PUBLISHED BY ELSEVIER INC.

ISSN 1936-8798/09/$36.00

DOI: 10.1016/j.jcin.2008.12.001

EDITORIAL COMMENT

# Patent Foramen Ovale Closure Without Echocardiography

## Are We Closing the Door Too Fast Too Soon?*

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Interventional cardiologists have firmly established their role in the diagnosis and treatment of coronary atherosclerosis. Assessment of hemodynamics has also been a long-standing role for the catheterization laboratory. However, the invasive cardiologist is now becoming involved in the treatment of structural heart disease. Various and increasingly complex procedures are being performed through a catheter-based approach, such as septal ablation for hypertrophic cardiomyopathy, balloon valvotomy, prosthetic leak repair, and percutaneous valve replacement. The past decade also has witnessed the emergence of percutaneous closure of patent foramen ovale (PFO) for secondary prevention of stroke. This procedure has been rapidly adopted into clinical practice with conservative estimates of >11,000 patients having received the Amplatzer PFO Occluder (AGA Medical Corporation, Golden Valley, Minnesota) since its introduction worldwide in May 2000 (1).

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It has been well accepted that catheter therapy for structural heart disease requires a team approach of both interventionalists and cardiovascular imaging specialists (2). The antiquated method of fluoroscopy does not compare to high resolution images of echocardiography or computed tomography scan imaging, which can show the direct relationships of catheters and devices to intracardiac structures. During PFO closure, transesophageal or intracardiac echocardiography has been thought to be essential to assist with defect sizing, to ensure device fit, and to examine for residual shunting or other persistent structural defects that need to be addressed after deployment of the device. The concomitant use of intraprocedural echocardiography does require either training in ultrasound imaging or partnership with noninvasive colleagues who need to be available during the procedure.

In the current issue of In this issue of *JACC: Cardiovascular Interventions*, Wahl et al. (3) provide important new data on percutaneous PFO closure performed *without* the need for adjunctive intraprocedural echocardiography. In this study, the authors extend their previous observations and examined 620 patients who underwent percutaneous PFO closure for secondary prevention of presumed paradoxical embolism (3,4). The salient findings of their report are successful device deployment in all patients, acute complications in 0.8%, complete closure of the defect in 91% of patients, and occurrence of embolic events in 13 patients (2.1%) during median follow-up of 2.6 years (97% complete). These results were achieved with empiric use of the Amplatzer PFO Occluder (AGA Medical Corporation) that was deployed with techniques using only fluoroscopy. These data have led the authors to propose that adjunctive, intraprocedural echocardiography is no longer necessary for performing percutaneous PFO closure.

Elimination of the need for adjunctive echocardiography during PFO closure has enormous implications for this relatively new procedure. Certainly, there would be cost savings with no need for echocardiographic equipment, and in cases where transesophageal echocardiography is used, general anesthesia is avoided. Procedure time would be shortened (median of 22 min in Wahl et al. [3]). Interventionalists without training in echocardiography would be at liberty to perform percutaneous PFO closure without the aid of noninvasive colleagues. In summary, percutaneous PFO closure would become a simpler, shorter procedure, and these changes likely would lead to an even wider utilization of the procedure than has been witnessed thus far.

However, the study of Wahl et al. (3) should not be misconstrued as suggesting that all interventional cardiologists can "go it alone" when performing PFO closure. Although successful device deployment was achieved in all patients, these favorable outcomes may well be more related to the large experience and clinical expertise of their group (>600 cases). The catheterization techniques used in this study still require knowledge and a skill set beyond that of many cardiologists, which must be developed with time and experience. For instance, the authors used the "Pacman" sign on fluoroscopy to indicate proper device deployment (5), which may seem simple but requires a learning curve and has not yet been embraced by others performing PFO closure. Experience with catheter manipulation in the left atrium is essential, particularly as perforations of both atria and both appendages during PFO closure have been the major source of complications in other reports (1,6).

Although Wahl et al. (3) state that intraprocedural echocardiography is no longer needed, a successful PFO closure procedure does require noninvasive expertise during

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

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the initial evaluation and selection of patients. A goal-oriented transesophageal echocardiography performed by a dedicated noninvasive cardiologist is essential for proper patient selection. Accessory abnormalities such as anomalous pulmonary venous drainage, sinus venous defects, or multiple or excessive fenestrations need to be ruled out by pre-procedure imaging. The pre-procedure study also is needed to determine device appropriateness and sizing by examining the extent of rims, tunnel defects, and relationship of the PFO to other structures such as valves and great vessels. Thus, these procedures need to be done in a center with a dedicated team of highly experienced invasive and noninvasive cardiologists, which may also account for the high success of the Swiss group, even if ultrasound is not used during the procedure.

The approach of Wahl et al. (3) does decrease procedure time and results in cost savings. We must ask ourselves if their data truly demonstrate efficacy of this technique, both in terms of complications as well as outcomes. The authors attribute a low rate of vascular complications to avoiding intracardiac echocardiography. However, such complications persisted in their study, can be minimized with careful venous access, and on the whole should be avoidable in experienced hands even with the use of large ultrasound catheters. The question as to whether patient outcomes are similar with their technique versus the conventional ultrasound assisted technique is still unclear. Evaluation of the efficacy of PFO closure is difficult as the goal is to prevent an event that has low frequency and may occur due to other mechanisms. For instance, "favorable rates" of recurrent embolism were present after PFO closure; recurrent embolism occurred at a lower frequency (2.1% over mean follow-up of 3.0 years) than has been observed in patients managed medically (3.8% to 12.0% at 1 year), and comparable to previous transcatheter closure studies (0% to 4.9% at 1 year) (7,8). However, previous studies of recurrent embolism have been limited by small numbers of patients, different antiplatelet and anticoagulation regimens, and use

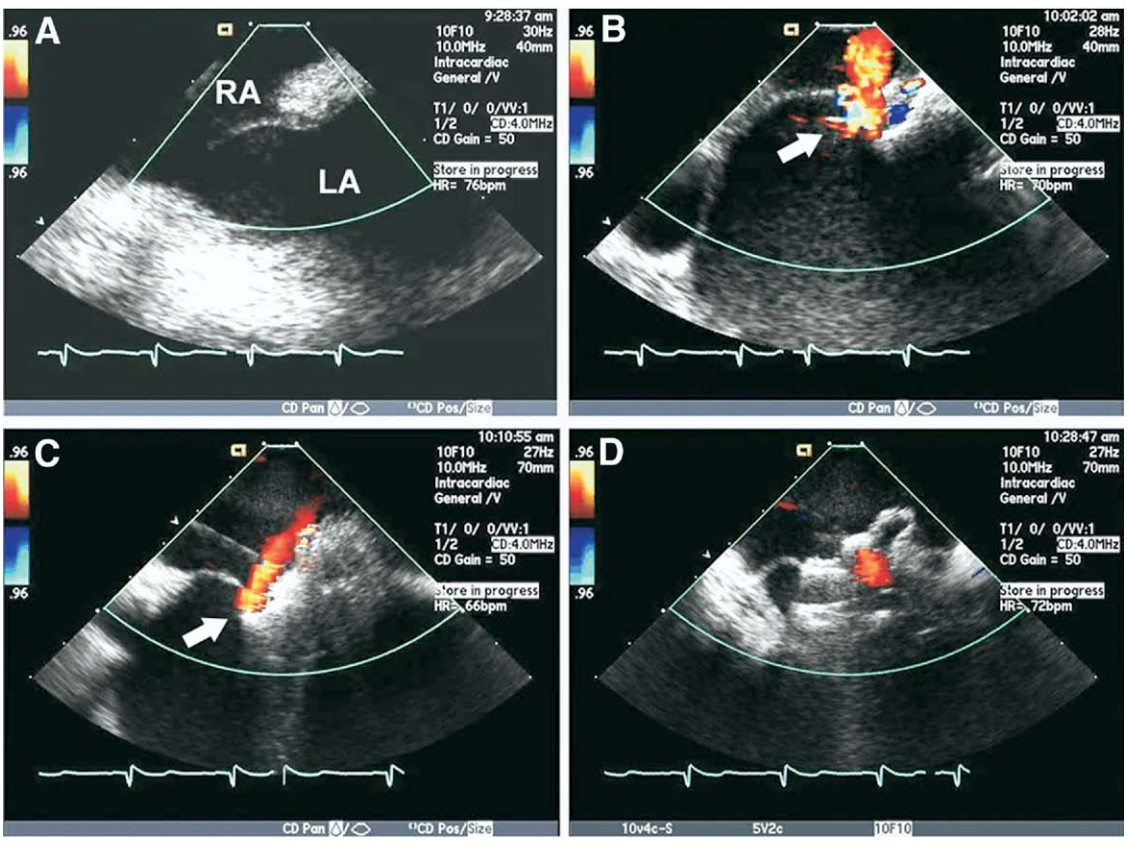


**Figure 1. Echocardiography During PFO Closure**

This patient presented for patent foramen ovale (PFO) closure after cryptogenic stroke. **(A)** A PFO and an atrial septal aneurysm with a single defect and bidirectional shunting were evident on pre-procedural transesophageal echocardiography (not shown) and intraprocedural intracardiac echocardiography (shown). **(B)** After placement of a 14-mm Amplatzer atrial septal defect occluder, severe shunting at the inferior margin of the device remained **(arrow)**, presumably due to stretching or tearing of the fossa ovalis membrane. **(C)** This significant shunting **(arrow)** remained despite placement of an 18-mm Amplatzer atrial septal defect occluder. **(D)** Complete closure was finally obtained with a 22-mm Amplatzer atrial septal defect occluder. LA = left atrium; RA = right atrium.

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 2, NO. 2, 2009
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of varying devices including technologies that are no longer available. Selection bias, markedly different baseline patient risk, and the multiple potential etiologies for stroke (e.g., atrial fibrillation, aortic atherosclerosis, and so on) make comparisons across these studies extremely difficult, thereby reducing the validity of recurrent embolism as a comparative end point.

The other end point to measure "success" is the presence and degree of residual shunting. In this study, successful device deployment occurred in all patients, but residual shunting occurred in 9% at follow-up, including moderate or severe shunting in 3%. Moreover, among the 78 patients who received a larger 35-mm device, residual shunting occurred in 27% and was moderate or severe in 8%. The degree of residual shunting is notable because these same investigators have reported residual shunt to be the only predictor of recurrent embolism after PFO closure, and that incremental benefit of PFO closure over medical therapy occurs in those with complete occlusion (9–12). In other studies where intraprocedural echocardiography was utilized, complete shunt elimination occurred in 98% to 99% of patients (13,14). It is important to consider that the goal of PFO closure may not be simply to decrease the size of a shunt, but to eliminate all shunting and thereby completely abolish the risk of paradoxical embolism. It is not clear whether or not knowledge of the residual shunt during the procedure would have led to changes in deployment, particularly as it is known that many patients have improvement of the shunt during follow-up (14,15). Nonetheless, we and others have utilized either different or multiple devices when confronted with new intraprocedural echocardiographic findings (Fig. 1) (16). In the current study, there were 8 patients who required a second closure for persistent residual shunt in follow-up, which might have been avoided by intraoperative echocardiography. Perhaps selective use of intraoperative imaging may be useful, for patients with tunnel defects, atrial septal aneurysms, and those requiring a larger device who had an increased incidence of post-procedure shunting.

Finally, the major question that must be addressed is not how the procedure can be done faster and better but whether a PFO closure should be done at all to prevent recurrent stroke. There still are no definitive data that PFO closure prevents stroke or its recurrence. At a time when carefully controlled, randomized studies are needed to determine clinical efficacy, important opportunities may have been missed when cohorts of >600 patients are able to be done at a single center. Although this important study by Wahl et al. (3) shows that the "door" between the atria can be closed safely and expeditiously, let us not close the door to further investigating the true efficacy of this technique.

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**Key Words:** patent foramen ovale ■ echocardiography ■ intracardiac.