

Considerations for ASD Closure

Understanding the devices and proper anatomic evaluation to prevent and manage possible complications.

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We would like to start with some good news when it comes to transcatheter closure of secundum atrial septal defects (ASDs) with an excerpt from an article published by our surgical colleagues, "Nationwide utilization of ASD/PFO repair has increased over time, largely attributable to the dramatic rise in percutaneous closure. Despite the substantial increase in utilization, mortality has remained constant."¹ In fact, surgical mortality rates for ASD closure are similar or higher than transcatheter mortality rates even when accounting for erosion-related mortality.^{2,3}

Among congenital and structural heart lesions, ASD and patent foramen ovale closures are perhaps the most common interventional procedures performed in cardiac catheterization suites. There are two devices approved by the US Food and Drug Administration (FDA) to close ASDs—the Amplatzer septal occluder (St. Jude Medical, Inc., St. Paul, MN), which has been approved for more than 10 years, and the Helex septal occluder (Gore & Associates, Flagstaff, AZ), which has been approved for approximately 7 years in the United States.

A number of complications linked to both devices have been described and published. Some of these are minor complications and are of no significant consequence, whereas others are major and may lead to significant consequences. To better understand the etiology of (and ways to prevent) complications, a brief description of devices, ASD anatomy (with factors that constitute high-risk ASD), and echocardiographic evaluation to recognize high-risk ASD are warranted. Please also see the *High-Risk Percutaneous ASD Closure* sidebar.

DEVICES

Helex Septal Occluder

The Helex septal occluder is composed of a nickel-titanium (nitinol) wire frame covered with expanded

polytetrafluoroethylene. The expanded polytetrafluoroethylene is treated with a hydrophilic coating to facilitate echocardiographic imaging of the occluder during implantation. When fully deployed, the occluder assumes a double-disc configuration that bridges the septal defect to prevent shunting of blood between the right and left atria. The device, therefore, has a non-self-centering design. The size of the device is based upon the size of the discs, which are symmetrical. In order to effectively close the ASD, the discs have to be approximately twice the diameter of the ASD.

Amplatzer Septal Occluder

The Amplatzer septal occluder is a self-centering device, and the waist sits inside the ASD. The left atrial disc rim is 6 to 8 mm larger than the waist (6 mm for

HIGH-RISK PERCUTANEOUS ASD CLOSURE

Complex ASD

- Deficient rims (two or more)
 - Aortic rim is deficient in nearly 50% of cases
 - Posterior rim, atrioventricular rim, coronary sinus rim
- Eccentric
 - Too close to atrioventricular valve, inferior vena cava, etc.
- Significantly oval
 - Dimensions of 15 X 25 mm
- Dynamic
 - Significant change in ASD size during atrial systole/diastole
- Fluttering septum (aneurysmal-like)
 - Small static defect that is much larger when balloon sized

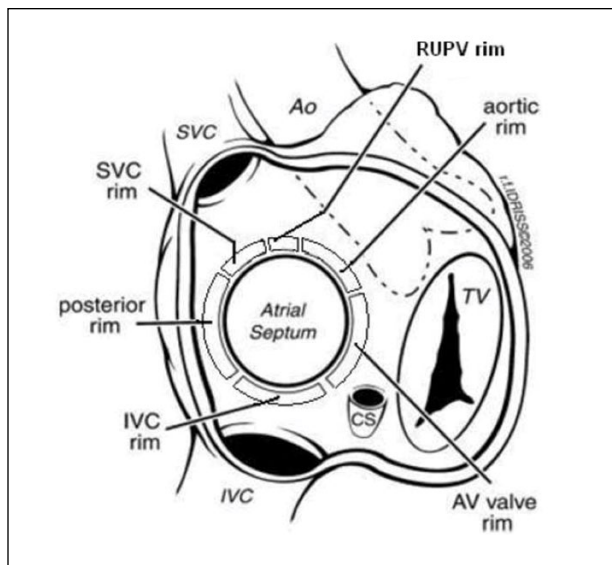


Figure 1. Atrial septum as seen from the right atrium with secundum ASD rims depicted. Ao indicates aorta; AV, aortic valve; CS, coronary sinus; IVC, inferior vena cava; RUPV, right upper pulmonary vein; SVC, superior vena cava; TV, tricuspid valve.

devices 4–10 mm, 7 mm for devices 11–32 mm, and 8 mm for device 34–40 mm), and the right atrial disc rim is 4 to 5 mm larger than the waist (4 mm for devices 4–10 mm, 5 mm for all remaining sizes). The discs, therefore, do not have to be twice the diameter of the defect, as the waist occupies the defect and does not leave the device much “wobble room” after placement. This unique characteristic enables the Amplatzer device to close defects that are as large as 40 mm.

As the size of the Amplatzer septal occluder device increases, the wire thickness increases to maintain the configuration of the device. The increase in size occurs at 11, 18, 26, and 32 mm. Hence, the 10-mm device is the softest device for 4- to 10-mm waist sizes because it has the largest disc relative to wire thickness, and the 11-mm device is the stiffest device for waist sizes 11 to 17 mm because it has the smallest disc relative to wire thickness.

The self-centering nature of the device makes it crucial that the device used is as close to the diameter of the defect as possible. This is the main reason that Amplatzer devices are available in 1-mm increments for up to 20-mm devices and 2-mm increments for devices that are 22 to 40 mm. Balloon sizing techniques recommended by the company mandate that stop-flow diameter be used instead of balloon-stretch diameter, which remains the conventional sizing technique for non-self-centering devices. When a self-centering device is placed in the defect, the waist completely occupies the defect, and the device has

no wiggle room (as opposed to a non-self-centering device with a fixed diameter that can adjust to contraction of the atrial chamber), hence the edges of the device remain at a fixed distance from the atrial free wall regardless of the timing of the cardiac cycle. An oversized device may tent the atrial free wall during systole or throughout the cardiac cycle. The most vulnerable part of the atrial free wall is the area close to the aorta, where the atrial septal rim and the free wall of the left and right atria are adjacent to the aorta. In ventricular systole, the aorta increases in diameter and may compress on the atrial septum and adjacent free atrial wall. An oversized device or deficient aortic rim may make the atrial free wall vulnerable to trauma.⁴

ASD ANATOMY PERTINENT TO DEVICE CLOSURE

Atrial Septal Rims

An ASD is surrounded by vital cardiac structures throughout its circumference (Figure 1). Anteriorly (toward the sternum) is the ascending aorta and aortic sinuses, superiorly and slightly posteriorly is the superior vena cava, posteriorly are the pulmonary veins, posteroinferiorly is the inferior vena cava (IVC), and anteroinferiorly are the atrioventricular valves. To safely and effectively close an ASD, the presence of atrial septal rims on which the discs of the device will lie is important. The atrial septal rim of greatest concern is the rim adjacent to the aorta (the aortic rim). However, the other rims are important as well. For example, deficiency or absence of an IVC rim may result in device embolization and increases the risk of arrhythmias because the edge of the device may impinge upon the conduction system. Deficiency of the atrioventricular valve rim may cause the device to impinge on the atrioventricular valves, with resultant mitral or tricuspid valve leaflet restriction and/or valvular regurgitation.

Malaligned Atrial Septal Rims

The atrial septum is a three-dimensional structure, and when an ASD is present, the atrial septal rims may not align. This is particularly true and important for the aortic and posterior rims. Generally, the aortic rim is in the middle of the noncoronary aortic sinus, but sometimes, the rim may be eccentric, and it usually tends to move leftward (Figure 2). When a device is placed in such defects, the right atrial disc will not straddle the aorta evenly but will be slightly tilted, with its edge digging in to the atria (adjacent to the aorta) (Figure 3). This scenario increases the chances of right atrial disc–related atrial free wall injury.⁵

Hyperdynamic ASD

In general, the size of all ASDs changes during atrial systole and diastole. During device selection, a device

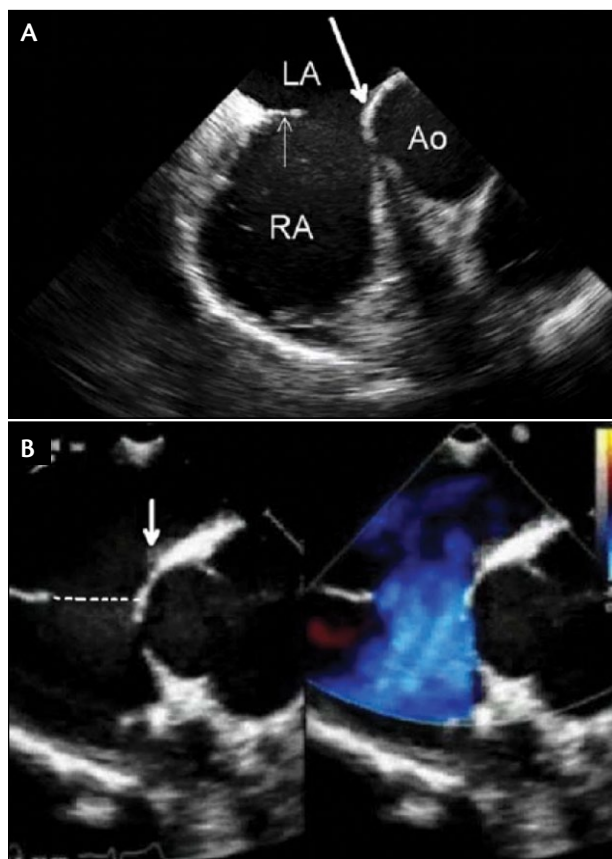


Figure 2. Transesophageal short-axis view of septal malalignment. The thick arrow identifies the aortic septal rim. The thin arrow depicts the posterior rim of the ASD (A). Dashed line (B) is the plane of an aligned ASD. See text for complete description. Ao indicates aorta; LA, left atrium; RA, right atrium.

that equals the larger size of the defect is usually chosen. Some defects, however, may be significantly hyperdynamic, which can cause the ASD size to increase or decrease more than 50% between atrial systole and diastole. Once the device is placed in such defects, the device is “too large” during atrial systole and “appropriately sized” during diastole. Such patients may be at increased risk of atrial wall trauma.⁵

Eccentric ASD

If the ASD is located high in the atrial septum (superior-inferior dimension), it will be closer to the aorta, and hence, device closure may increase the risk of tissue trauma.⁵

Echocardiographic Evaluation

A thorough echocardiographic evaluation of the anatomy of the interatrial septum and surrounding structures is crucial to effectively planning ASD closure,

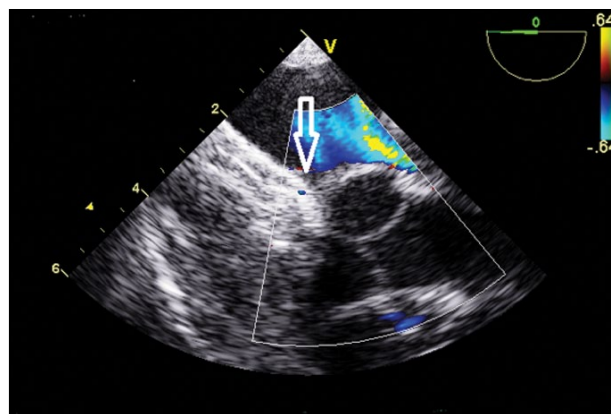


Figure 3. Amplatzer septal occluder device in malaligned atrial septum. Notice that the left atrial disc tip (open arrow) is toward the right side of the aorta.

accounting for the aforementioned high-risk scenarios. In 2011, Bell-Cheddar and Amin⁶ published criteria for effective evaluation of ASD. The ASD should be evaluated in three standard views: aortic short-axis view, four-chamber view, and bicaval view. The aortic short-axis view should be further evaluated sequentially from 30° through 80° in 10°- to 15°-increments (Figure 4). Such evaluation is crucial because the aortic rim may span approximately 20% to 25% of the circumference of the ASD.

PREVENTING COMPLICATIONS

Intraprocedural Complications

Most intraprocedural complications of ASD closure are catheterization-related and range from minor to major. Minor and very common complications are transient benign arrhythmias and air embolism without significant clinical sequelae. Major catheterization complications include stroke and malignant arrhythmias, such as complete heart block, which may also appear after completion of the procedure. These complications can be minimized by paying proper attention while advancing catheters, taking utmost care to de-air catheters and sheaths, and proper anticoagulation. The activated clotting time should be approximately 250 seconds throughout the procedure, and heparin should never be reversed at the conclusion of the procedure because it increases the risk of thrombus formation on the device.⁷

Device-Related Complications

There is potential for pulmonary vein perforation related to sheath placement, but fortunately, there has only been one such complication reported.⁴ The most common complication reported to the manufacturers and the FDA is device embolization. Device embolization

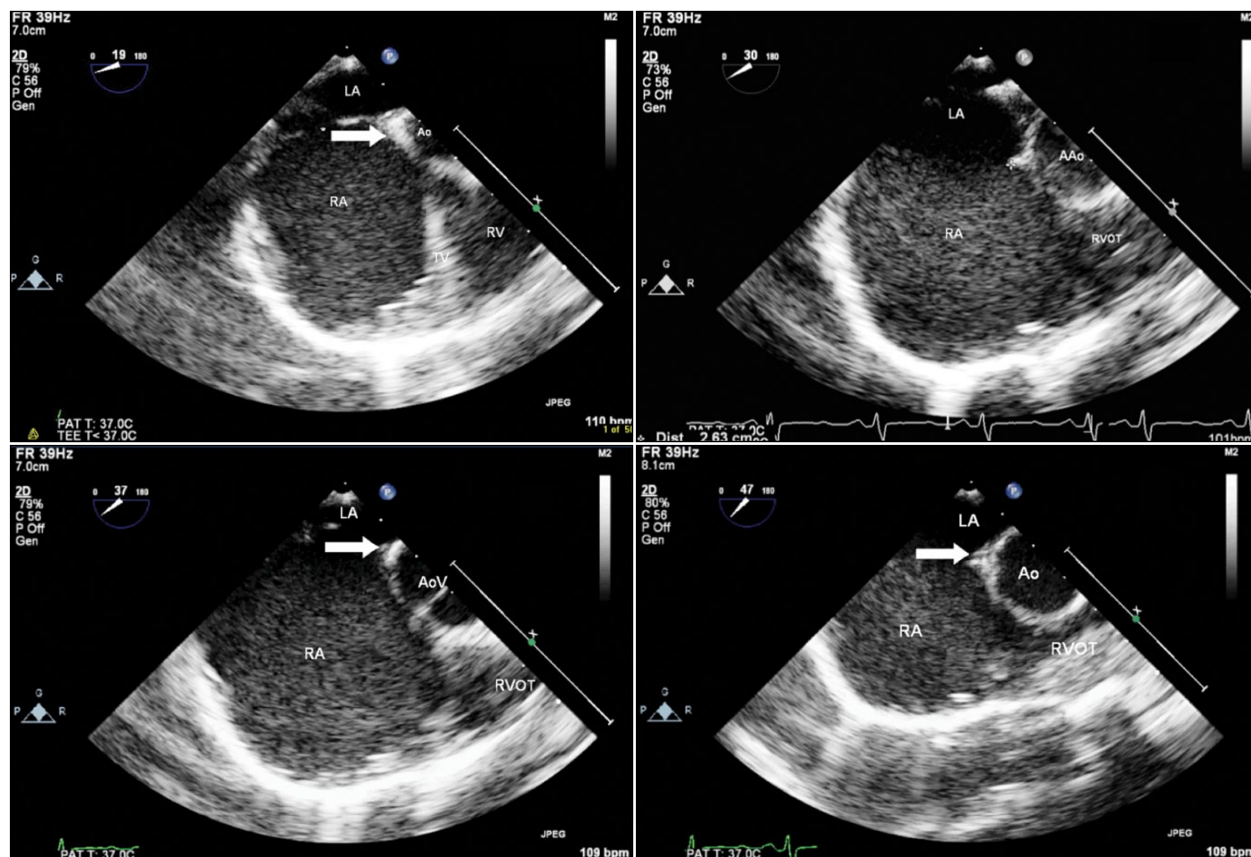


Figure 4. Aortic rim evaluation by transesophageal echocardiography in multiple and consecutive short-axis views (from top left to bottom right). AAo indicates ascending aorta; Ao, aorta; AoV, aortic valve; LA, left atrium; RA, right atrium; RVOT, right ventricular outflow tract; TV, tricuspid valve.

most commonly occurs in the cardiac catheterization laboratory and during the first 24 hours after device placement. It is rare after the patient has been discharged to home but has been described months after placement.^{8,9} The opposite is true of device-related erosion, which is rare in the cardiac catheterization laboratory. However, the risk increases significantly during the first 96 hours; thereafter, the incidence decreases to a negligible level, with sporadic cases reported after 6 months to several years after implantation.⁵

Device Embolization

As previously stated, device embolization can be minimized by thorough echocardiographic evaluation of the ASD. ASDs with a diminished or absent IVC rim are particularly prone to embolization. Interrogation of the IVC rim is important in all patients but crucial in patients with large ASDs. A typical procedural scenario that should raise the suspicion that the IVC rim is deficient is difficulty with device implantation due to prolapse of the left atrial disc into the right atrium despite sufficient aortic rim.

The most common cause of device prolapse, however, is aortic rim absence or significant deficiency. Hence, careful patient selection based on echocardiographic assessment of the interatrial septum and adjacent structures will help in reducing the risk of device embolization.

The second most common cause of device embolization is physician error. This type of embolization occurs in the catheterization laboratory, as both discs are either in the left or the right atrium at the time of release. Again, it cannot be stressed enough to thoroughly evaluate the position of the device by echocardiography after placement.⁸

Device-Related Cardiac Perforation (Erosion)

Device-related cardiac tissue injury was initially described with use of devices in the 1990s. The Hausdorf sheath (Cook Medical, Bloomington, IN), Angel wings (Microvena Corporation, White Bear Lake, Minnesota), and Cardia devices (Cardia, Inc., Burnsville, MN) have all been shown to cause cardiac perforation. Erosion with these devices was recognized during the trials or during initial commercial use. They were taken off of the market

TABLE 1. DEVICE-RELATED COMPLICATIONS

Complication	Management
Device embolization	Anticoagulation, attempt percutaneous retrieval, surgical consultation for possible open retrieval
Device erosion	Emergent echocardiography, pericardiocentesis for pericardial effusion and tamponade, emergent surgical consultation
Thrombus formation	Anticoagulation, transesophageal echocardiography, surgical consultation in rare instances
Acute mitral regurgitation	Replacement of the device with a smaller device, surgical consultation
Heart block	Device removal, pacemaker placement if late-onset heart block

for several reasons other than erosion, except for Angel wings, which had caused pericardial effusion during the trial.¹⁰⁻¹³

During the FDA approval trials for the Amplatzer device in the United States, there was no case of documented erosion in nearly 1,000 cases. After the device received pre-market approval, cases of erosion started to emerge and continued to occur at a concerning rate. Unfortunately, the exact risk of erosion is very difficult to calculate because the denominator (total number of devices placed) is not available. The risk of erosion, therefore, may be lower or higher than advertised (0.1%–0.3 %).⁴

Naturally, there have been extensive discussions regarding erosion and how to minimize its risk. Since the first in-depth publication on this subject, there have been several reports that do not seem to agree on the etiology of erosion. It is clear though that the cause of erosion is multifactorial and may need in-depth analysis in a prospective fashion to figure out the cause(s) of erosion. Device oversizing remains one of the most important causes of erosion and is easily preventable. However, erosion occurring in cases without device oversizing is of significant concern. A recently published analysis of 12 consecutive cases of erosion was primarily focused on identifying the echocardiographic markers of erosion and reducing the risk of its occurrence.⁵

The markers of erosion were based on the location of the defect (high defect), extent of aortic rim deficiency (in degrees around the circumference and size < or > 5 mm), absence of aortic rim in a four-chamber view (also termed “bald aorta”), malalignment of the posterior and aortic rim (septal malalignment), dynamic nature of the defect, and thin consistency of the posterior rim. After device placement, if the edge of the device was seen to tent the atrial roof in a short-axis view in relationship to the transverse sinus, the risk of erosion significantly increased. The limitation of the study was that it was a descriptive study, not a case-control study, and inferences made were based on a limited number of cases without an appropriate control group for comparison.

To further minimize the risk of erosion, correct device sizing by carefully and nonaggressively employing the stop-flow balloon diameter method is recommended. Patients with aortic rim deficiency spanning 30° or more should not be selected for device closure. Patients with septal malalignment in the absence of 5 mm of rim should be avoided. In patients with a thin posterior rim in addition to a deficient aortic rim, careful attention should be paid to device size selection.⁵ It should be noted that only 1% to 2% of the total cases being considered for device closure will have these mentioned feature(s). More than 95% of the defects can still be closed safely in the catheterization laboratory.

MANAGING COMPLICATIONS

Device Embolization

Both the Amplatzer septal occluder and Helex septal occluder devices can be retrieved in the cardiac catheterization laboratory. The most common site for device embolization is the left atrium followed by the aorta, right atrium, or pulmonary artery (Table 1). If the device is in one of the ventricles, retrieval may be difficult.²

For an Amplatzer septal occluder, a sheath size that is at least 2 to 4 F larger than the sheath that was used to deliver the device is desirable. The initial and primary objective is to bring the device into the IVC and out of the heart (Figure 5). Heparin should be given as soon as the diagnosis is established if the patient is not in the cath lab.

An Amplatz GooseNeck snare (Covidien, Mansfield, MA) or En Snare (Merit Medical Systems, Inc., South Jordan, UT) can be used to snare the female screw site of the right atrial disc. This screw is the most easy to grab compared to other parts of the device. A large snare is neither desired nor helpful. A 15- to 20-mm snare, regardless of device size, is usually helpful; however, if snares of this size are not available, smaller snares can be used as well. If the device is stuck in the chorda of the right or the left ventricle, it is better to refer the patient to surgery; the device can be retrieved by the surgeon, and the defect is closed during the same procedure.

If the device is in the pulmonary artery, attempts should be made to capture and retrieve the device by advancing

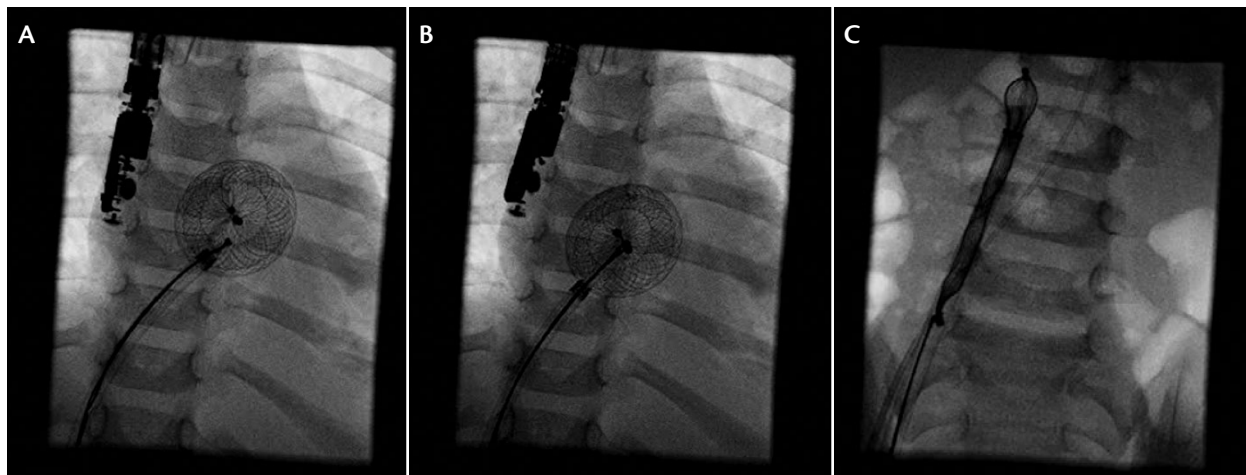


Figure 5. Snaring of a large Amplatzer septal occluder device in the left atrium with a GooseNeck snare and sheath (A). Retraction of the device into the inferior vena cava (B). Retrieval of the Amplatzer septal occluder into a larger sheath in the inferior vena cava (C).

the sheath into the pulmonary artery. If the device is captured and cannot be retrieved in the sheath, pulling it out across the right ventricle may cause injury to the tricuspid valve unless the sheath was advanced over the wire that was placed through a balloon-tipped catheter. A balloon-tipped catheter would avoid tricuspid valve chordal entrapment during its advancement to the pulmonary artery. After the device has been snared, it may not easily pull into the sheath (Figure 6). Some physicians bevel the sheath to increase its size. This helps in capturing the female screw into the sheath. The remainder of the device can then be gently pulled inside the sheath.

In some cases, physicians have used a second venous access to hold the device with a snare before snaring the female screw. The traction facilitates in capturing of the device into the sheath. If for some reason, the female screw is pointing away from the snare, a pigtail catheter or a balloon-tipped catheter can be used to flip the device so that it is easier to snare the female edge of the screw.⁸

For the Helix septal occluder, the same general principles apply for capturing the device. It is important to snare the left atrial eyelet, opposite the locking loop. Attempts to snare the easier right atrial eyelet and locking loop will not unlock the device, but rather move the device en bloc. Because the device is conformable, it is possible to use a large-loop snare and capture the left atrial disk for retrieval. A large, stiff-tip braided sheath, such as a 10-F Flexor sheath (Cook Medical) works best. Other sheaths tend to allow one of the eyelets to embed into the sheath tip, making retrieval more problematic.¹⁴ It is important to inform your surgeon once embolization has occurred, as retrieval is not possible in all cases.

Device Erosion

All patients should be made aware of this complication. Instructions must clearly indicate that if patients experience any shortness of breath or dizziness, they should immediately consult the physician, go to the emergency department, and clearly state that they had this procedure and device implanted. This will alert the emergency department physician to call for an emergent echocardiogram. If a pericardial effusion is seen, and impending tamponade is identified, the effusion should be drained, the cardiac surgeon alerted, and the patient should be typed and cross-matched. Care should be taken while inserting the needle to drain pericardial fluid because an iatrogenic bloody tap will lead to an erroneous diagnosis of erosion. All markers



Figure 6. Difficulty retracting a snared Amplatzer septal occluder into the sheath.

(Courtesy of Frank Ing.)

of erosion should be evaluated by echocardiography. A bloody tap is almost always diagnostic unless it was clearly iatrogenic.

If pericardial tamponade occurs within a few hours of the procedure, it may be a catheter-related injury, and after draining the fluid, the patient should be observed before surgical referral unless the defect was determined to be high risk by echocardiographic evaluation.

Because erosion has occurred at more than 5 years after such procedures, all patients should be informed to always mention their ASD closure procedure to the emergency department physician if they experience hemodynamic compromise.¹⁵

Thrombus Formation

Thrombus formation is a relatively minor complication and should not occur if the patient is on adequate antiplatelet therapy. If it does occur, hospitalization with intravenous heparin typically dissolves the thrombus within a few days. A surgical option should always be considered as well.

New-Onset Mitral Regurgitation

In patients with atrioventricular valve rim deficiency, the edge of the device may sit on the anterior mitral valve leaflet and result in mitral regurgitation. If this is noticed in the cardiac catheterization laboratory, the device should be removed and replaced with a smaller device if the size of the defect allows it. Otherwise, the procedure must be aborted in favor of surgery. Mitral leaflet injury has been reported in some cases due to impingement by an Amplatzer device and wire fracture of a Helex device.¹⁶

Heart Block

Occurrence of heart block in the catheterization laboratory or a few days after the procedure can be reversed if the device is removed. Some physicians advocate steroids, but these do not help with heart block caused by a device implanted in an ASD.¹⁷

Nickel Allergy

In 2008, nickel was named contact allergen of the year because of a rising incidence of nickel allergy in the United States.¹⁸ Both the Amplatzer and Helex devices are made of nitinol, with approximately 45% nickel and 55% titanium. Nickel allergy is fairly common in humans, especially women. Fortunately, the allergic reaction is limited to skin contact (mast cells) and does not cause systemic reactions. In rare cases, systemic effects of nickel allergy have been described. These symptoms include chest discomfort, new-onset or worsening of migraine-type headaches with or without aura, and palpitations.¹⁹ Fortunately, these cases are rare, and the symptoms subside in a few months. Some physicians have used steroids to obviate these symptoms. In very rare instances, device removal has been performed. A nickel patch test is available, and some physicians advocate its use in patients with a previous history of nickel allergy. In general, placement of a device in patients allergic to nickel is safe and does not require any treatment. Patients should be made aware that in very rare instances and severe symptoms, the device may need to be removed.

CONCLUSION

Percutaneous ASD closure is a common procedure in the cardiac catheterization lab. The keys to successful

TABLE 2. THE 10 COMMANDMENTS OF SAFE AND EFFECTIVE ASD CLOSURE

Commandment	Complication Common to Closure Type
1. Thou shalt not have arrhythmias.	s, d
2. Thou shalt not have residual defects.	s, d
3. Thou shalt not have late device embolization.	d
4. Thou shalt not have thrombus formation.	s, d
5. Thou shalt not have erosions.	d
6. Thou shalt not have aortic valve issues.	d
7. Thou shalt not have mitral valve issues.	s, d
8. Thou shalt not have cognitive dysfunction.	s
9. Thou shalt not have embolic phenomenon.	s, d
10. Thou shalt not have late heart failure.	s, d
Abbreviations: d, device implantation; s, surgery.	

implantation include thorough echocardiographic evaluation, meticulous technique, prevention and capability of managing possible complications and adherence to the “10 Commandments of Safe and Effective ASD Closure” (Table 2). The echocardiographic markers described are rare, and in our experience, < 1% of secundum ASD are high-risk defects, giving us a chance to close more than 99% of cases. ■

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