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EDITORIAL COMMENT

# Closure of the Patent Foramen Ovale

## The End of the Sound and Vision Era Approaching*

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We have seen it before and we will see it again: a new pair of trousers is at first worn only with a belt and suspenders. But after wearing them for a while and never losing them, the suspenders are disposed of and only the belt remains. Interventional cardiology offers several examples of this. The abandoned temporary pacemaker for percutaneous coronary angioplasty and echocardiography for balloon mitral valvuloplasty are just 2 of them.

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The act of percutaneously closing a patent foramen ovale (PFO) may be accomplished in as little as 10 min from the needle puncture of the femoral vein to the patient putting his finger on the groin while the sheath is removed and then walking out of the catheterization laboratory, as would happen after donating a pint of blood at a Red Cross station. Complications are exceedingly rare with the belt (fluoroscopy) alone (1–3). The paper of Hildick-Smith et al. (4) in this issue of *JACC: Cardiovascular Interventions* deals with the question whether and when suspenders (echocardiographic guidance) might still be needed or recommended. And then again, it does not. It convincingly shows that, in the majority of consecutive patients, the omission of ultrasound guidance did not impair the result of PFO closure. However, it does not provide evidence about whether ultrasound guidance did improve the results in the minority in whom it was used.

Arguments in favor or disfavor of using intraoperative ultrasound during PFO closures are depicted in Table 1. Although not all of the arguments in favor can be discarded lightly, it can be foretold that the more common PFO closure will become, the more the procedure will have to be simplified. The risk of suboptimal placement or device embolization is extremely small if the fluoroscopic assessment is exploited in the correct projection using contrast medium (Fig. 1).

Additional shunts should have been documented during the pre-procedure transesophageal echocardiogram (TEE), for which I concur with Hildick-Smith et al. (4), in seeing a necessity. During the procedure, additional small shunts are likely to be missed, even when echocardiographic guidance is used, unless they are in the PFO plane on which the ultrasound imaging will be focusing.

The use of a few milliliters of contrast medium should not pose a problem in any patient. A rare circumstance, such as an urgent need for PFO closure in early pregnancy, may impose PFO closure exclusively (5) or almost exclusively (6) guided by ultrasound.

The sharing of responsibility at the crucial moment of device release from the implantation gear is an important feature in the beginning of the learning curve of an operator. However, the second opinion from the echocardiographer is of little value, if he or she is also inexperienced, which is usually the case in an institution embarking on PFO closure. For a rookie operator in an experienced institution, the advice of a PFO-savvy interventional cardiologist is usually available.

The arguments against using ultrasound guidance appear more compelling. To avoid undue inconvenience and risk to the patient, intubation and general anesthesia is usually

**Table 1. Arguments for and Against Ultrasound Guidance During PFO Closure**

| |
|---|
| For |
| Additional imaging technique to avoid suboptimal placement or device embolization |
| Reduced risk of missing additional shunts |
| Immediate information about tightness |
| No need for contrast medium injections |
| Sharing of responsibility among two physicians |
| Against |
| Significant prolongation of procedure engendering additional risks of thrombosis or air embolism |
| Transesophageal echocardiography |
| Need for intubation and general anesthesia to avoid discomfort and bronchial aspiration |
| In case of sedation only, discomfort and risk germane to esophageal intubation in supine position |
| Intracardiac echocardiography |
| Second venous access (larger than the one required for PFO closure) |
| Additional intravascular and intracardiac manipulations not protected by a guidewire |
| Cost of disposable probe |

PFO = patent foramen ovale.

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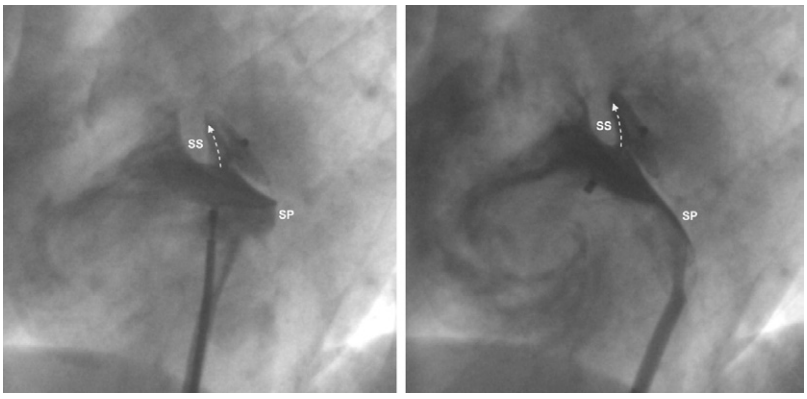


**Figure 1. Angiographic Aspect of a 25-mm Amplatzer PFO Occluder Before and After Release**

Provided a correct view is chosen depicting the 2 disks in perfect profile without any overlap (usually a left oblique projection with cranial tilt), the correct position of the device can be unequivocally ascertained before **(left)** and documented after **(right)** release. The left halves of the disks are separated by the muscular septum secundum (SS), whereas the septum primum (SP) is thin, wraps around the inferior rim of the device before release (device position tilted by the stiff pusher cable), and extends from the lower rim after release. The **dashed arrow** indicates the actual PFO tunnel. The fact that the interdisk connector is not passing the PFO at its very top **(top of arrow)** is explained by the fact that the PFO slit has to be pictured as a sad mouth with a device connector typically hanging low in either mouth angle. PFO = patent foramen ovale.

considered a prerequisite for TEE guidance. This more than triples the time of the intervention and generally requires a third physician in addition to the echocardiographer. Using TEE under simple sedation and local anesthesia is overshadowed by the risk of bronchial aspiration of saliva due to the patient being in the supine position.

The use of intracardiac echocardiography (ICE) also prolongs the procedure significantly but it does not necessarily require an additional physician. However, introducing the ICE probe (not wire-guided) is a fairly rough act with at least a doubled risk of puncture site problems and cardiac perforation. A single operator gets distracted by trying to keep the ICE probe properly directed while also handling the device closure equipment. Moreover, the additional expense of approximately U.S. $2,000 is to be considered.

There are 2 major prerequisites to turn PFO closure into what could come close to a mechanical vaccination acceptable for all people with a PFO (approximately 25% of the general population) or at least those with a dangerous variation of it (approximately 4%), in whom the 2 septa are barely touching and the septum primum is extremely mobile and flimsy, which is usually referred to as atrial septal aneurysm.

First, it has to be efficient and safe. A complete closure rate of 100% will never be achieved but, with the current technology of choice (3), a significant and "unfiltered" (unimpeded by the implanted device) residual shunt persists in <5% of patients. A second device can remedy those 5% with a second intervention even more swiftly than the initial one. Safety is at least comparable with what is usually accepted for a vaccine. The only procedure complication, occurring at a rate approaching 1%, is an arteriovenous fistula at the groin. This is clinically benign but may need local surgery. The dreaded bacterial infection of the device has been reported, but only in a couple of isolated

**Table 2. Ischemic Stroke Classification (Revised)**

| |
|---|
| Local arterial occlusion |
| Lacunar |
| Intracerebral |
| Vertebral |
| Internal carotid |
| Common carotid |
| Brachiocephalic |
| Arterial embolus |
| Plaque/ulcer/dissection |
| Intracerebral |
| Carotid |
| Vertebral |
| Brachiocephalic |
| Ascending aortic |
| Cardiac embolus from |
| Left ventricle |
| Left atrium |
| Left atrial appendage |
| Myxoma or other tumor |
| Vegetation (septic embolus) |
| Paradoxical embolus |
| Patent foramen ovale |
| Atrial septal defect |
| Pulmonary fistula |
| Pulmonary venous bed embolus |
| Cryptogenic |

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cases in the world literature. Even assuming underreporting, these cases have to be seen against the background of devices having been implanted for PFO closure worldwide in more than 100,000 people. The same holds true for erosion of a free atrial wall by the device. This has been reported in only 2 of more than 50,000 people having been fitted with an Amplatzer PFO occluder (AGA Medical, North Plymouth, Minnesota). Such an incidence of an admittedly severe side effect is indeed comparable with the severe side effects of recommended vaccinations against childhood diseases. The second prerequisite is that the intervention is simple and this forfeits the use of ultrasound guidance.

Before we can convince people that the general population might need vaccination against a disease, they have to be convinced that the disease needs prevention. The current misclassification of strokes mediated by the PFO as an entity only to be considered after excluding all other ischemic stroke causes (after the establishment of the diagnosis of cryptogenic [unexplained] stroke) needs to be revised. The PFO can be the cause of an ischemic stroke with and without the presence of other acknowledged ischemic stroke reasons (Table 2). The term cryptogenic has to be pushed beyond the PFO and perhaps even beyond the embolism from a clot originating form the pulmonary venous bed, a mystic medical black box, the discussion of which is beyond the scope of these remarks.

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**Key Words:** patent foramen ovale closure ■ intracardiac echocardiography ■ percutaneous closure ■ transesophageal echocardiography.