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## Echocardiographic Assessment of Percutaneous Patent Foramen Ovale and Atrial Septal Defect Closure Complications

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Jonathan J. Passeri, MD; Igor F. Palacios, MD; Michael H. Picard, MD

**A**trial septal defect (ASD) is a common congenital defect (1 in 1000 live births) and accounts for up to 40% of clinically relevant acyanotic shunts in adults.<sup>1</sup> Patent foramen ovale (PFO) is much more common and is present in more than 25% of adults.<sup>2,3</sup> The clinical syndromes associated with ASD/PFO represent a significant health burden. Surgical closure is the most common therapy for these defects, and it is associated with low morbidity and mortality. However, it remains a surgical procedure requiring cardiopulmonary bypass, a significant postoperative recovery, and a sternotomy scar that may be undesirable to young patients.

Catheter-based techniques for the treatment of ASD/PFO were pioneered by King and Mills in 1975.<sup>4</sup> Since then, significant device development and modifications have been made (Table 1). Percutaneous therapy is now the preferred strategy for ASD/PFO closure, by patients and physicians alike, in the absence of complicated anatomy or another indication for traditional cardiac surgery, because it is technically simple and associated with negligible morbidity and mortality.<sup>5</sup> Longer-term follow-up, however, remains necessary to more completely evaluate the safety and efficacy of such devices.

The role of 2-dimensional (2D) transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) during the assessment and management of ASD/PFO has been demonstrated.<sup>6–8</sup> Although universal practice standards, in the form of consensus committee guidelines or professional society recommendations, still have to be established for the use of echocardiography in this context, it is used by a majority of groups who perform these procedures. In our institution, TTE with color Doppler and/or agitated saline contrast injection is most frequently the method used to diagnose interatrial communication. Once the diagnosis has been made and percutaneous closure is deemed clinically appropriate, a careful intraprocedural assessment of interatrial septal anatomy is performed by TEE. Specifically, in the case of PFO, accurate measurement of the length of the tunnel between the septum primum and secundum and evaluation for concomitant interatrial septal aneurysm is performed. It is our practice to guide closure device placements using TEE. The multiple roles of intraprocedural TEE include confirma-

tion of interatrial septal anatomy, preclosure and postclosure assessment of adjacent cardiac structures, including the mitral and aortic valves, systemic and pulmonary veins, and direct visualization of device position and efficacy. After successful device placement, TTE is used at routine intervals to confirm device stability and to evaluate for residual interatrial shunting. Both intraprocedural TEE and postprocedural TTE also play an important role in identifying complications of percutaneous device closure.

In recent years, intracardiac echocardiography (ICE) has been used to guide numerous percutaneous ASD/PFO closures and is the imaging modality of choice in many centers.<sup>9,10</sup> ICE is typically performed intraprocedurally using an 8 or 9F catheter, which is introduced via a second femoral venous sheath. As in TEE, 2 standardized orthogonal sections are usually used to obtain defect measurements and then to guide optimal device deployment. Most commonly, the transverse section on the aortic valve plane and the longitudinal section of the 4-chamber plane are used<sup>11</sup> (Figure 1). The advantages of ICE are multiple. The quality of the images may be superior to TEE because the transducer is within the cardiac chambers enabling high-resolution, close-up visualization of structures; accurate assessment of the interatrial septum, position and size of the defects, adequacy of the rims, and drainage of the pulmonary veins is then possible. ICE also retains an advantage over TEE in imaging the postero-inferior portion of the interatrial septum. The use of ICE obviates the need for general anesthesia, and therefore an anesthesiologist, as well as an echocardiographer—this serves to reduce the cost of the procedure. Disadvantages of ICE include the need for insertion of a second venous sheath, the requirement for supplemental training, the expense of single-use ultrasound catheters, and potential provocation of transient atrial arrhythmias. In addition, ICE has a more limited field of view than TEE and thus is less suited for the evaluation of far-field device complications. Importantly, with single operators, it may be challenging to manipulate both the ICE catheter and the closure device at the same time. At the present time, there are insufficient data to support the exclusive use of either TEE or ICE, and selection of either is left to the discretion of the interventionalist.

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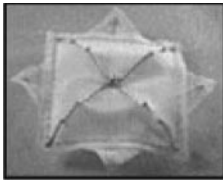
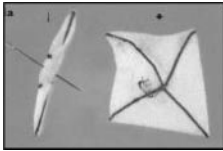
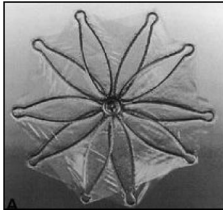
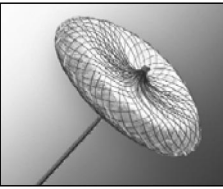
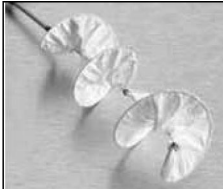
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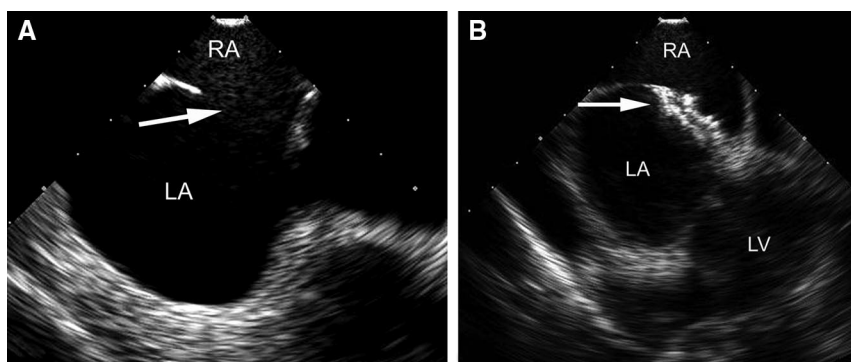
**Table 1. Summary of Devices Most Frequently Used for Percutaneous Closure of ASD or PFO**

Name	Design	Advantage	Disadvantage
CardioSEAL	 Double umbrella; not self-centering	Frequently used; flexible	Not self-centering; difficult to assemble and withdraw; may promote thrombus formation
Sideris buttoned device	 Self-centering; double umbrella	Flexible; device centering on demand	Reports of embolization
ASDOS	 Two self-opening umbrellas; polyurethane membrane	Useful in patients with interatrial septal aneurysm	Risk of frame fracture; membrane perforation (one report)
Amplatzer ASD Occluder	 Self-centering double disc	Easily withdrawn; frequently used; easy to use	Not for use in those with nickel allergy; late erosion
Helix	 Nitinol guide with PTFE sheath	Flexible; low profile; small surface; easily withdrawn (even following deployment)	Seldom used in PFO closures; embolization; residual shunting; challenging visualization by TTE

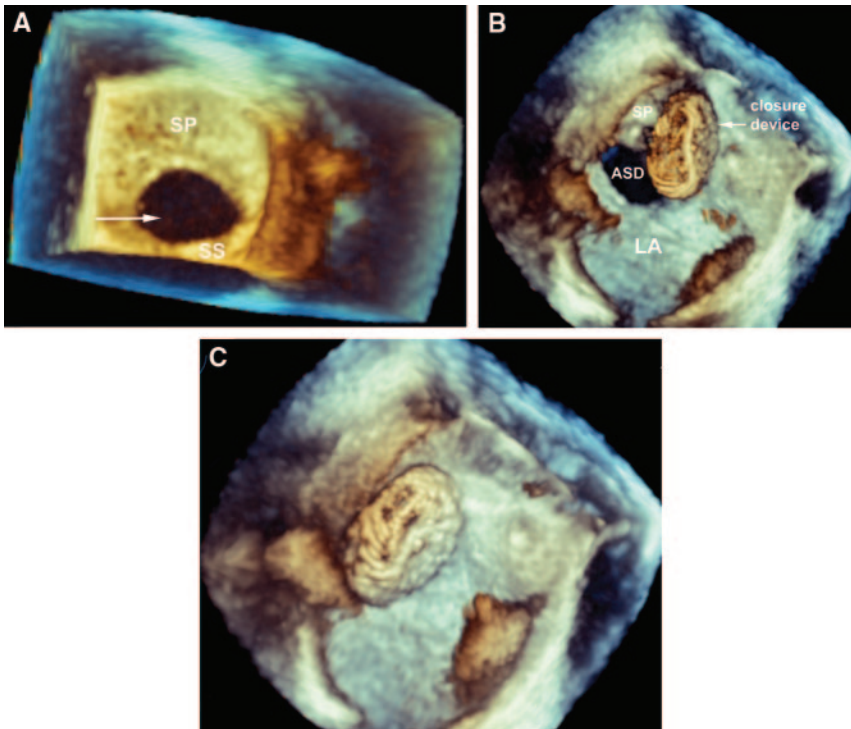
ASDOS, Atrial Septal Defect Occluder System; PTFE, polytetrafluoroethylene. Reproduced in part, with permission, from Cruz-Gonzalez et al. *Rev Esp Cardiol*. 2008;61:738–751.

Although 2D echocardiography is the most widely used technique to assess interatrial septal anatomy, it may underestimate the true dimensions or the complexity of the ASD, as the septum is neither a “flat” plane<sup>12</sup> nor the defect a perfect circle. Three-dimensional (3D) TTE and TEE, both real-time and with image postprocessing, have been shown to be feasible for the qualitative and quantitative assessment of

ASD.<sup>13,14</sup> 3D provides unique views of the interatrial septum and allows en-face views of the ASD. These views clearly define the morphology of the defect, as it has been shown to change during the cardiac cycle,<sup>15</sup> and its relation to contiguous cardiac structures thereby providing details which cannot be attained as easily by any other imaging technique (Figure 2). Information gathered by this technique may have



**Figure 1.** Intracardiac echocardiogram with transducer in the right atrium (A) showing a secundum ASD (arrow). In another patient, CardioSeal device closure of a PFO is demonstrated (B). LA indicates left atrium; LV, left ventricle; RA, right atrium.



**Figure 2.** Three-dimensional TEE demonstrating left atrial views of an ASD (A, arrow). The left atrial disk of an Amplatzer device occluder is initially deployed within the left atrium (B) and is positioned against both septum primum (SP) and secundum (SS). Proper placement of the device with adequate coverage of all rims of the interatrial septum are then confirmed (C). SP indicates septum primum; SS, septum secundum; ASD, atrial septal defect; LA, left atrium.

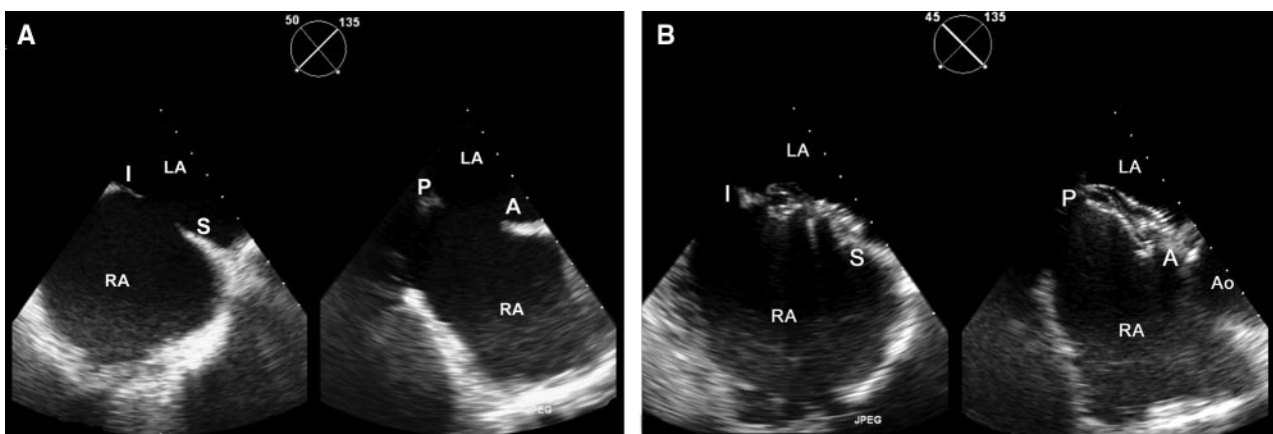
major implications in the selection of patients for device closure.

The use of 2D biplane imaging, a feature of commercially available 3D imaging transducers and software, is a complementary and sometimes sufficient option to the use of 3D imaging (Figure 3). The advantages of this imaging modality are a high frame rate and a superior temporal resolution. The 2 orthogonal planes provide additional information compared to 1 single imaging plane—a feature highly desired during the interventional procedure when one needs to determine whether all aspects of the closure device are well seated. Initial reports of the advantages of 3D TEE in guiding catheter interventions have recently been published.<sup>16–18</sup>

The echocardiographic evaluation of interatrial communications has led to a better understanding of what constitutes

appropriate indications and contraindications to percutaneous closure (Table 2).<sup>19–21</sup> Technical advancements in the field of percutaneous device closure are being made at a rapid rate, and as such the technology is now more widely available. As more devices are implanted, our understanding of the benefits and the risks of these procedures continues to improve. Recently, a number of complications of percutaneous ASD/PFO closure procedures have been reported, some at the time of intervention and some in the short- and long-term postprocedure follow-up period. Intraprocedural ICE and TEE and postprocedural TTE are useful for identifying complications of percutaneous closure.<sup>19,22–24</sup>

This article will review important complications of percutaneous ASD/PFO closure, with an emphasis on the role of echocardiography for their diagnosis and management.



**Figure 3.** Real-time biplane transesophageal acquisition (A). Once an adequate image is obtained (left panel), a complete 360° complementary view (right panel) can be obtained and ensures accurate measurement of the dimensions of the ASD and correct placement of the device occluder across both septum primum and secundum (B). I indicates inferior rim; S, superior rim; P, posterior rim; A, anterior rim; LA, left atrium; LA, left atrium; RA, right atrium; Ao, aorta.

**Table 2. Indications and Contraindications for the Percutaneous Closure of ASD and PFO**

Indications	
ASD	
Isolated secundum ASD with a pulmonary/systemic flow (Qp/Qs) ratio >1.5:1, signs of right ventricular volume overload	
PFO	
Cryptogenic stroke and evidence of right to left shunt*	
Contraindications (absolute or relative)	
Patent foramen ovale or small ASD with Qp/Qs <1.5:1 or with no signs of right ventricular volume overload	
A single defect too large for occlusion (>38 mm)	
Multiple ASDs unsuitable for percutaneous closure	
Defect too close to the superior vena cava, inferior vena cava, pulmonary veins, atrioventricular valves, or coronary sinus	
Anterior*, posterior, superior, or inferior rim <5 mm	
Abnormal pulmonary venous drainage	
Associated congenital abnormality requiring cardiac surgery	
ASD with severe pulmonary arterial hypertension and bidirectional or right to left shunting	
Intracardiac thrombi diagnosed by echocardiography	
History of severe allergy to iodinated contrast agents	

\*Controversial.

### Complications

In a recent meta-analysis of PFO closure in 1355 patients, performed between 1998 and 2004, major complications (including death, tamponade, fatal pulmonary embolism, need for urgent surgery, and transfusion) occurred in 1.5% of patients and minor complications (including atrial arrhyth-

mias, transient heart block, asymptomatic device thrombosis, device embolization not requiring surgery, and device arm fracture) occurred in 7.9% of patients.<sup>25</sup> Other minor complications such as device entrapment within a Chiari network have been reported.<sup>26</sup> A more accurate determination of the incidence of complications can only be made once a sufficiently long follow-up is achieved in these patients. Complications can occur at the time of the interventional procedure, early postprocedure, or late during follow-up (Table 3).

### Pericardial Tamponade

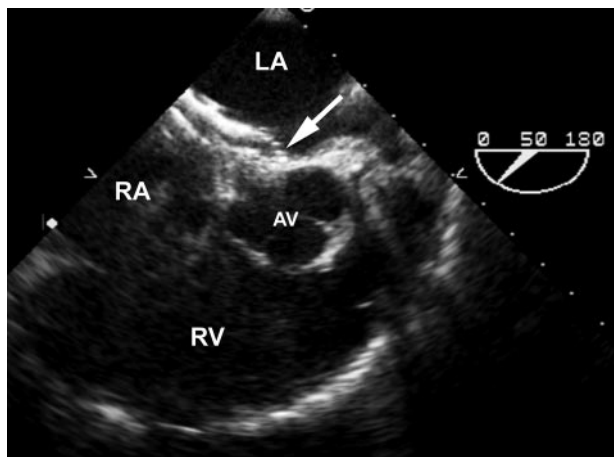
As with all percutaneous intracardiac procedures, the risk of cardiac perforation exists during ASD/PFO closure. Cardiac tamponade has been reported in approximately 0.5% to 1% of patients after ASD/PFO closure.<sup>27,28</sup> With device closure of ASD or PFO, tamponade most frequently results from perforation of the left atrial appendage during anchoring of the trans-septal guide wire. Less commonly, the right atrium, right ventricle, or right/left upper pulmonary vein may be the location of perforation.<sup>29</sup> Device erosion through adjacent cardiac tissue, as later reviewed, is another cause of pericardial tamponade.

The identification of cardiac tamponade involves integration of clinical, hemodynamic, and echocardiographic data. Intraprocedural TEE or ICE should be used continuously throughout the procedure to monitor the sudden development of a pericardial effusion, especially during excessive manipulation of intracardiac catheters. Assessment of the pericardial space should also be a compulsory component of postprocedural TTE, usually performed at 24 hours postprocedure to confirm device positioning.

**Table 3. Summary of Potential Early and Late Complications After Percutaneous ASD or PFO Device Closure and Role of Echocardiography in Their Management**

Complication	Potential Consequence	Treatment	Role of Echocardiography	Preferred Modality
<b>Acute/early</b>				
Cardiac perforation	Cardiac tamponade	Cardiac surgery	Diagnosis	TTE/TEE/ICE
Device embolization	Valvular dysfunction; embolization	Percutaneous or open surgical retrieval	Diagnosis; guiding percutaneous retrieval	TTE/TEE/ICE
Hemorrhage	Hemodynamic instability; death	Transfusion; surgical intervention	N/A	N/A
Fatal pulmonary embolism	N/A	N/A	Diagnosis	TTE/TEE
<b>Chronic/late</b>				
Device embolization	Valvular dysfunction; embolization	Percutaneous or open surgical retrieval	Diagnosis; guiding percutaneous retrieval	TTE/TEE
Device erosion	Fistula formation; atrial/aortic perforation; cardiac tamponade	Cardiac surgery	Diagnosis	TEE
Conduction disturbance	Complete heart block; junctional rhythm	Monitoring unless hemodynamically significant	N/A	N/A
Device thrombosis	Embolization	Anticoagulation	Diagnosis	TEE
Infective endocarditis	Septic embolization; abscess formation	Antibiotics ± cardiac surgery	Diagnosis	TEE
Device arm fracture	Device erosion; cardiac perforation; interatrial shunt	Cardiac surgery	Diagnosis	TEE

N/A indicates not applicable.



**Figure 4.** TEE at midesophageal level (transducer plane angle, 50°) demonstrating Amplatzer occluder device impinging on the aortic root (arrow) because of lack of sufficient anterior rim. LA indicates left atrium; RA, right atrium; RV, right ventricle; AV, aortic valve.

### Device Erosion

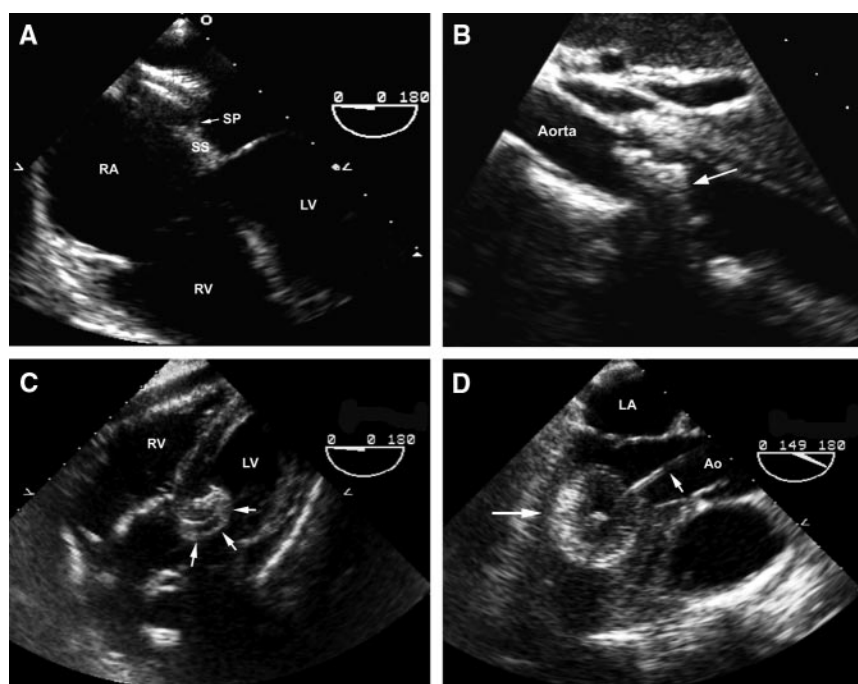
The majority of ASD/PFO closure devices become fully endothelialized within several months after deployment and thus, pose little risk of erosion or migration. Over time, important modifications to device and implantation techniques have reduced the incidence of this potentially catastrophic complication. However, perforation of the right atrial roof, left atrial roof, and the aortic root by one aspect of the device have been reported following device implantation.<sup>30–33</sup>

Erosions have been reported with multiple devices, including the Amplatzer Septal Occluder, the Atrial Septal Defect Occluder System, and the Angel-Wings device.<sup>29,30,34,35</sup> Of these, rare cases of aorto-atrial fistulas have been published, but none of these cases involved structural deterioration of the actual devices.<sup>35,36</sup> In comparison, atrial free-wall erosion

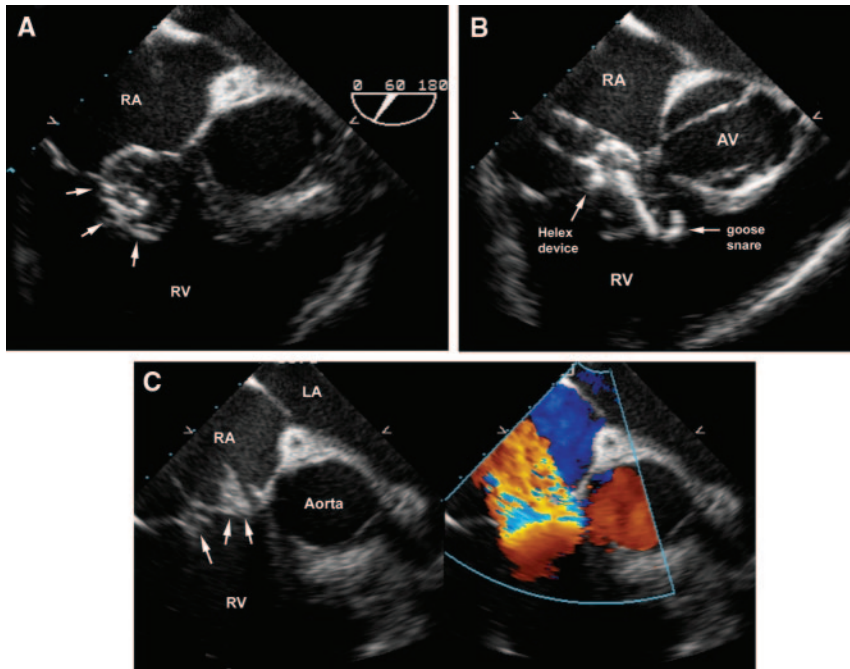
is a more common complication. In the series reported by Amin et al,<sup>29</sup> a panel of physicians conducted a review of all reported cases of hemodynamic compromise post-ASD closure. Erosion after ASD closure using the Amplatzer septal occluder occurred in 28 patients over the course of 6 years. In 89% of the cases, the device-treated ASDs were located high on the septum, with insufficient antero-superior rims (Figure 4). Of the 28 erosions, 5 involved the left atrial roof near the aortic root, whereas 6 involved the roof of the right atrium. The authors concluded that deficient rims in vulnerable areas could increase the mobility of the device with resultant excessive friction between the device and an atrial wall. Device diameter was identified as another major issue, and oversizing ( $\geq 1.5$  times the size of the ASD) was found to increase the risk of erosion. As such, conservative sizing may result in lower erosion rates. Other studies are in accordance with these risk factors.<sup>29,33</sup> Other identified risk factors were all related to the potential for abrasion of the atrial or aortic wall by the device: splaying of the atrial disks across the aortic root and extreme movement of the deployed device before release (termed the Minnesota wiggle).<sup>29</sup>

Erosion or perforation can occur as soon as 48 hours after the procedure, but also long after device implantation, sometimes without the development of any symptoms. Of the 28 (86%) cases of erosion reported by Amin et al, 24 occurred in the first 3 months whereas the latest occurred 3 years after the initial procedure. This time span and lack of symptoms underscore the need for long-term monitoring for potential complications. Although death from such mechanical complications remains rare, the risk is estimated to be around 0.11%.<sup>37</sup>

With the use of an Amplatzer Septal Occluder, the erosion typically occurs in the left atrial roof, likely because of the larger left atrial disk. Its nitinol wire frame makes it a relatively rigid device, facilitates its positioning, and improves its stability once implanted. The downside of this



**Figure 5.** A, TEE at midesophageal level demonstrating dislodgement of an Amplatzer device after attempted PFO closure—the device has remained attached only to the septum primum. B, TTE showing an embolized Amplatzer device, within the abdominal aorta, 24 hours after attempted ASD closure. C, An embolized Amplatzer device (arrows) is visible within the left ventricular outflow tract on TEE. D, Percutaneous retrieval of the device in panel C, under TEE guidance, was achieved using a gooseneck snare in retrograde fashion through the aortic valve. SP indicates septum primum; SS, septum secundum; LA, left atrium; LV, left ventricle; RA, right atrium; RV, right ventricle.



**Figure 6.** TEE demonstrating an embolized Helex device caught within the tricuspid valve apparatus (A). Attempted snaring, after incorrect placement of the device, resulted in its embolization into the tricuspid valve apparatus. Under TEE guidance, transcatheter gooseneck snare retrieval was achieved via an inferior vena cava approach (B). Snaring of the device resulted in tearing of the septal and anterior leaflets of the tricuspid valve (C, left panel, arrows) and severe tricuspid regurgitation (right panel). RA indicates right atrium; RV, right ventricle; AV, aortic valve; LA, left atrium.

rigidity is the increased chance for erosion through adjacent tissues. No cases of erosion have been reported with the Helex device; however, relatively few devices of this type have been implanted compared with older models. Although most patients found to have device erosion are usually treated with surgical repair, there have been deaths directly attributed to free-wall perforation and tamponade.

Complete intraprocedural TEE or ICE evaluation during the placement of an ASD/PFO closure device is helpful for risk assessment regarding the potential for erosion into the atrial wall or the aortic root. Careful attention should be paid to whether the device impinges on the aortic root and to whether the device contacts any portion of the atrial wall other than the interatrial septum (Figure 4). Ideally, these observations should be performed before device deployment and communicated to the interventionist. This strategy will allow repositioning of the device while it is still attached to the delivery cable.

### Device Embolization

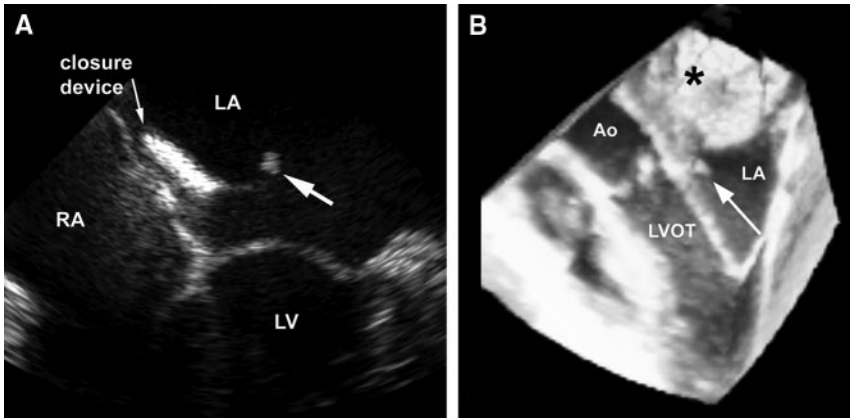
Several reports of embolization of ASD/PFO closure devices have been published.<sup>38–42</sup> This remains, however, a relatively rare complication. Among studies reporting complications from percutaneous ASD closure, 11 cases of device embolization were documented in a total of 599 patients.<sup>26,43,44</sup> Ultimate stability of the device depends on anatomic factors, including adequate superior, inferior, anterior, and posterior margins of the septum adjacent to the defect. Clinicians may be tempted to ignore a small or nonexistent anterior rim when using the newer, self-centering devices,<sup>45,46</sup> as evidenced by 1 report in which up to 40% of patients with deficient anterior rims underwent percutaneous closure of their ASD with the Amplatzer closure device.<sup>45</sup> There are no data to support the notion that the use of self-centering devices prevents or reduces embolization. Furthermore, 2 reports have shown that an anterior margin of less than 5 mm may predispose to early

and late device embolization.<sup>29,47</sup> Hypermobility of the interatrial septum was hypothesized to be a risk factor for unsuccessful percutaneous device closure of ASD and PFO.<sup>48</sup> However, an evaluation of 69 device placements at our institution revealed no significant correlation between exaggerated septal mobility and the success of device closure of interatrial communications.<sup>48</sup> All 69 placements involved the Sideris closure device, however, which is no longer in use.

One of the many roles of echocardiography in guiding device closure of ASD/PFO is to ensure proper placement of the device across the interatrial septum. Identification of immediate or early device embolization is possible with the TEE or ICE probe still in position (Figures 5A, C, D and 6). Postprocedure TTE (Figure 5B) or TEE (as necessary) allows accurate identification of device malpositioning and embolization. Unfortunately, the use of echocardiography becomes limited when the device embolizes out of the heart and beyond the abdominal aorta at the hepatic level or into the peripheral vasculature. Once the location of the embolized device has been determined, especially if it is intracardiac, percutaneous device retrieval is made easier with echocardiographic guidance.

### Device Thrombosis/Endocarditis

In a recent study of 1000 consecutive patients, the incidence of device thrombosis was reported to be 2% after ASD/PFO closure.<sup>49</sup> Three patients had minor cerebrovascular accidents, and one experienced a transient ischemic attack. Thrombus appears to be more common with devices containing uncoated metal arms such as the CardioSEAL, StarFLEX, and PFOStar than with the polyester fabric-coated Amplatzer device or the polytetrafluoroethylene-coated Helex device.<sup>50</sup> Most thrombi were detected within the first month after device implantation. These “early” thrombi were usually observed on TEE or intraprocedural ICE but not on TTE (Figure 7). Proper compliance with antiplatelet agents is essential to prevent device thrombosis. To our knowledge, there have been no reported



**Figure 7.** A, 2D TEE demonstrating thrombus (thick arrow) formation, immediately after ASD closure, on the left atrial side of an Amplatzer Multi-Fenestrated Septal Occluder (Cribriform). B, 3D TEE postprocessed to show a left atrial disk en face view and demonstrating, more specifically, thrombus (arrow) located at the anterior edge of the Amplatzer device (\*), on the left atrial side immediately adjacent to the aortic valve. LA indicates left atrium; RA, right atrium; LV, left ventricle; LVOT, left ventricular outflow tract; Ao, aorta.

cases of infective endocarditis affecting an ASD/PFO closure device yet; theoretically, the risk remains as long as the device has not been endothelialized.

Follow-up TEE is clearly superior to transthoracic imaging to rule out overlying thrombus on the closure device. In cases of recurrent stroke or peripheral embolization after PFO closure, for example, TEE is indicated to evaluate device positioning, to assess for residual shunt, and to rule out thrombus adherent to either atrial disk. So far, the only established risk factor for thrombosis is the material of the device.<sup>49–51</sup> Although the use of devices with uncoated metal struts has decreased recently, there remains a significant percentage of patients with such devices. Thorough follow-up of these patients appears necessary because they are at an ongoing risk of thrombus formation. Determination of echocardiographic predictors of device thrombosis remains an important area for future work.

**Residual Shunt**

It is not uncommon to see a residual shunt in one or more areas of the interatrial septum after attempted device closure of an ASD/PFO. Residual shunts are commonly diagnosed during routine postprocedure TTE with color Doppler echocardiography or by agitated saline contrast injection, both at rest and with the Valsalva maneuver. In our experience, complex patterns of residual shunting have been noted. Interatrial shunting may occur from around the device or from within the device. Residual right-to-left shunts, seen immediately after device closure of PFO, often disappear or decrease, as the device endothelializes. However, in a certain percentage of patients, persistent shunting (in either direction) is seen many months postprocedure. Serial echocardiographic evaluations can be used in these cases to follow the degree of shunting. Appearance of symptoms should prompt a thorough evaluation of the closure device by TEE to rule out a new or worsening shunt.

In a European multicenter trial, device implantation was attempted in 200 patients with either ASD or PFO. At 1 year after implantation, the residual shunt rate was 3% (Table 4).<sup>26</sup> Such residual shunting is not considered as a complication of device closure; however, it can become clinically relevant should the shunt provide, as in the case of an ASD, significant volume overload to the right heart or recurrent embolic phenomena. Membrane perforation of the ASD Occluder System, with severe left-to-right shunting, 8 years after

closure has been reported in 1 case recently.<sup>52</sup> Clearly, this is an extremely rare complication, and this specific type of ASD occluding device has not been in use since 2000. At the present time, regular long-term follow-up is recommended in all patients with similar types of ASD occluding devices.

**Conclusion**

As percutaneous therapies gradually replace surgical repair of ASD/PFO, the incidence of complications of such techniques is likely to increase. Knowledge of the potential complications of device closure and their predictors will help reduce their occurrence. Complications range from minor to life-threatening and potentially fatal. Factors involved in the incidence of complications include the interventional technique, the anatomy and size of the defect, and the type of device placed. Echocardiography has long been instrumental in the preprocedural assessment of interatrial septal anatomy. Both ICE and TEE provide complementary and necessary imaging modalities to fluoroscopy during closure device implantation. TTE and, if needed, TEE play an important role in following patients post-ASD/PFO closure device implantation. Although 2D echocardiography is a valuable tool for minimizing the occurrence of a complication, more recently developed RT3DE adds a valuable imaging perspective and supplements the information obtainable by 2D imaging. In the event of a complication, it becomes paramount to use echocardiography not only to diagnose but also to aid with therapy where appropriate. With the advent of newer imaging techniques, faster acquisition times, and improved spatial resolution, the use of echocardiography, especially as an

**Table 4. Residual Shunt After ASD Closure With the Atrial Septal Defect Occlusion System**

Interval After Closure (months)	No. of Patients	Shunt Size		
		None	Small	Moderate/Large
0	126	79 (63%)	36 (29%)	11 (8%)
6	91	62 (68%)	24 (26%)	5 (6%)
12	69	49 (71%)	18 (26%)	2 (2%)
24	18	15 (83%)	3 (17%)	0

Values are given in absolute numbers with percentages in parentheses. Reproduced, with permission, from Sievert et al. *Am J Cardiol.* 1998;82:1405–1413.

adjunct to percutaneous interventional techniques, will only become more valuable.

## Disclosures

None.

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KEY WORDS: heart septal defects ■ echocardiography ■ catheterization ■ complications