Catheter Closure for ASD

A number of technical considerations may improve the likelihood of success in transcatheter atrial septal defect closure procedures.

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Transcatheter atrial septal defect (ASD) closure has become a widely recognized alternative to surgical closure for suitable secundum ASDs. The implantation procedure is relatively straightforward in many cases, but technical considerations may improve the chances of short- and long-term success and potentially reduce the likelihood of complications. Although a number of different devices are available worldwide, only two devices (Amplatzer septal occluder [AGA Medical Corporation, Plymouth, MN] and Helex septal occluder [W. L. Gore & Associates, Flagstaff, AZ]) have been approved by the US Food and Drug Administration for ASD closure in the United States. In this article, we discuss some of the technical considerations relating to patient selection, device selection, and conduct of the implantation procedure. Our comments in this article relate to patients with an isolated secundum ASD and a significant left-to-right shunt with volume overload of the right ventricle as the indication for ASD closure.

PATIENT CONSIDERATIONS

Transcatheter closure devices have been successfully deployed in young infants and in very elderly patients. Except in rare patients with significant comorbidities, ASD closure in infants has no demonstrated benefit compared to closure in early childhood. We generally recommend elective closure in children at approximately 4 to 6 years of age. Waiting until this age offers a greater margin of safety relating to catheter sizes and ease of handling any potential complications compared to performing the procedures in younger and smaller children. Reasonably healthy elderly patients with an ASD but without significant comorbidities (such as severe pulmonary hypertension, diastolic dysfunction, or atrial fibrillation) may have significant symptomatic improvement after ASD closure. In our center and others, age alone has not been associated with increased risk of procedural complications.[1]

ASD CONSIDERATIONS

Current transcatheter ASD closure devices are designed for closure of secundum ASDs; they are not indicated for closure of sinus venosus ASDs or ostium primum ASDs. Different types of devices can be readily used for secundum ASDs that are solitary, multiple ASDs, or residual ASDs after previously attempted surgical or transcatheter closure. Most secundum ASDs are solitary, and hemodynamically significant defects usually are greater than 6 to 8 mm in diameter by transthoracic two-dimensional echocardiography. Defects with a resting diameter > 25 to 30 mm in adult patients are generally considered relatively large.[2] In children, we would generally consider a defect with a diameter more than one-half the length of the atrial septum, measured in an apical four-chamber view to be a large defect.

Current transcatheter ASD closure devices have been designed to simplistically occlude a relatively central defect in a thin septum with a rim of septal tissue surrounding all or most of the ASD. Hemodynamically significant ASDs, however, often do not conform to this ideal concept. In our experience, the majority of large secundum ASDs are located adjacent to the aortic root. Little or no septal tissue is present over at least a small segment of the ASD in this region. Therefore, the finding of little or no septal rim immediately adjacent to the aorta in some views has not been considered by us to be unusual or a contraindication for device placement.[3] Location of the ASD more toward the pulmonary veins, superior vena cava, inferior vena cava, or atrioventricular valves is seen in approximately 5% of patients. Septal rim deficiencies in these areas may be a

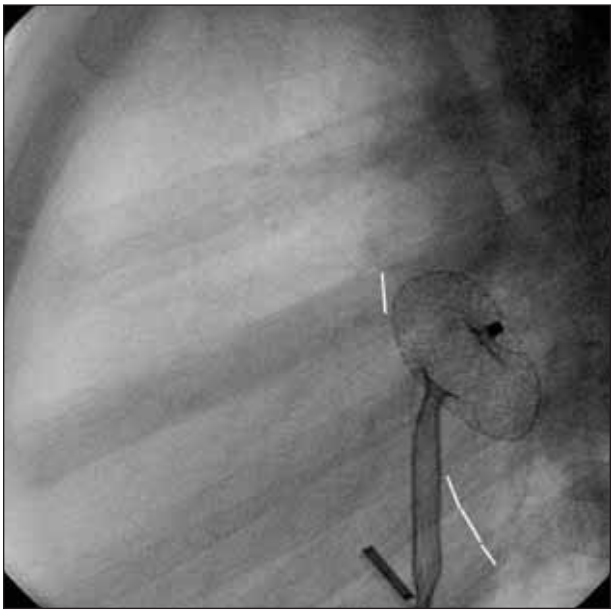

Figure 1. The lateral view of an Amplatzer ASD device being delivered with a straight side-hole delivery sheath, demonstrating a more parallel orientation of the device relative to the atrial septum. The white lines show the approximate location of the atrial septum.

relative contraindication for transcatheter closure, but experienced operators have successfully closed ASDs with unusual extensions into all of these areas using some of the more advanced techniques.[4-6] Approximately 10% of patients may have multiple ASDs. Most often, multifenestrated defects are associated with a thin and aneurysmal atrial septum. Usually, the defects are relatively closely spaced and can frequently be covered by a single "double-disk" type of device placed through one of the most centrally located small defects. In rare instances, defects may be separated by more than 15 to 20 mm. These widely spaced defects may require the use of more than one device. Very large secundum ASDs may have deficiencies of the septal rim in more than one region. These types of defects may be anatomically so large that the largest available transcatheter ASD device would not completely cover the defect or, in children, the required device may be too large to conform within the confines of the atrial chamber. Secundum ASDs that are not amenable to transcatheter closure in experienced centers occur in less than 20% of patients evaluated.[2]

DEVICE CONSIDERATIONS

The Amplatzer septal occluder is a self-expanding, woven nitinol mesh device designed to expand within the ASD and remain in place primarily by the expansion of the device against the walls of the ASD itself. It is our opinion that the Amplatzer septal occluder is the easiest device to deliver. It is simply pushed out of the appropriately placed delivery sheath, and it forms its intended shape with no additional manipulation needed. The device can be easily withdrawn back into the sheath and redeployed if necessary. The device has left and right atrial disks on either side of the central waist to provide some additional support. It is important to be cognizant of the fact that the left atrial disk is 12 to 16 mm larger than the nominal size of the device (which is the diameter of the central waist, not the left atrial disk). The left atrial disk will extend against adjacent structures in areas where the septal rim is less than the extension of the left atrial disk past the central waist of the device. The Amplatzer septal occluder is manufactured in sizes (waist diameters) from 4 to 38 mm for use in the United States, and slightly larger sizes are available elsewhere.

The Amplatzer cribriform occluder (AGA Medical Corporation) device and the Helex septal occluder are double-disk devices with a narrow central waist. The Amplatzer cribriform occluder device is similar in construction and delivery to the Amplatzer septal occluder but is designed primarily to close multiple ASDs. The Helex septal occluder is formed from a single length of nitinol wire draped with expanded polytetrafluoroethylene. The device is delivered incrementally and is more complicated for the operator to deliver. The delivery process involves several steps, and the operator must have a thorough understanding of how the device configures. The device is very soft and flexible. A unique feature is that a safety cord remains attached to the device even after it is released from the more rigid portions of the delivery system. The device is also more readily retrievable than other devices if it should embolize. The Helex device has only a thin central connection between the two disks. Therefore, because it is a noncentering device, the center of the device could be located at the center of an ASD or could slide toward the edge of the defect depending on the adjacent structures and the forces of atrial contraction. The largest Helex device is 35 mm in actual diameter, and the device is generally not indicated for closure of ASDs measuring more than 18 mm.

PROCEDURAL CONSIDERATIONS

Gentle technique and close attention to detail are important in achieving optimal results from transcatheter ASD closure procedures. These procedures involve the use of relatively stiff catheters and guidewires, large sheaths, and devices that can be large,

stiff, and thrombogenic. Adequate anticoagulation from the earliest parts of the procedure is recommended. Meticulous attention to detecting and eliminating air in large delivery sheaths is critical. Nearly every large series includes a small number of patients who have had perforations of the atria, thrombi, and transient ST changes with hypotension (almost certainly caused by air emboli). These are complications that should be infrequent. Patients with an ASD often also seem to be much more prone to developing atrial arrhythmias than the general population. These probably are not completely preventable, and methods of treatment should be anticipated.

There are significant variations in methodology for selecting the best device size for a given patient. We believe that there is enough advantage to careful balloon sizing of the defect to make balloon sizing part of our routine practice. Our device selection depends on balloon sizing for solitary defects, but the sizing is done with some specific techniques and precautions. We select a sizing balloon that is ideally approximately two times the echocardiographic estimate of the defect size. The balloon is placed over a stiff guidewire that has been carefully placed in a left pulmonary vein. Use of a large sizing balloon allows for measuring the waist created by the defect without ever fully inflating the balloon and thus avoiding the possibility of inadvertently enlarging the defect. The balloon is inflated only until cessation of flow, as determined by color Doppler. We prefer to measure the balloon waist created by the ASD both fluoroscopically and echocardiographically (either intracardiac echocardiography or transthoracic echocardiography), because one method may provide better delineation than the other in different patients. We find that the two measurements are always very close when excellent images are obtainable with both methods. We believe that balloon sizing helps account for variations in the firmness of the septal rims for deciding device size. We generally select an Amplatzer septal occluder equal to or 1 mm larger than the balloon occlusion diameter or a Helex device 1.8 to 2.3 times the balloon occlusion diameter. If balloon sizing is not practical, other operators have used Amplatzer septal occluders 4 to 6 mm larger than the largest echocardiographic diameter for defects < 14 mm and devices 5 to 8 mm larger than the largest echocardiographic diameter for defects ≥ 14 mm.[7] In patients with multiple small ASDs, we generally use a double-disk type device large enough to cover most, or all, of the detected holes. Balloon sizing of the most central defect is not necessary if that defect is small relative to the large device chosen to also cover adjacent defects. Special care may be needed to manipulate the delivery system specifically through the most central defect rather than through one of the more peripheral defects.

Placement of any of the transcatheter ASD closure devices would ideally be done by deploying the left atrial disk precisely in the plane of the septum on the left atrial side and then deploying the right atrial disk exactly parallel to the septum on the right atrial side. Unfortunately, devices are delivered from the femoral veins, and advancing or withdrawing the delivery sheath or catheter results in a suboptimal angle of approach. In many cases, the device can be adequately delivered and configured even at a suboptimal angle. The device will generally change orientation when the delivery mechanism is released. For more difficult cases, a number of methods have been proposed to improve the angle of approach to the septum.[8] Some interventionists advocate deploying the Amplatzer device in the left or right pulmonary vein, allowing the device to snap toward the atrial septum as the proximal portion of the device is uncovered. Others have advocated using a stiff sheath or a balloon catheter to hold the cephalad portion in a position to prevent it from prolapsing as the right atrial disk is deployed. Our preferred method is to use a long sheath, which we modify by cutting the curved portion of the sheath, in a direction that holds the left atrial disk at a more optimal angle (Figure 1) and in a more appropriate position as the right atrial disk is deployed.[9]

Before a device is released, we always try to ensure that we can identify an atrial septal rim between the left and right disks of the device in the anterior superior region near the aorta and at the inferior edge of the device near the inferior vena cava. We also ensure that the device does not distort or impair the motion of the mitral or tricuspid valves. In patients with deficient rims, it is important to be certain that the device straddles whatever rim is present. In some cases, ultrasound imaging with more than one modality—intracardiac, transthoracic, or transesophageal echocardiography—may be helpful.

LONG-TERM CONSIDERATIONS

Transcatheter closure of appropriate secundum ASDs is now generally viewed as the procedure of choice in centers with experienced operators. Surgery may still be required for up to 20% of unselected ASD patients because of limitations of the current transcatheter closure devices. Short- to intermediate-term outcomes of transcatheter ASD closure are at least as good as those of surgically treated patients. The major long-term concern that has arisen regarding transcatheter ASD closure devices is the rare, but potentially catastrophic, erosion

of a device into the aorta or pericardium. This complication most commonly occurs within days to weeks after implantation, but can occur even years after a procedure. The mechanism of erosions is not well understood. Most advocate avoidance of overly large devices, but overly large device size does not always appear to be present. Controversy continues over how best to prevent these rare events.[10] Erosions have been reported with all of the commonly used devices, except the Helex device. Because of this possible long-term safety advantage, we tend to use the Helex device in smaller defects, especially in younger children. A break in the nitinol frame may eventually occur in approximately 6% of the larger sizes of Helex devices, but these breaks have been without apparent clinical consequence, except in one reported case.[11] Truly long-term studies of late outcomes of all of the transcatheter ASD closure devices are needed to better understand the lifelong consequences of these devices and to further minimize potential late complications. ■

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