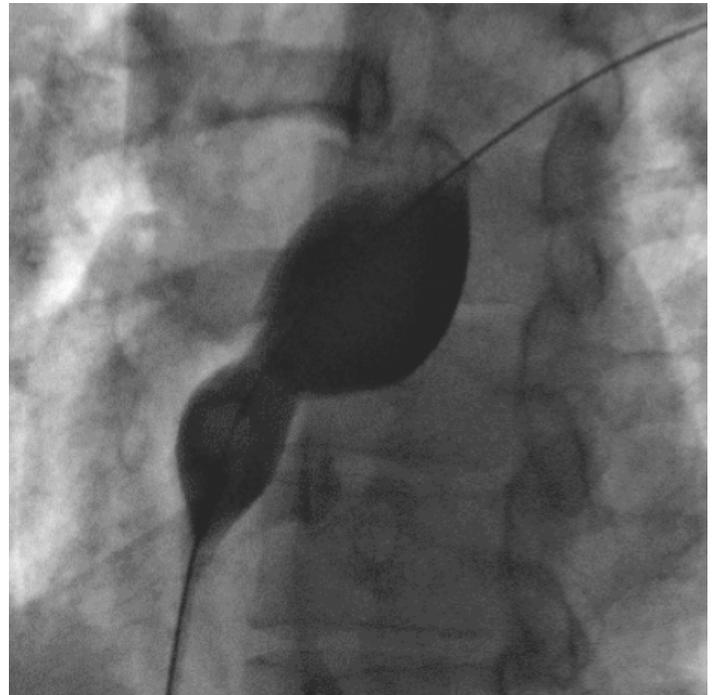


Figure 2. Balloon sizing.

neously. Her medical history displayed similar events in 2004 and 2005 associated with headache, and since then she has been treated for migraine. Cranial CT scan did not show any pathological findings correlating with the symptoms. An additional MRI revealed a partial stroke of the right middle cerebral artery with mainly parietal located spots. Following diagnostics

included a duplex scan of the carotid arteries, 24-hour ECG, transcranial Doppler examination (TCD) and transthoracic echocardiography (TTE) but were without pathological findings. Transesophageal echocardiography (TEE) revealed a PFO with an atrial septal aneurysm. All other cardiovascular risk factors could be excluded. Our patient was kept in the stroke unit for observation. Eight days after the initial event she was discharged without residual symptoms. She was informed about different treatment options and decided to have an interventional PFO closure in order to avoid lifelong anticoagulation therapy. To bridge the period until the intervention she started coumadin therapy with target INR 2-3 whilst in the hospital.

In February 2008 she had the first attempt in the referring center to have the PFO closed with a 25mm Amplatzer PFO occluder, but the device was unable to grasp the septum. Then a 30mm Amplatzer PFO occluder was introduced but could not be set in a stable position as well. Both devices could be retrieved without any complication. In March 2008 there was a third attempt to close the PFO with a 35mm Amplatzer PFO occluder which could encompass the septum, but due to the aortic root pressing the cranial part of the occluder discs apart, the blood flow to the right atrium from the vena cava superior was obstructed. So that occluder as well was retrieved without complication. In June 2008, the patient was referred to our center. Balloon sizing measured a PFO of 14mm diameter (Figure 2) and TEE confirmed the atrial septal aneurysm (Figure 1). After the difficulties encountered with the regular PFO occluders, we decided to choose a 16mm Amplatzer ASD occluder to close the PFO. Using fluoroscopic guidance, intracardiac echo (ICE) and TEE the correct position of the device could be confirmed (Figures 3, 4 and 5). The patient was prescribed Aspirin 100mg for 6 months and Clopidogrel 75mg for 3 months to prevent thrombus formation on the device, and also to bridge the period while residual shunt might still be present. She was discharged one day after the procedure. Follow-up investigation after 3 months showed that the device was in stable position, and that there was no thrombus formation and no residual shunt.

Device Information

Ever since PFO closure has been first reported in 1992, there has been a rapid development of different devices. A variety of different occluders and experimental methods are available today [6,9]. The Amplatzer® (AGA Medical, MN, USA) family of devices is used with worldwide experience, and includes the Amplatzer PFO and the Amplatzer septal occluder. While the septal occluder was originally designed to close secundum type atrial septal defects (ASDs), it is occasionally implanted in large PFOs [6]. The devices are very similar in terms of material and shape. They are both composed of a nitinol wire mesh that is shaped into two discs connected by a waist and polyester fabric inserts facilitating device endothelialization after placement. One major difference between them is that on the ASD occluder the left atrial disk is larger, whereas on the PFO occluder the right

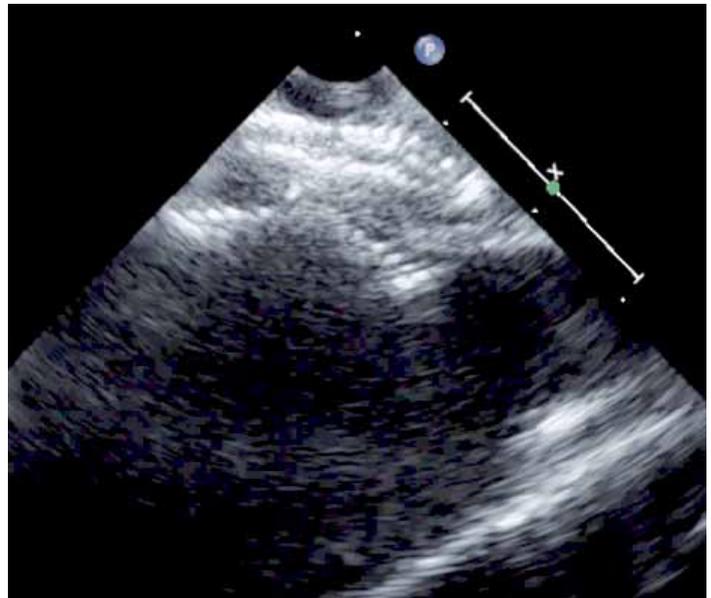


Figure 3. TEE long axis view after implantation.

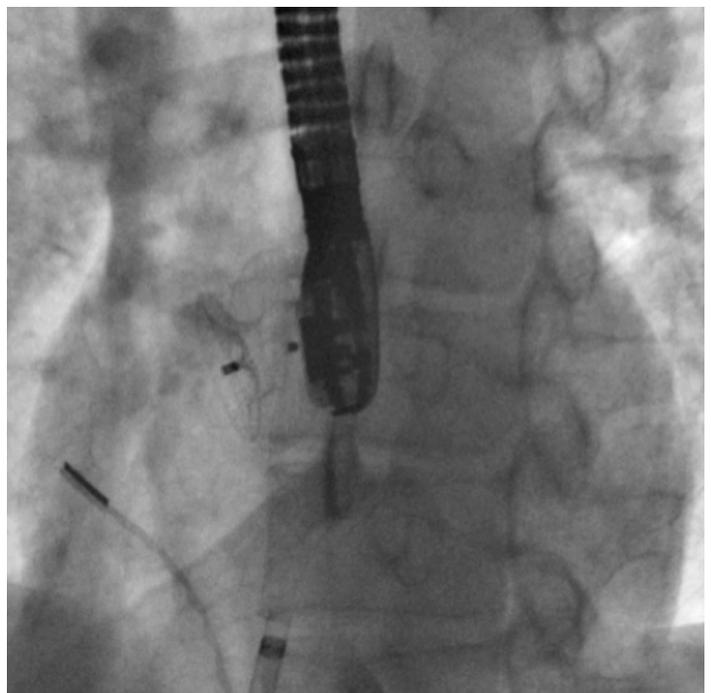


Figure 4. Device after release.


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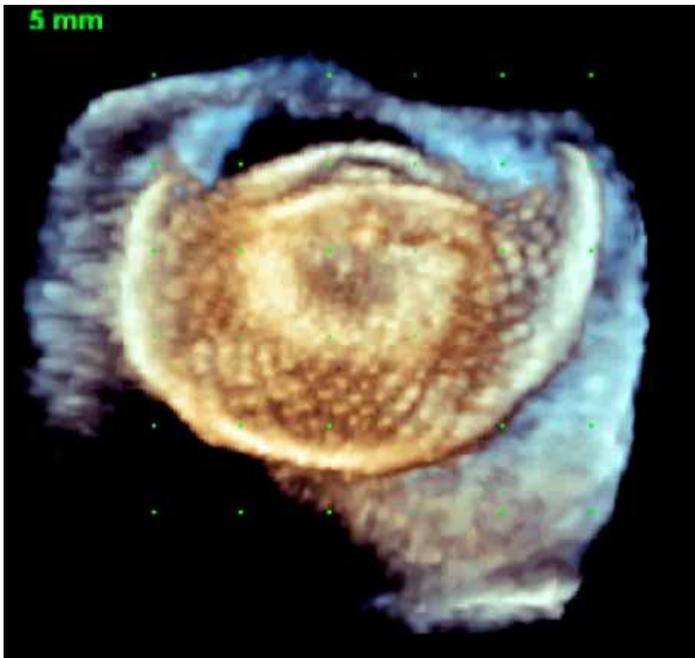


Figure 5. TEE 3D view of device.

atrial disk is larger (except on the 18mm device on which both disks are the same size). Another difference is that the diameter of the waist connecting the two disks varies in the ASD occluder by device size (up to 40 mm), whilst the PFO occluder has a 3 mm connecting waist in each of its available sizes. Both devices can be expanded and collapsed throughout the entire procedure, thus allowing for complete retrieval up to the point of final detachment from the delivery cable [6,9].

Device Selection

There is a variety of possible morphological differences in patent foramen ovale. Based on our own records the size measured in fluoroscopy may vary from 2mm to 26mm (mean 9.2 ± 3.5 mm). Also, the tunnel between septum primum and septum secundum may differ in length between 4 and 24 mm (mean 12.5 ± 3.6 mm). An atrial septal aneurysm is one of the particularities mentioned and is present in 2.2% of the general population [2]. It is important to select a device that suits the given anatomy best in order to ensure optimal placement and function. Good position of the device is given when it is stable and the septum is embraced at all parts. The occluder discs should be adapting to the septum. Also, it has to be ensured that none of the valves is impaired in its function.

Concerning the example of our case report, there have been three attempts to close the PFO with a PFO occluder. Sometimes,

“Transcatheter closure of PFO has become a safe standard procedure today, since side effects are minimal compared to surgery.”

if there is a large PFO (≥ 16 mm) or an atrial septal aneurysm, it is more secure to select an ASD occluder which has a larger left atrial disc and a larger connecting waist and thus, provides more stability.

Discussion

Transcatheter PFO closure is seen as an alternative to lifelong antiplatelet or anticoagulation therapy, especially in young patients who have suffered paradoxical embolism or cryptogenic stroke and do not bear other common cardiovascular risk factors. The procedure usually is technically easy and straight forward but occasionally more difficult as in the case described here. Clinical trials have shown transcatheter closure to be safe and effective, and systematic reviews and meta-analyses of these trials also suggest a benefit to percutaneous closure over medical antiplatelet or anticoagulation therapy in secondary prevention [10,11]. Randomized trials catheter closure versus medical therapy are ongoing.

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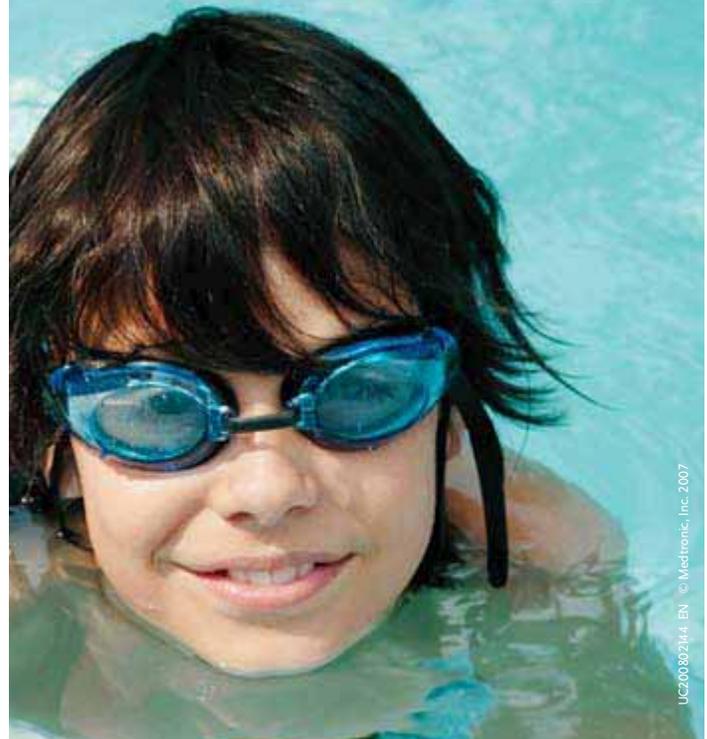


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Case Study: Closure of Patent Foramen Ovale in a Patient with Decompression Illness

By Alice A. Perlowski, MD and Jonathan M. Tobis, MD

Case Study

A 49 year old female recreational scuba diver surfaced from an hour long dive near Maui's Kihei Coast, and experienced the acute onset of severe pain in her left temple. The patient had performed two dives that morning: one to a depth of 88 feet, and a second to a depth of 60 feet. Approximately thirty minutes after the conclusion of her second dive, the patient experienced a headache, weakness in her left leg, low back pain, and a tightening sensation in her chest, abdomen and pelvis. The patient was taken urgently to a local hospital, where she was diagnosed with decompression illness (DCI).

The patient had a non-contrast head CT and laboratory testing which were unremarkable. The patient was administered 100% oxygen by nasal cannula and intravenous fluids. She was airlifted to the island of Oahu, where she was decompressed for over four hours in a hyperbaric oxygen chamber. The patient's symptoms resolved, with the exception of minor residual left sided head pain, which was similar to her typical migraine headaches.

“The patient had many risk factors for cryptogenic stroke, including her large right-to-left shunt and severe varicose veins. In addition, the patient desired to continue to scuba dive at substantial depths, which would have placed her at risk for repeat episodes of decompression illness.”

The patient returned to the mainland after two days in the hospital in Hawaii. As recommended by her primary physician, she underwent a transesophageal echocardiogram with intravenous injection of agitated saline. This study was significant because it showed a large patent foramen ovale (PFO) with significant right-to-left shunting (Figure 1). The patient was referred to our institution for consideration of percutaneous closure of her PFO.



Figure 1. Transesophageal echocardiogram with bubble study showing right-to-left shunting across large patent foramen ovale (arrow).

In addition to her decompression illness, the patient had a medical history significant for refractory migraine headaches with aura since the age of 15. These headaches occurred 1-2 days per week and lasted several days, often interfering with her ability to work as a freelance journalist. The patient had been on several combinations of rescue medications, including Imitrex and Zomig, in addition to nonsteroidal anti-inflammatory agents. The patient also had a history of severe varicose veins, requiring a stripping procedure of the left leg veins 2 years prior. The patient had never been diagnosed with a stroke or TIA. She did not use oral contraceptives, and had never been pregnant. She denied tobacco or alcohol use.

Physical examination was unremarkable, with the exception of varicose veins in both legs. Oxygen saturation was normal. Hypercoagulability work-up was unremarkable. Due to several risk factors for cryptogenic stroke, she had a brain MRI which was negative for evidence of white matter lesions or infarcts.

The patient had many risk factors for cryptogenic stroke, including her large right-to-left shunt and severe varicose veins. In addition, the patient desired to continue to scuba dive at substantial depths, which would have placed her at risk for repeat episodes of decompression illness. The patient was offered percutaneous closure of her PFO, with the understanding that this would be done off-label, since



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there is currently no FDA approval for this procedure for any indication. The patient was started on aspirin 81 milligrams per day, and elected to proceed with closure of her PFO.

During the procedure, the patient had a transcranial Doppler study which showed Grade 5/5 bubbles at rest with injection of agitated saline, indicating a significant right-to-left shunt. Intracardiac echo (ICE) performed during the procedure also showed significant spontaneous right-to-left shunting with injection of agitated saline. A standard 0.038 J wire and multipurpose catheter were used to cross the PFO, and the standard J was exchanged for an Amplatz Extra Stiff wire, which was placed in the left superior pulmonary vein. A 25 mm Helex (Gore) device was advanced over the wire and deployed in the interatrial septum under ICE and fluoroscopic guidance.

Final ICE and fluoroscopic images revealed that the Helex device was positioned appropriately on both sides of the interatrial septum (Figure 2). The left atrial disk lay flat on the left side of the interatrial septum, while the right atrial portion appeared slightly less compressed, due to the long dimension of the PFO tunnel. With injection of agitated saline in the right femoral vein, no bubbles were seen crossing from right to left atrium on intracardiac echo. Transcranial Doppler score decreased from a baseline of Grade 5 to Grade 3. The patient was discharged home after a four hour observation pe-

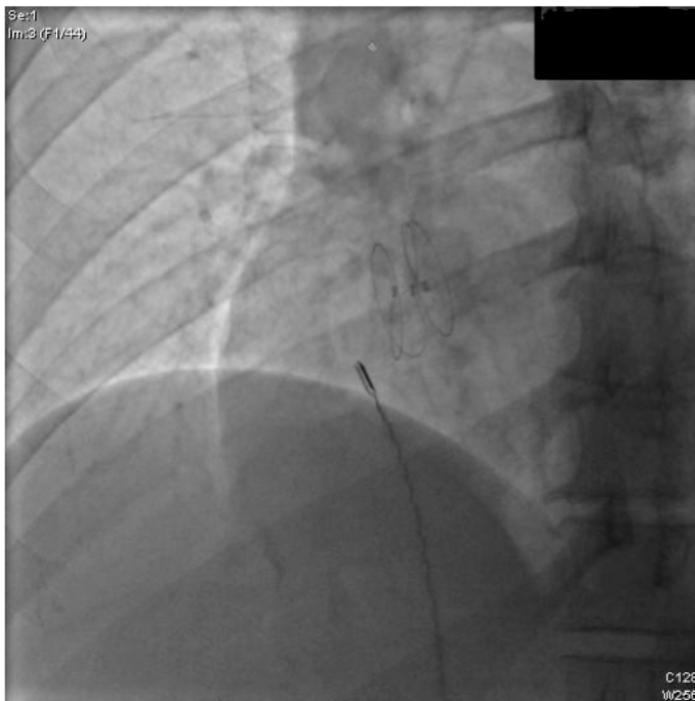


Figure 2. Fluoroscopic image of 25 mm Helex (Gore) device post-deployment. Intracardiac echo probe seen in the right atrium.

riod with prescriptions for daily aspirin 81 mg and Plavix 75 mg.

The patient's post-procedure course was relatively uneventful. Two days after the procedure, she experienced epigastric discomfort, which was thought to be related to stomach irritation due to the aspirin/Plavix combination and resolved with the addition of a proton pump inhibitor. She continued on dual antiplatelet therapy for one month. Repeat TEE was performed two months post closure, which revealed stable position of the Helex device with no evidence of residual right to left shunting on bubble study (Figures 3 a, b). The pa-

tient continues to experience migraines, although she considers them less frequent and severe compared to pre-closure. The patient has not yet returned to scuba diving, although is planning another dive in Hawaii in the near future.

Discussion

Decompression illness (DCI) occurs due to a reduction of barometric pressure as a diver surfaces, causing inert gases which are dissolved in tissues and body fluids to enter the circulation. Gas bubbles form in the venous circulation during nearly all dives, and are effectively filtered out by the lungs. If the amount of nitrogen gas overwhelms the filtering capacity of the lungs, or in the presence of an intracardiac right to left shunt, bubbles can enter the systemic circulation, causing embolization to the body's tissues.

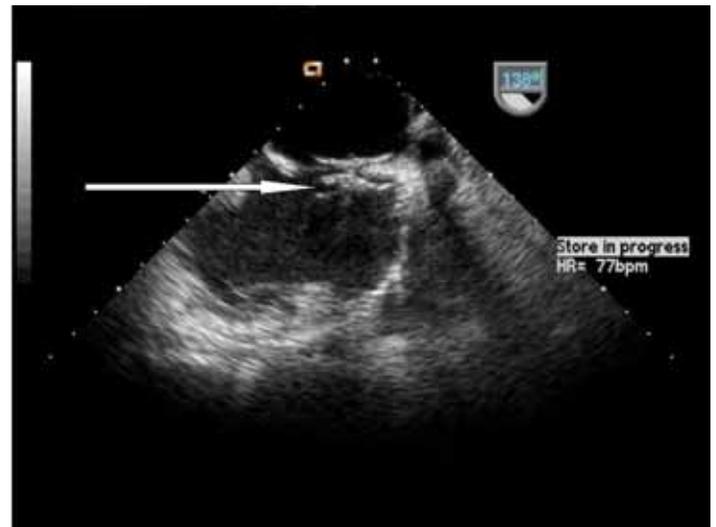


Figure 3a. Transesophageal echocardiogram performed two months post-closure shows Helex device in stable position in interatrial septum. Right atrial disk (arrow) slightly less compressed compared to left, due to length of PFO tunnel.



Figure 3b. Transesophageal bubble study performed two months post-closure shows bubbles in right atrium (arrow) do not cross into left atrium.

In minor (Type 1, musculocutaneous) cases of DCI, gas embolization results in symptoms such as joint pain (classic "bends"), fatigue, and pruritis. In more severe (Type 2, or neurological) cases of DCI, patients can experience numbness, tingling, paralysis or CNS collapse due to bubble embolization to the spinal cord and brain. In cases of arterial gas embolism, where larger gas bubbles enter the systemic circulation directly from ruptured alveoli, embolization to the coronary and cerebrovascular circulation can result in myocardial infarction, stroke, and death. The treatment in all cases of DCI is with intravenous fluid resuscitation and hyperbaric oxygen therapy.

According to DAN (Divers Alert Network) [1], a collection of retrospective studies have shown that in the general population the incidence of DCI is 2-4 cases per 10,000 dives [2], translating to approximately 1,000 cases per year. However, several studies have shown that the incidence of DCI is significantly higher in divers with a patent foramen ovale, by as much as 5 times [3-6].

The correlation between intracardiac shunting and decompression illness was first reported by Wilmshurst in a 1987 case report describing an arterial gas embolization occurring in a diver with an atrial septal defect [3]. Several subsequent reports have confirmed that divers with patent foramen ovale are at increased risk for decompression illness [4-5]. Torti et al. [5], in a population of 230 scuba divers, found that 27% had a PFO by TEE criteria. Twenty-nine percent of the 63 divers with PFO had experienced ≥ 1 major DCI event, as compared to 6% of the 167 divers without PFO ($p=0.016$). The presence of a PFO increased the relative risk of a DCI event 5 times.

The anatomy of the PFO and degree of right to left shunting is directly related to the risk of DCI. Cartoni et al. [6], demonstrated in a population of professional scuba divers, that the risk of DCI episodes correlated with the presence of a right to left shunt at rest and with higher mobility of the interatrial septum. It has also been demonstrated that the degree of right to left shunt on TEE bubble study is directly correlated with the risk of major DCI events. Divers with Grade 1 bubble studies by TEE appear to be at equivalent risk to those without a PFO, while in those divers with Grade 2 and 3 bubble studies, risk of DCI increases by 4.4 and 6.6 fold, respectively (95% CI) [5].

Of note, there appears to be a clear link between the occurrence of DCI and the presence of migraine with aura. In a study published in 2001 by Wilmshurst, et al. [7], 200 divers who presented with DCI were enrolled and studied retrospectively. All patients underwent transthoracic contrast echocardiography to evaluate presence and degree of interatrial shunt. Those with patent foramen ovale with a large right to left shunt had an increased prevalence of migraine with aura in daily life (47.5%) compared with 10% prevalence in those with smaller right to left shunt or those present only with Valsalva, or 13.8% with no shunt ($p<0.0001$). Post-dive migraines with aura were also more prevalent in those with large right to left shunts (26.3%) compared with those with smaller shunts, or no shunt (12.5%, 1.3%,

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respectively, $p < 0.0001$). These findings were replicated by the same group with an additional 200 divers in 2005 [8].

The observation by Wilmshurst and his colleagues that a clear association exists between decompression illness, migraine with aura, and patent foramen ovale with right to left shunting generated a new hypothesis for the pathophysiology of migraine headaches. In those patients with PFO with right to left shunting presenting with decompression illness, inert gas bubbles in the venous system normally filtered by the lungs pass across the PFO into the systemic circulation, causing symptoms of DCI. Similarly, in patients with PFO with right to left shunting, vasoactive chemicals and/or microemboli normally filtered by the lungs, may pass into the systemic circulation and subsequently, the brain, triggering migraine headaches in susceptible individuals.

The appropriate management of divers with a patent foramen ovale remains a controversial issue. According to the Divers Alert Network website [1], "At present, most diving physicians agree that the risk of problems associated with a patent foramen ovale are not significant enough to warrant widespread screening." The rationale of this group of dive experts is that despite 1/4 of the population having a PFO, DCI remains a relatively rare occurrence. Therefore, the recommendation by DAN is that those divers with a diagnosed PFO should consider a more modest dive profile: avoid deep diving, repetitive dives in a single day, and avoid the Valsalva maneuver on ascent. In addition, due to the rarity of DCI and potential for procedural complications, DAN does not advocate percutaneous or surgical closure of PFOs in divers for the prevention of DCI.

In Europe, closure devices are widely available and approved for the closure of ASD and PFO, and are routinely used in cases of DCI. Emerging from these groups are several small studies and case series that have demonstrated benefit of percutaneous closure of PFO in scuba divers presenting with decompression illness. Walsh, et al. [9] described a series of 7 professional scuba divers who presented with DCI, who underwent closure of their PFOs with an Amplatzer Septal Occluder. In these patients, who were followed for 3-12 months, "successful implantation allowed them to continue their livelihood." Although these case reports are promising, there are no large randomized controlled trials that have been performed in this population.

It is our hypothesis that patients may benefit from percutaneous closure of their PFO if there is a documented history of severe decompression illness, and the patient wishes to continue to dive. Our recommendation to perform closure is strengthened if the patient also has risk factors for forming venous thrombosis or stroke (hypercoagulability, varicose veins, migraine, or abnormal MRI). We estimate that the risk of developing a stroke in a person with a PFO is approximately 1 per 1000 per year. We recommend that women who have a PFO should not take birth control pills, and prescribe aspirin 81 mg/day for our patients who have a PFO, especially if they are taking a long car or plane trip.

In the United States, there are no FDA-approved indications for PFO closure, even in cases of cryptogenic stroke. Therefore, the use of a closure device for the prevention of repeat cryptogenic stroke, migraine headaches, or DCI is performed as an "off-label" procedure and only after informing the patient of this fact. Several randomized clinical trials are underway which are studying percutaneous closure of PFO to prevent cryptogenic stroke or severe migraine headaches. To our knowledge, there are currently no prospective randomized controlled trials of PFO closure for DCI.

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Pictured above are: Jonathan Tobis, MD and his son, Matt.

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Patent Foramen Ovale In Children - Is There A Need For Follow-up?

By Juan Villafañe, MD,

Introduction

A Patent Foramen Ovale (PFO) is an essential communication of the fetal circulation and some types of congenital heart defects (CHD).

A PFO is an interatrial communication formed by three components:

1. A thick "septum secundum" with its base anchored to the superior and medial aspect of the right atrium,
2. A thin and mobile flap (or foramen valve) named "septum primum" which is anchored at the crux of the heart and to the left of the "septum secundum," and in most patients,
3. A tunnel-shaped interatrial communication (IAC) formed by the overlapping of the "septum secundum" and foramen valve.

Lack of complete fusion between the two septa results in a PFO. Over 75% of neonates and approximately 25-35% of normal adult hearts have a PFO [1, 2, 3]. About 44% of adults with a history of cryptogenic

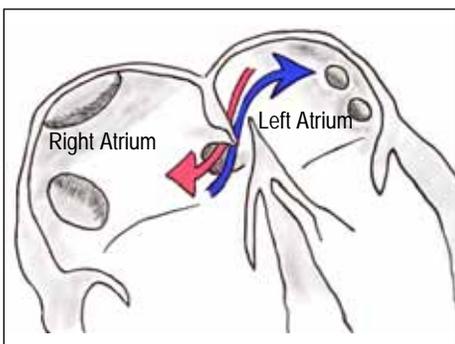


Figure 1. Incompetent patent foramen ovale. Overlapping of the septum secundum (right atrial side) and septum primum (left atrial septum) makes it possible for atrial shunting.

stroke are found to have a PFO. In these cases, the foramen valve is incompetent, and potentially could permit intermittent right-to-left atrial shunting (see Figure 1).

A PFO has been associated with: migraine headaches, paradoxical emboli, cryptogenic stroke, transient ischemic attacks, myocardial infarction, high-altitude pulmonary hypertension or edema, orthodeoxia platypnea syndrome and decompression sickness in scuba divers [4]. On the other hand, premature closure of PFO may be detrimental in patients with d-Transposition of the Great Arteries, Hypoplastic Left Heart Syndrome, Pulmonary Vein stenosis and pulmonary vascular obstructive disease.

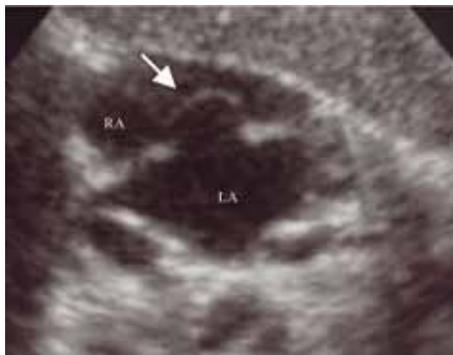


Figure 2. Subcostal two-chamber view demonstrating an atrial septal aneurysm bowing into the right atrium (see arrow).

A PFO may be associated with an atrial septal aneurysm (ASA) which is characterized by a mobile and redundant septum (see Figure 2). An ASA found in a neonate or young child tends to regress or disappear, while others may persist, in association with an IAC [2, 5]. In children most ASA are a benign finding. Atrial septal aneurysms have been related to: atrial arrhythmias, systolic clicks, atrial ventricular valve prolapse, Atrial Septal Defect (ASD), PFO or systemic and pulmonary embolism.

An ASA of the entire atrial septum is a very rare finding and has been observed with complex CHD [6]. Some experts recommend long-term follow-up in cases of ASA, even without evidence of an IAC. Several echocardiogram findings have been identified as potential risks for paradoxical emboli and stroke, besides ASA with IAC. These findings include an IAC diameter greater than 4 mm (in adults), spontaneous right to left atrial shunting, severe left-to-right shunting during Valsalva and a prominent Eustachian valve (see Figure 3). To date, there still exists controversy about which PFOs need closure [4, 7]. A much more common dilemma faced by pediatric cardiologists on a daily basis is if there is a need for follow-up echocardiogram evaluations in children with PFO. In addition, the distinction between a PFO and ASD may be hard to make by echocardiography.

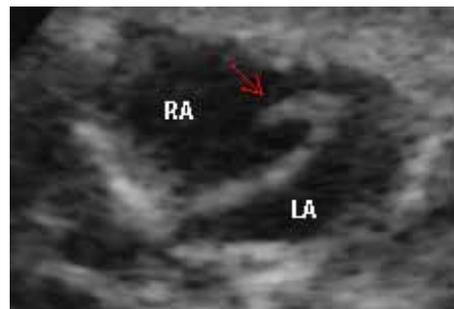


Figure 3. Subcostal 2-chamber view showing part of the Eustachian valve (see arrow).

PediHeartNet Survey on Follow-up for Patent Foramen Ovale

In the month of September 2008, a survey was taken via PediHeartNet to find out the out-patient management of children with PFO (Table 2 at the end of this article). Out of 68 responses, we found that 40% of physicians do not schedule any follow-up for children with an isolated PFO. Only 6%

1 out of 125 babies born this year will have a congenital heart defect...



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Table 1: Typical Characteristics of Atrial Septal Defect and Patent Foramen Ovale		
	Atrial Septal Defect	Patent Foramen Ovale
Sex	Mostly female	Females=males
Size	Small defect to Common Atrium	Small, usually less than 3-4 mm in children
RV Size	May be enlarged	Normal
Morphology	Circular or oval-shaped	Tunnel-like opening
Auscultation	Fixed splitting of S2 and pulmonary flow murmur	No fixed splitting or murmur
Electrocardiogram	RHV-RVE, RAD, RAE, IRBBB	Normal
X-ray	Cardiomegaly, prominent pulmonary artery segment, increased pulmonary vascular markings	Normal
M-mode Echocardiogram	Paradoxical Septal Motion	Normal Septal motion
2D Echo	T sign or "matchhead" sign	Foramen flap, overlapping septa. Defect usually not visible.
	Normal left atrial size	Prominent left atrium.
Spectral Doppler	Continuous wave pattern	Intermittent wave pattern and higher velocities.
Color Doppler	Jet(s) perpendicular to septa. Color signal may transverse the right atrium toward the free wall	Jet orientation may consist of an oblique flow toward the tricuspid valve. Higher velocity and narrow jet.

of respondents would follow all patients with any type of PFO. About half of the respondents would follow the patient if unclear about the IAC being a PFO or a small ASD. The most chosen follow-up interval was one to two years.

Of the group of "follow-up" responders, about two-thirds of them would re-evaluate patients with a prominent right heart (or RV hypertension/chronic lung disease), associated ASA, atypical atrial shunting, or if the PFO was larger than 3 (to 7) mm in diameter. A few cardiologists mentioned a follow-up in reference to a "moderate-size" PFO becoming larger with time. Almost half of the "follow-up" re-

sponders stated that they wanted to confirm closure of the PFO as one of the reasons for follow-up. A smaller percentage of these responders stated that parent's choice played a role in the decision making (parental anxiety, previous sibling with SIDS or CHD). The patient's age played only a minor role in the decision making.

Over 80% of all physicians would inform the family about the presence of a PFO. Almost two-thirds of responders would take out time to address any need for follow-up and potential risks such as deep-sea scuba diving and the association of PFO and stroke, especially in older patients. Some of the cardiologists ex-

pressed their concern about PFO being labeled as a pre-existing condition.

Patent Foramen Ovale or Atrial Septal Defect? (Table 1)

Since the advent of color-Doppler echocardiography, it is not uncommon to detect an atrial shunt, especially in infants (Figure 4). The recent survey included a section about which echocardiogram findings may be useful differentiating between PFO and ASD. Almost 80% of responders consider the size of the IAC as most important, followed by right heart dimensions. Less than one-third of the responders mentioned, in order of frequency, multiple color-Doppler jets, color-Doppler pattern, direction of jet, spectral-Doppler wave (continuous or intermittent), shunt location, T-sign, visible foramen valve or overlapping septa.

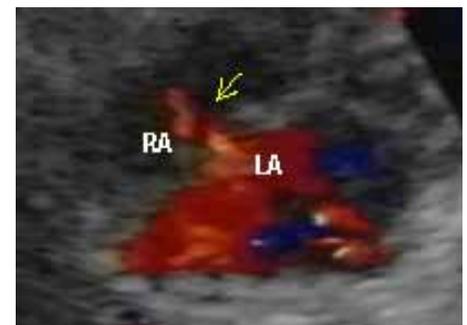


Figure 4. Color-Doppler mapping of the interatrial septum showing a small left to right shunt at the fossa ovalis (see arrow).

Discussion

A PFO in an infant is considered a "normal variant" by many cardiologists. Children with an isolated PFO have an excellent prognosis. In adults, PFO is usually an incidental finding in about one-fourth of this population. A Patent Foramen Ovale in adolescents and adults has been associated by some with cryptogenic stroke. There are many confounding factors present in the adult population including an epidemic of atrial fibrillation, hypertension and thrombogenic states such as: preg-



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Table 2. Survey PEDIHEARTNET.COM on Patent Foramen Ovale, September 2008:

- Do you schedule follow-up visits for patients with an isolated PFO?
 No Yes, ALL Yes, depending on:
 PLS REPLY BELOW IF YOU ANSWERED "depending"
 On the SIZE, if LARGER than ____ mm
 Prominent Right HEART
 On pt's AGE, if OLDER than ____ years
 UNCLEAR if it is a PFO or a small ASD
 +FAMILY Hx of Stroke or Hypercoagulopathy
 + SEPTAL ANEURYSM
 Bidirectional shunt or R-L shunt
 + Microcavitations R-L shunt
 Our PRACTICE POLICY is to follow ALL PFO
 Parent's CHOICE (previous sibling SIDS, had a "Hole," CHD, etc.)
- If you answered YES:
 How often do you follow them? Every ____ yrs.
 What is the reasoning?
 See above Reasons
 Want to confirm closure
 Other reasons: _____
- If you find a PFO in an infant, do you tell the parents?
 Yes No
 In an older kid, do you tell? Yes No
 Do you address any need for Follow-up? Yes No
 Do you give them the option for Follow-up? Yes No
- What helpful techniques do you use in trying to differentiate between PFO and small ASD?
 None
 Size
 Direction of JET
 PWDoppler with intermittent or continuous shunt signal
 Fenestration or more than one jet
 Right Heart Dimensions
 Color Doppler pattern
 Other, state: _____
- Any other comments about PFO that you would like to share? _____

nancy, obesity, diabetes, gene mutations, Leiden factor, protein C and S deficiency. In spite of the benign course of an isolated PFO in infants and children, there still exists controversy as to the need for follow-up. Radzik et al [8] suggested that infants with an IAC of less than 3 mm in diameter need not be followed as all of these defects will be closed by age 18 months of age. Patients with a defect of 3 mm or more should be re-evaluated by 15 months of age. An IAC with a diameter of 8 mm or more may have little chance of closing spontaneously.

The recent PediHeartNet survey showed that 40% of responders would not schedule any type of follow-up for patients with an isolated PFO no matter what the size. About half of the responders stated that they would follow the patient if unclear about the IAC being a PFO or small ASD.

About two-thirds of this group would follow those children with a PFO larger than 3 (to 7) mm in diameter, prominent right heart or ASA. The jury is still out.

Biography

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Acknowledgements

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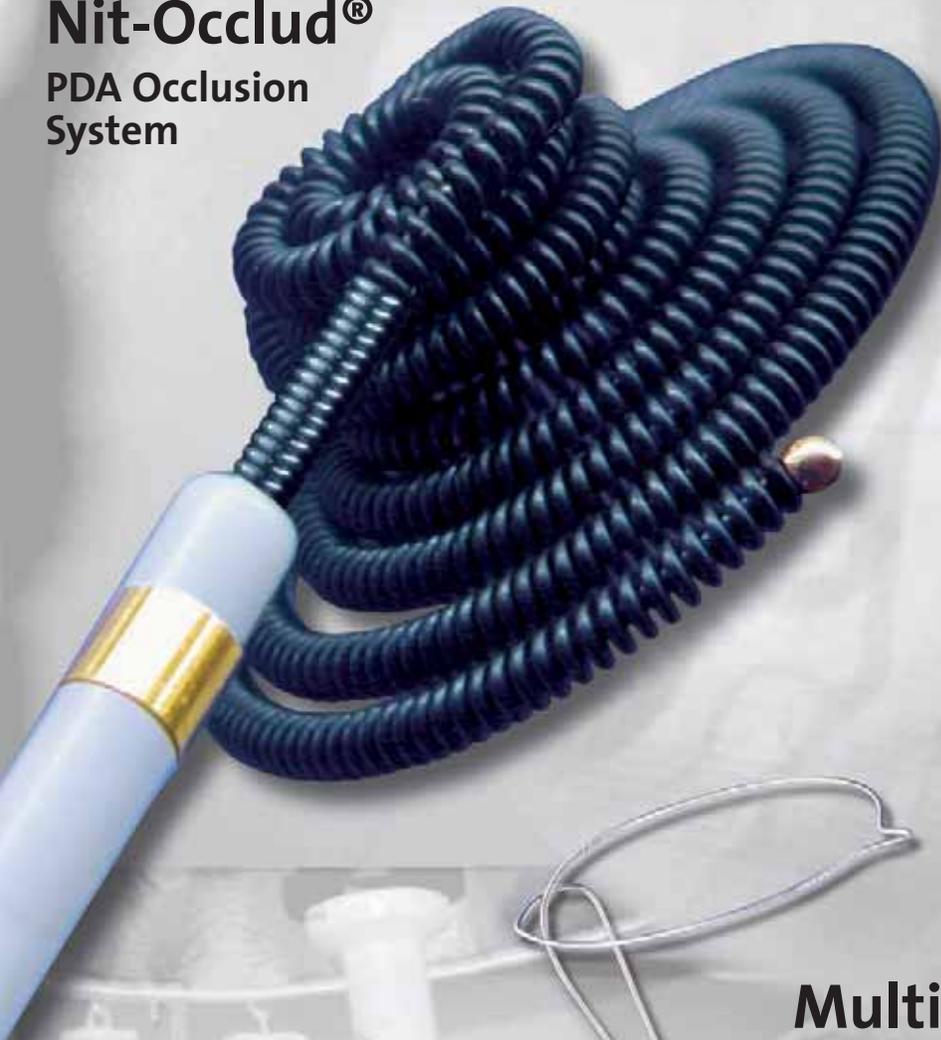
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Highlights From 2008 "Speciality Review In Pediatric Cardiology" Board Review/CME Course-Chicago

By Maria Serratto, MD, Course
Founder and Director

On September 15-19 Chicago was the venue of the 17th "Specialty Review in Pediatric Cardiology" sponsored by the University of Illinois at Chicago College of Medicine, Department of Pediatrics, Division of Pediatric Cardiology and the Society of Pediatric Cardiology Training Program Directors (SPCTPD) and the Children's Memorial Hospital of Chicago.



Dr. Serratto introducing the 2008 Course.

For the first time the course availed itself of the input of a co-director, Dr. Wayne Franklin of Children's Memorial Hospital, Associate Professor of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago and former President of the SPCTPD.

The attendees were physicians seeking Board certification and re-certification or established specialists interested in updating their knowledge in this specialty.

The course was extremely successful as indicated by the record number of partici-



Drs. Serratto and Franklin interacting with the attendees.



Lunch break.

pants from throughout the United States and several foreign countries

The curriculum was structured to meet the requirements for Board certification as well to provide an updating in this rapidly evolving specialty offering CME accreditation. To this end sessions were held with structured lectures, board simulation sessions

using state of the art ARS system and informal discussions with the faculty.

The farthest-traveling attendee came from Delhi, India. He postponed his re-certification for several months in order to first attend the course. Other foreign attendees came from Kuwait and Canada.

At the end of each hard-working day the participants had an opportunity to enjoy the cultural, entertainment and shopping facilities Chicago offers.

From the post-course evaluations we were gratified to learn that our efforts provided a rewarding and significant education experience for the attendees with 99 % of them satisfied with the faculty, content and organization of the course. Sample comments are listed here: "Excellent course..." "Great!" "Very helpful..." "Excellent board review..."

The course was videotaped by Educational Symposia Inc. (ESI), a CME accredited provider. The resulting CD/DVD, providing AMA Category 1 credits will be available for purchase from ESI in early 2009.

We are looking forward to seeing our next group of attendees in 2010!

CCT

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Medical News, Products and Information

Parents of Dying Newborns Need Clearer Explanation of Options

Newswise — Parent-doctor discussions about whether to maintain or withdraw life support from terminally ill or severely premature newborns are so plagued by miscommunication and misunderstanding that they might as well be in different languages, according to a small but potentially instructive new study from Johns Hopkins Children's Center reported in the September issue of *Pediatrics*.

In-depth interviews with 26 mothers of babies who died shortly after birth at three mid-Atlantic hospitals revealed that what mothers said they were told by doctors was often at odds with what physicians recorded in the medical chart with respect to options offered and accepted. This qualitative study explored themes rather than frequencies and investigators did not report specific frequencies of responses as part of the study.

A range of choices exists for managing critically ill newborns, those born with lethal anomalies or at less than 22-25 weeks gestation, including orders to perform aggressive resuscitation to delivering compassionate care only. Parents and doctors must often make complex decisions in a matter of minutes, a situation compounded by the parents' emotional stress and, often, the new mother's own medical status.

Results of the interviews show that few mothers recalled discussing the full range of options, from aggressive resuscitation to palliative care through the end of life. In fact, few recalled discussing resuscitation as an option at all, while the written medical records often indicated that such options were discussed. For example, one mother reported being told nothing could be done for the newborn, while the medical chart indicated that various options were discussed at length.

Many moms found doctors' language confusing. Few recalled being offered comfort end-of-life care, even when the discussion was noted in the medical charts.

Tuning out much of doctors' grim predictions about morbidity and death, most mothers said they based their decisions about life support on things such as hope, spirituality and religion.

"What this study tells us is doctors should become better at delivering grim prognoses unequivocally, yet compassionately, but many doctors are uncomfortable expressing emotion during such intense moments," says study investigator Nancy Hutton, MD, head of the pediatric palliative care program at Hopkins Children's. "Some doctors might think showing empathy and

being positive could give parents a false sense of hope, but there are ways to be hopeful and realistic at the same time, we just need to train doctors to do it better."

"We found that the parents of gravely ill newborns, who are understandably overwhelmed are quite confused by the often technical and vague 'doctor speak,'" says lead researcher Renee Boss, MD, a neonatologist at Hopkins Children's. "We, as physicians and caregivers, really need to come up with a clearer way of talking with parents during this incredibly hard time."

Most mothers said they wanted to make decisions together with the doctors, not alone. They reported mistrusting physicians who seemed detached and appeared to be acting "by the book."

Because mothers in the study reported a deeper sense of trust toward physicians who expressed emotion, regardless of the prognosis they had for the infant, researchers say obstetrics and neonatology training should emphasize paying attention to emotion and expressing empathy when delivering bad news. Also, physician organizations, such as the American Academy of Pediatrics, should address this need with new guidelines on how physicians should discuss life-sustaining options with parents.

The interviews took place on average three years after the infant's death.

Other investigators in the study: Pamela Donohue, Sc.D, Anna West, MHS, and Leslie Sulpar, MSN, all from Johns Hopkins.

Riley Hospital for Children Installs DX-S™ System from Agfa HealthCare in Neonatal Intensive Care Unit

On October 23, 2008, Agfa HealthCare, a leading provider of IT-enabled clinical workflow and diagnostic imaging solutions, announced that Riley Hospital for Children, a nationally recognized pediatric healthcare facility, and Indiana's only comprehensive children's hospital, has purchased a DX-STM system for its Neonatal Intensive Care Unit (NICU). Riley Hospital chose Agfa HealthCare's DX-S for its workflow benefits and image quality. The system is placed within the NICU department, allowing portable x-rays to be completed without leaving the patient area.



+++ www.iccaonline.org +++ 8th International Course on Carotid Angioplasty and Other Cerebrovascular Interventions +++ www.iccaonline.org +++

Agfa HealthCare's DX-S is a groundbreaking CR (Computed Radiography) system that uses the Directrix™ needle-based detector solution and Scanhead™ line-to-line CR simulation and light collection technology. Directrix significantly improves X-ray sensitivity, while the line-to-line Scanhead system produces the image in seconds, allowing portable x-rays to be completed quickly to minimize disruption in the nursery environment. The DX-S system at Riley Hospital includes Agfa HealthCare's most advanced automated digital radiography image processing software, MUSICA® Platinum which is tuned to enhance pediatric image processing.

"Having a convenient system that can combine superior image quality and enables portable x-rays to be completed, without leaving the patient area, was critical to our selection of a new imager for our NICU," said Dr. Mervyn Cohen, Eugene Klatt Professor of Pediatric Radiology. "The improved image quality of the DX-S can also decrease the number of exposures due to repeats caused by inadequate exposure technique."

The DX-S solution is designed to deliver a full range of imaging exams directly to the point of care with minimal wait times. It is used in environments where patient comfort, exam speed and imaging flexibility are of paramount importance, including Emergency, Trauma, Pediatric, Neonatal, and General Radiography departments. A leading alternative to DR (Direct Radiography), the DX-S provides the flexibility and economical advantages of CR with DR quality. It includes Agfa HealthCare's easy-to-operate workstation, which allows technologists to complete exams with fewer mouse clicks.

"With advanced technology driving the imaging system, powerful software aiding the imaging process and a design that improves the experience for the clinician, the DX-S system has certainly become a welcome addition to Riley Hospital," said Brian Hilgers,

Vice President, Imaging, Agfa HealthCare, USA. "We are proud that Riley recognized the value that this workflow-friendly system with superior image quality brings to its facility."

The purchase was made through a local Quantum dealer, Radiation Services of Indiana.

For information on Riley Hospital for Children, visit: www.rileyhospital.org. For more information about The Agfa HealthCare, visit: www.agfa.com/healthcare

Study Examines How Doctors Discuss Medical Errors

We can learn from our mistakes, but how willing are we to talk about them? And what happens when those making mistakes are physicians, who are often expected to be infallible?

A new University of Iowa study shows that most general practice doctors in teaching hospitals are willing to discuss their own patient care errors with colleagues, but about one in four do not. At the same time, nearly nine of ten doctors said that if they wanted to talk about a mistake, they knew a colleague who would be a supportive listener. The findings were reported in the Oct. 1, 2008 issue of the *Journal of Medical Ethics*.

The results suggest that it is important to ensure that learning occurs not just with the person who made the mistake, but also among their peers, said the study's lead author, Lauris Kaldjian, MD, PhD, Associate Professor of Internal Medicine at the University of Iowa Carver College of Medicine.

"Discussing medical errors can be a form of professional learning for doctors. Mistakes should be considered shared commodities



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- **LIVE CASE DEMONSTRATIONS** from multiple international venues featuring approved and non-approved devices will be transmitted daily from many cardiac centers around the world. During these live cases, the attendees will have the opportunity to interact directly with the operators to discuss the management options for these cases.

ACCREDITATION
 CME accreditation will be available. Please see the PICS website for detailed information.

ABSTRACTS
 Interventional abstracts will be presented at the World Congress meeting June 22-26, 2009

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and used for all they're worth," said Kaldjian, who also is director of the college's Program in Bioethics and Humanities. "The findings also point to some challenges for physicians seeking emotional support after making an error."

The study results were based on surveys of 338 faculty and resident physicians at teaching hospitals in the United States. Previously published findings by Kaldjian and colleagues, based on the same data set, showed that doctors' actual communication of medical errors to hospitals and patients seems to occur less than it should when compared to physicians' positive attitudes about communicating such errors.

The two earlier studies also found that the more serious the outcome or harm from a hypothetical error, the more likely a doctor said they would communicate it to patients or hospitals. Similarly, the current study used hypothetical scenarios to reveal the likelihood of doctors discussing an error that results in no harm at 77%, minor harm at 87%, and major harm at 94%.

Kaldjian pointed out there is much value in sharing all errors. "Sometimes you make a mistake and nothing happens. Other times, something bad happens," he said. "But in both cases, we need to focus on the mistake because near-misses -- where no harm was done -- are also valuable learning tools."

The most harmful types of errors trigger automatic institutional reviews. However, other errors may not. "Along with helping improve patient care, discussing both types of medical errors can provide important opportunities for learning and emotional support for physicians," Kaldjian said. "However, the formal settings in which shared learning takes place are unlikely to be optimal for providing the individual support needed by the physician who made the mistake."

"Physicians can go through a lot of turmoil when they make a mistake, even if it hasn't caused serious harm to a patient. While there are some formal group settings in the profession for learning from mistakes, emotional support may require

the privacy and reassurance that are found in one-on-one conversations with trusted colleagues," he added.

More than half of the physicians in the study (57%) said they had tried at least once to promote the value of discussing errors by discussing one of their own errors in front of students or physicians in training.

"It's encouraging that physicians try to be role models, especially for medical students and younger physicians, and some hospitals even have peer-support teams to help physicians in the aftermath of an error, though such teams appear to be rare," Kaldjian said.

Kaldjian also noted that doctors who consider themselves their "own worst critic," and do not discuss their errors with others lose out on additional perspectives.

"There can be wisdom and comfort in the words of our colleagues, especially when we have reason to trust their insights," he said. "Medical science also encourages an investigative attitude about errors and can motivate us to be as objective as possible about errors and their circumstances without denying the profound need for emotional support."

Overall, Kaldjian said, increased discussion of errors amongst medical professionals is extremely important for professional learning and emotional support. Such discussions may also help physicians encourage each other to disclose errors to patients as part of patient care and to report them to institutions to improve patient safety.

The investigation involved researchers with the Center for Research in the Implementation of Innovative Strategies in Practice at the Department of Iowa City Veterans Affairs Medical Center; Hospital of St. Raphael in New Haven, CT.; Yale University School of Medicine; and Penn State College of Medicine and Hershey Medical Center.

For more information, visit www.uiowa.edu.

Do you or your colleagues have interesting research results, observations, human interest stories, reports of meetings, etc. that you would like to share with the congenital cardiology community?

If so, submit a brief summary of your proposed article to Congenital Cardiology Today at: RichardK@CCT.bz

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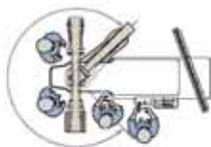
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