Cardiac Catheterization
and
Imaging
(From Pediatrics to Geriatrics)
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Foreword
Charles E Mullins
Dedicated to

Dr William J Rashkind
Father of Pediatric Interventional Cardiology, who pioneered catheter interventional techniques in infants and children

Dr Joseph K Perloff
who laid a strong foundation for the clinical recognition of congenital heart diseases in adults

Dr Andreas Grüntzig
who pioneered coronary angioplasty

and

Living legend, Dr Kurt Amplatz
who has paved the way for catheter-based device closures that leave no scars on the chest!

We respectfully salute these great GURUs for laying the solid foundation on which a great empire of cardiac catheterization and catheter-based interventions rests.
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This book is a reference encyclopedia of cardiac catheterization. It is authored by many contributors, tapping into their broad spectrum of expertise and years of experience in their particular areas of cardiac catheterization.

The text is unique for multiple reasons. First, it covers the spectrum of patients from the fetus to the geriatric patient. This includes coverage of congenital heart and central vascular lesions in the fetus, neonate, pediatric, and adult patients as well as extensive coverage of the acquired heart and vascular disease in the adult. The sections on coronary artery disease and its management especially are very comprehensive.

In addition, the text encompasses the entirety of cardiac, cardiovascular catheterization from the history of cardiac catheterization, the preparation of the patient, the imaging modalities available in preparation and during the procedure, the capital and expendable equipment required and, of course, the details of the techniques as well as the complications for all of the innumerable diagnostic and therapeutic procedures currently available to the interventional cardiologists.

The entirety of cardiac catheterization procedures starting with the basic techniques of catheter introduction, catheter manipulation, hemodynamics and anatomic assessment are included. From there, the latest therapeutic/interventional procedures including the latest equipment and procedures for cardiovascular support are covered. Finally, complications and their management are covered within each section on specific procedures. The exception is a separate chapter on contrast-induced nephropathy, which of course, potentially is common to every catheterization using contrast.

Finally, different from most texts on interventional cardiac catheterization and a welcome addition is the inclusion of an extensive section on electrophysiological diagnostics and therapeutics in the catheterization laboratory—those procedures which are performed in “the other room” from the general interventional procedures and from which many interventionalists might learn something!

The title of this text, edited by Dr IB Vijayalakshmi, Cardiac Catheterization and Imaging (From Pediatrics to Geriatrics) is a gross understatement on the magnitude of its encyclopedic content. The book should be a valuable reference source for the library of any interventional cardiologist, and/or institution supporting a cardiac catheterization laboratory.

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Among the greatest achievements in the cardiovascular medicine over the past century are the advent, development and refinement of invasive, diagnostic as well as therapeutic modalities in cardiac catheterization and catheter-based interventions. Courmand in his 1956 Nobel Lecture rightly said that, “The Catheter is ... the key in the lock”. How true are his words even to this day. Cardiac catheterization is the “gold standard” for the anatomical and physiological assessment of cardiac anomalies, coronary and most peripheral vascular diseases prior to interventions or surgery. It plays a vital role in children and in adults with congenital heart disease (CHD). Real-time fluoroscopy with contrast injection, coupled with rapid digital angiography has provided high-resolution images of the heart and the vessels offering a road map to cardiac surgeons for successful surgical management and interventional cardiologist to accomplish nonsurgical intervention with very high success rate.

In the preinterventional era, surgery was the only option. Over the past couple of decades, catheter-based interventions have taken over and become the minimally-invasive, effective and very attractive alternative to surgery in most patients with coronary artery diseases. Unique indications have developed in selected cases with valvular and peripheral vascular diseases. Greater understanding of the technical knowledge is now required for a wider range of available catheters, balloons, delivery systems, and devices. Novel applications have extended to acquired valve diseases, paravalvular leaks, postinfarction ventricular septal rupture, closure of left atrial appendage and degenerative diseases of the aorta. Transcatheter interventions are also used for palliative procedures in high-risk individuals where surgery could lead to high morbidity and mortality.

In the current era, nonsurgical and catheter-based interventions have revolutionized the management of congenital heart defects, such as pulmonary stenosis/regurgitation, aortic stenosis, coarctation of aorta, atrial septal defects, ventricular septal defects, patent ductus arteriosus, aortopulmonary window, ruptured sinus of Valsalva, aortic ventricular tunnels, coronary arteriovenous fistulae and palliation in many complex CHDs.

The book addresses the scope of cardiac catheterization and catheter-based interventions that have increased by leaps and bounds over the past fifty years. Thorough background knowledge of normal and abnormal cardiac anatomy, physiology and hemodynamics is required by the operators. We have therefore discussed these essentials in many chapters. Each chapter/set of chapters is arranged in an organized format, starting with a concise discussion of the lesion(s), followed by indications, procedural details, precautions and potential pitfalls. Contributions from a wide range of experts are amalgamated in the book. The goal has been to address a wide range of procedures/interventions available for a diverse group of diseases or defects. New emerging procedures and future directions for valvular diseases are also discussed.

The book offers the spectrum of cardiac catheterization and catheter-based interventions from pediatric to geriatrics. It covers literally the scope of these procedures from ‘womb to tomb’. It is intended as a practical guide for the interventional treatment of congenital, structural heart disease, coronary and peripheral vascular diseases to be used by invasive pediatric and adult cardiologists. Wherever possible, an attempt has been made to emphasize practical aspects related to procedures; such as patient selection, absolute and relative indications, contraindications and potential complications.

Some of the procedures discussed in the book are emerging techniques in the forefront of interventional cardiology, and may not be practiced in every cardiac catheterization laboratory. These represent the expertise of selected interventional cardiologists from around the world. The goal has also been to share clinical experiences in order to provide a practical procedural reference guide to catheter laboratory staff at all levels. We hope to offer guidance in acquiring these skills, while sharing the experience of using these techniques. Diagnostic catheterization only is as good as the accuracy of the acquired data and since all the interpretations are based on it.

The information contained in the book is free from bias. The fundamental concepts and recommendations are based on evidence-based data, clinical guidelines and peer-reviewed research. It also represents an accumulation of knowledge, techniques and procedures that have been learned, utilized and/or developed by various experienced cardiologists with rich experiences in teaching cardiac catheterization and interventions. We are grateful to all the authors for their contributions. We are truly grateful to Dr Chitra Narasimhan for untiring selfless help.

We are extremely fortunate and deeply indebted to the legendary Charles E Mullins, who has done the pioneering work and has contributed immensely for the growth of catheterization, especially most commonly used ‘Mullins sheath’; for writing the fabulous foreword for the book.

IB Vijayalakshmi
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**INTRODUCTION**

Atrial septal defects (ASD) are relatively common accounting for about 10% and 30% of all congenital heart diseases diagnosed in children and adults, respectively. An ASD creates a source for intracardiac shunting at the atrial level, and if left untreated may potentially lead to chronic volume overload state with risk of late morbidity; therefore, closure of hemodynamically significant defects is recommended. There are four different types of ASDs that have different anatomical and clinical features: ostium secundum, ostium primum, coronary sinus defects and sinus venosus ASDs. The primum ASD (15–20% of cases) is located in the inferior part of the atrial septum, near the crux of the heart and is associated with atrioventricular septal defects. The sinus venosus type (5–10% of cases) is located in the superior or inferior part of the septum, near the superior or inferior vena cavae entry to the right atrium. The superior part is usually associated with partial anomalous pulmonary venous drainage. The uncommon coronary sinus septal defect (< 1%), allows shunting across the ostium of the coronary sinus. None of these defects is amenable for device closure due to anatomical limitations.

Secundum ASDs are the most common (75% of cases), usually located at the level of the fossa ovalis. The vast majority of these defects result from complete absence, deficiency or multiple fenestrations of septum primum. In rare cases, secundum ASDs may result from incomplete development of the superior limbus of septum secundum. The superior limbus forms the superior and posteriorninferior boundaries of the defect. When the fossa ovalis valve is absent, the defect is typically circular resulting in shallow inferior/posteroinferior rims, whereas if the fossa ovalis valve is only deficient, the defect is typically elliptical in shape. Fenestrations can be variable and located anywhere in the septum primum. Secundum ASDs can vary widely in sizes, locations and shapes and it is important to note that these defects involve the fossa ovalis and do not include the vena cava, right pulmonary veins, coronary sinus or atrioventricular valves. However, the relationship to these structures is important when considering device closure. The anatomical rims viewed from the right atrial surface are as follows: the posterosuperior rim is the distance to the superior vena cava, the anterosuperior rim is the distance to the aorta, the posteroinferior rim is the distance to the inferior vena cava, and the anteroinferior rim is the distance to the tricuspid valve. Secundum ASDs are generally suitable for transcatheter device closure and has largely replaced surgical repair as the primary method of treatment in the majority of cardiac centers. In this chapter, we will review the state-of-the-art transcatheter techniques used in closing simple and complex secundum ASDs.

**PROPER PATIENT SELECTION FOR TRANSCATHETER CLOSURE OF SECUNDUM ASD**

It is important to understand the natural history of unrepaired ASDs in order to prevent the potential for significant long-term complications. Under normal physiologic conditions, flow through an ASD occurs from left-to-right to variable degree depending on the defect size, ventricular compliance and
the pulmonary vascular resistance. Excessive flow through the defect will eventually result in chronic right heart volume loading state, eventually leading to long-term complications in the second or third decade of life. These include premature death, atrial arrhythmias, reduced exercise tolerance, right ventricular diastolic and systolic failure, left ventricular diastolic failure and pulmonary arterial hypertension.\textsuperscript{5,6} The indications for surgical or percutaneous closure of an ASD are mainly related to its hemodynamic significance and include right atrial/right ventricular enlargement regardless of symptoms, paradoxical embolism and documented orthodeoxia-platypnea.

Transcatheter device closure is safe and effective when performed by experienced operators in properly selected patients; with major complications, such as cardiac perforation or device embolization, occurring in less than 1\% of patients. It is estimated that 85–90\% of all secundum ASDs are amenable to transcatheter closure including “complex” defects. Defect closure has evolved from a surgical procedure requiring cardiopulmonary bypass to a percutaneous procedure usually requiring only an overnight hospital stay. Comparative studies with surgical repair have shown the advantage of device closure in offering a more rapid improvement in right ventricular remodeling and differences in periprocedural morbidity.\textsuperscript{7–9} Although device closure should be considered the treatment of choice in most cases, there are special circumstances in which surgical repair should be considered as will be discussed below.

The presence of an ASD does not always necessitate closure depending on the clinical scenarios. Small ASDs with a diameter less than 5 mm and no evidence of right ventricular (RV) volume overload are generally managed conservatively with clinical and echocardiographic monitoring for progressive right heart dilation. In patients with either severe irreversibly pulmonary hypertension or severe left ventricular dysfunction, ASD closure is an absolute contraindication as it is physiologically needed to act as a “pop-off valve” for either the right or left ventricle, respectively. Other contraindications are outlined in Table 1.

Some patients with secundum ASDs are better served by surgical repair; those include patients with associated cardiac anomalies, other types of ASDs (primum, sinus venosus, coronary sinus defects), and those with unsuitable defect anatomy. Patients with stretched defects larger than 36 mm, or inadequate atrial septal rims defined by less than 5 mm, or those with proximity of the defects to the vena cavae, atrioventricular (AV) valves or coronary sinuses are usually referred for surgical repair. However, device closure has been routinely performed in defects with deficient rims, particularly of the anterosuperior septum which is present in 30–50\% of cases. Attempted closure in the presence of 2 or more deficient rims is not advisable with higher risk of device embolization. Weight restrictions have lessened over time and multiple reports demonstrated safe and effective closure in patients weighing less than 15 kg.

<table>
<thead>
<tr>
<th>Table 1 Contraindications for percutaneous closure of secundum ASD</th>
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<tr>
<td>Small ASDs of no hemodynamic significance</td>
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<tr>
<td>Severe irreversible pulmonary artery hypertension and no evidence of left-right shunt</td>
</tr>
<tr>
<td>Other types of ASDs (primum, sinus venosus, coronary sinus defect)</td>
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<tr>
<td>Unsuitable defect anatomy (see text)</td>
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<tr>
<td>Severe LV dysfunction with elevated LVEDP (&gt; 14 mm Hg)</td>
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<td>Poor state of the patient</td>
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<td>Current systemic or local infection</td>
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<tr>
<td>Bleeding disorder</td>
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<tr>
<td>Nickel allergy (relative contraindication)</td>
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<tr>
<td>Presence of intracardiac thrombus</td>
</tr>
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Abbreviations: ASD, atrial septal defect; LVEDP, left ventricular end diastolic pressure.

Whereas percutaneous closure of “simple” ASDs is more straightforward and successful, percutaneous closure of complex ASDs may require a variety of technical modifications to facilitate successful closure (see below). Characteristics of complex ASDs that portend a greater technical challenge include:

- Very large ASD in excess of 30 mm (unstretched diameter)
- ASD with more than one rim deficiency
- ASD with a rim deficiency other than an isolated deficiency of the retroaortic rim, particularly inferior vena cava (IVC) rim deficiency
- Multiple ASD and/or multifenestrated septum
- Aneurysmal atrial septum
- ASDs in small infants (< 5 kg).

**Imaging to guide ASD closure**

Transcatheter closure of ASDs requires precise delineation of the defect size, morphology, location and the rest of the atrial septal tissue. Echocardiography has evolved as the imaging modality of choice for the diagnosis of ASDs and plays an important role in the planning, guidance and follow-up of a successful transcatheter ASD closure. With advances in echocardiography technology, the imaging options have extended beyond the traditional two-dimensional transthoracic echocardiogram (2D TTE) and TEE (transesophageal echocardiogram) to include three-dimensional transthoracic echocardiogram (3D TTE), three-dimensional transesophageal echocardiogram (3D TEE) and intracardiac echocardiography (ICE) which provide images that are unique and complimentary to fluoroscopy. A detailed assessment prior to the catheterization is a crucial step in the planning for the transcatheter closure of an ASD to determine whether the defect is amenable to device closure, to identify
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the number of defects and to exclude the presence of any other congenital anomalies.

**TRANSCATHETER DEVICE CLOSURE WITH 2D-TEE**

**Measurement of the Rims**

To close the ASD, it is important for the interventionist to have good knowledge of the atrial septal rims and the structures that surround the ASD (Fig. 1). The atrial septum rim is classified as follows: aortic rim, the atrial septal rim that is adjacent to the aortic valve; superior vena cava (SVC) rim, the rim adjacent to the SVC; superior rim, the rim between the SVC rim and the aortic rim; posterior rim, the rim opposite to the aortic rim; inferior vena cava (IVC) rim, the rim adjacent to the IVC; atrioventricular (AV) rim, the rim adjacent to the AV valve. Complete echocardiographic assessment of an ASD should include measurements in three views that are utilized during the procedure: (1) the aortic short-axis view (between 20–40 degrees omniplane), to identify and evaluate the aortic rim and the posterior rim; (2) bicaval view (between 100–130°), to evaluate the SVC and IVC rims; and (3) four-chamber view (0–10°), to evaluate the AV valve rim. An adequate rim is defined as more than 7 mm. However, a minimum of a 5 mm rim of atrial septum around the defect has been suggested as a prerequisite for device closure. A deficient rim is anything less than 5 mm while absent rim if it is less than 1 mm.10

**Defect Sizing**

Views for defect sizing are optimal between 20° and 70° with careful search for the plane with maximal defect diameter. Balloon sizing is recommended for all defects that will be closed and is particularly helpful in irregularly shaped defects that have inconsistent echocardiographic dimensions on different imaging planes. Typically an AGA sizing balloon (18, 24, and 34 mm sizes) (AGA Medical, Plymouth, MN) or NuMED sizing balloon (20–40 mm) (NuMED Inc., Hopkinton, NY) is introduced directly through the skin over an extra-stiff wire placed in the left upper pulmonary vein. The balloon sizing technique employs the inflation of the balloon just until there is color Doppler TEE confirmation that the balloon successfully occludes the defect without residual shunts, this is followed by deflating the balloon until shunting reappears, then reinflating to eliminate the shunt (stop-flow technique).11

The diameter of the inflated balloon across the defect is then measured by echocardiography and fluoroscopy. The best echo view for measurement is to observe the balloon in its long axis. In this view, the indentation made by the margins of the ASD can be visualized and precise measurement can be made. It is important to immediately stop inflation when the shunt is abolished to avoid oversizing the defect which can be detrimental and can lead to potential complications. In some situations, balloon sizing can be cumbersome, such as in small patients with large defects and deficient rims. During balloon sizing, stop-flow diameter may not be achieved and even a minor indentation may not be seen by fluoroscopy. For such cases, total atrial septal length can be used to determine the size of the device. The total atrial septal length is determined by adding the AV valve and superior septal rims on the four-chamber view to the average diameter of the defect obtained by at least two views.

**Device Deployment**

Transesophageal echocardiogram has the major advantage of providing continuous monitoring of device position during deployment. After visualizing the catheter crossing the defect, the left atrial disk is deployed and pulled back against the atrial septum. If the left atrial disk is positioned properly, it should assume a flat appearance against the septum. If the left atrial disk is pulled prematurely before the waist is expanded, the left atrial disk may prolapse into the right atrium. Similarly, if the left atrial disk is not pulled sufficiently against the septum, the right atrial disk may inadvertently be released into the left atrium. Multiple views should be performed to confirm the presence of atrial tissue between the two disks, to exclude the presence of any other shunts, and to ensure that the device is not interfering with adjacent structures.

**INTRACARDIAC ECHOCARDIOGRAPHY**

Since its introduction to guide device closure of ASD and PFO in the early 2000s, ICE has evolved into an established imaging modality for such procedures. The main advantages of ICE over TEE for ASD closure include avoidance of general anesthesia, better visualization of the left atrium...
and posteroinferior part of the septum, shorter procedure times and the ability of the interventionist to perform the procedure as well as the imaging part without the need of additional echocardiographic personnel. Several ICE systems are currently commercially available including the AcuNav catheter (Siemens/Biosense Webster, CA), ViewFlex catheter (St. Jude Medical, MN) and the Ultra ICE catheter (Boston Scientific, Boston, MA).

The AcuNav catheter is available in 8-F and 10-F catheters, multifrequency (5-10 MHz), 64-elements, linear phased array ultrasound catheter. The catheter is steerable via a four way tip articulation allowing maneuvering in four directions. Equipment with a locking knob allows the tip of the catheter to be fixed in a desired orientation (Fig. 2).

Imaging Protocol for ASD Closure

**Intracardiac echocardiography** (ICE) imaging is initiated after positioning the catheter in the mid-right atrium to obtain the neutral or “home” view. In this view, the ICE catheter is parallel to the spine with the transducer facing the tricuspid valve (Figs 3A to D). In this position, the tricuspid valve, right ventricular inflow and outflow, and long axis of the pulmonary valve are seen. The atrial septum is not well seen in this view, however on occasion the anterior septum can be visualized. The “septal” view is obtained by rotating the catheter slightly posterior and rightward to face the atrial septum (Figs 4A to D). In this view, the entire length of the atrial septum and the defect are well seen. After advancing the catheter more cephalad toward the SVC and more rightward rotation, the SVC or “long-axis view” is obtained where the transducer faces the atrial septum and SVC is seen draining into the right atrium (Figs 5A to D). The atrial septum is visualized in a superior/inferior plane and corresponds to the TEE bicaval view. The inferior septum can be better visualized by withdrawing the catheter toward the IVC. The superior and inferior rims, as well as the defect, can be measured. While the ICE catheter is in a “locked” position, the entire catheter is rotated clockwise until it sits in a position where the transducer is under the aortic valve. Minor adjustments with less posterior flexion and more leftward rotation can demonstrate the “short-axis” view where the anterior and posterior atrial septal rims can be visualized (Figs 6A to D). This view corresponds to the short-axis view on TEE (with the right atrium in the far field and left atrium in the near field). After assessing the defect and the septal rims, balloon sizing and device deployment are performed as described above in either the short or long axis view.

Procedural Considerations

In recent decades, many devices have been developed for percutaneous closure of ASDs with high success rates. In this section, we will review the procedural details of the two commonly used devices, the Amplatzer Septal Occluder and the Gore HELEX Septal Occluder.

Depending on whether TEE or ICE is being used, the procedure can be performed under general anesthesia or conscious sedation, respectively. If ICE is used, two sheaths are inserted in the femoral vein. An 8-F or 10-F sheath is used for the ICE catheter, and a 7-F or 8-F sheath is used for the right heart catheterization. Both sheaths can be placed in the same femoral vein (if patient’s weight is > 35 kg) or bilateral veins (if patient’s weight is < 35 kg) (Figs 7A and B). If the femoral venous route is not available, we advocate the transhepatic approach as device deployment would be difficult using the subclavian or internal jugular veins approaches. An arterial line can be inserted, but seldom necessary unless patient’s condition is critical. After sheaths placement, unfractionated heparin at a dose of 100 units/kg is given with ACT goal of more than 200 seconds. Anticoagulation is very important during the procedure to avoid thrombus formation on the wires, catheters or devices. Intravenous antibiotic like cefazolin is usually given and repeated every 6–8 hours for total of 3 doses, however protocols differ between institutions. Aspirin at 81 mg/day is usually started 3 days prior to the procedure, and if allergic to aspirin, clopidogrel (Plavix) at 75 mg/day should be used.

Hemodynamic and Angiographic Evaluation

A complete right heart catheterization as well as an antegrade left heart catheterization through the ASD should
be performed. Particular attention should be given to the pulmonary artery pressures, pulmonary vascular resistance, Qp: Qs, as well as pulmonary capillary wedge pressure, left atrial pressure and left ventricular end diastolic pressure. In patients with left ventricular systolic/diastolic dysfunction where the ASD might function as a “pop-off”, documentation of left sided filling pressures is assessed both at baseline and with balloon occlusion to determine candidacy for closure. ASDs complicated by significant pulmonary hypertension are discussed separately here.

Although angiography may not be absolutely necessary, a right upper pulmonary venous angiogram is recommended for the majority of the patients (Fig. 8). This is usually performed using the hepatoclavicular projection [35 left anterior oblique (LAO) and 35 cranial]. This profiles the anatomy, shape and length of the atrial septum and serves as a road map that allows rotating the device and aligning it with the septum. Furthermore, the atrial septal length can be measured accurately using this angiogram, this is particularly helpful in small children where the device size may be
limited by the total atrial septal length. In situations where anomalous pulmonary venous drainage cannot be excluded, angiogram in the main pulmonary artery with levophase is recommended.

**Defect Sizing**

Crossing an ASD is straightforward most of the time. In the majority of cases, the defect can be crossed successfully using a Swan-Ganz catheter. However, if this fails, stiffening the catheter using a wire or switching to a multipurpose catheter might be needed. The catheter is positioned in the IVC/RA junction and advanced towards the septum while maintaining clockwise torque to point the tip posteriorly. If unsuccessful, the catheter can be pulled from the SVC while maintaining clockwise posterior torque to orient the catheter along the atrial septum until it crosses the defect.

After crossing the defect, the catheter is rotated clockwise and positioned in the left upper pulmonary vein. The catheter is then exchanged with a 0.035” extra-stiff, J-tipped exchange-length wire to give the best support for balloon advancement in the atrium (Figs 9A to D). The catheter and sheath are removed followed by introducing the sizing balloon directly through the skin and over the wire. Either
Amplatzer sizing balloon or NuMED sizing balloon (NuMED Canada, Cornwall, Ontario, Canada) can be used for static balloon sizing. The Amplatzer sizing balloon is available in three diameters: 18, 24, and 34 with a shaft size of 6–8 F, and can be used to measure maximum defect sizes of 20, 27 and 40 mm respectively. The balloon catheter is angled at 45º and there are radiopaque markers for calibration at 2, 5 and 10 mm. The NuMED sizing balloon ranges from 20 mm to 40 mm and has a shaft size of 8–9 F. The balloon selected is then inflated using the stop-flow technique as described above and balloon measurement is obtained in the long-axis view (Figs 10A to E). For fluoroscopic measurement of the balloon waist, angulate the X-ray tube so the beam is perpendicular to the balloon. Correct fluoroscopic angulation can be determined by ensuring wide separation of the markers on the balloon catheter. The balloon diameter is then measured at the site of the indentation. If a discrepancy exists between the echocardiographic and fluoroscopic measurements, the echocardiographic measurement is usually taken as it is more reliable. Once the size is determined, deflate the balloon and pull it back so that it occludes the venous entry site maintaining hemostasis, leaving the wire in the left upper
Section 4: Interventional Techniques for Shunt Lesions

It is important to avoid keeping the balloon catheter within the left atrium for prolonged time to avoid the risk of thrombus formation. This is a good time to recheck ACT level while device is being prepared.

Device Selection

Device selection depends on the size of the defect and the characteristic of the atrial septum. Currently in the US, only two devices are FDA approved for ASD closure, the Amplatzer Septal Occluder (ASO) and Gore HELEX septal occluder. For small defects, device choice is largely based on operator preference. However, as erosions have not been reported with the HELEX septal occluder, we prefer using this device for smaller ASDs. The Gore HELEX septal occluder is not recommended for defects larger than 18 mm or septal thickness greater than 8 mm as the 35 mm HELEX device is rather soft and flexible and may not provide the overall stability required for successful closure. Typically, a device 1.8–2 times the size of the defect is selected for closure. For Amplatzer septal occluder, a device size that is 0–2 mm greater than the stop flow diameter is usually selected if
the rims were adequate (> 5 mm). However if the superior/ anterior rim is deficient, we tend to select a device 4 mm larger than the balloon “stop-flow” diameter. It is important to avoid selecting a device that is more than 50% larger than the 2D diameter of the defect as this can potentially lead to device erosion.

**DEVICES DESCRIPTION**

**Amplatzer Septal Occluder**

(AGA Medical, Plymouth, MN)

The ASO is a self-expandable, self-centering, double-disk device made of nitinol (55% nickel; 45% titanium) wire mesh constructed from a 0.004–0.0075 inch nitinol (Fig. 11A). Nitinol has superelastic properties with shape memory, which allows the device to be placed inside a small sheath for delivery and then to regain its original configuration once outside the sheath. The ASO is tightly woven into two retaining disks connected in the center by a 3–4 mm smaller and slightly thicker circular waist, corresponding to the atrial septum. The device size is determined by the waist diameter and is manufactured in various sizes ranging from 4 mm to 40 mm (1 mm increments up to 20 mm; 2 mm increments up to 40 mm). The left atrium (LA) disk is larger than the right atrium (RA) disk. For devices 4–10 mm in size, the LA disk is 12 mm and the RA disk is 8 mm larger than the central waist. For devices larger than 11 mm and up to 32 mm in size, the LA disk is 14 mm and the RA disk is 10 mm larger than the central waist. For devices more than 32, the LA disk is 16 mm and the RA disk is 10 mm larger than the waist. Both of the disks and the waist have a separate single thin layer of polyester fabric sewn within their circumference. The polyester patches prevent flow through the device, enhance thrombosis within the device and promote closure of the defect. There is a small metal pin at the center of the left atrial disk that holds together the nitinol wires. For the attachment to the delivery
cable, there is an attach screw-in sleeve in a small metal strut recessed into the center of the right atrial disk. A microscrew at the end of the delivery cable attaches within the sleeve on the device. For device deployment, we recommend using a 6-F delivery system for devices less than 10 mm, 7-F for devices 10–15 mm, 8-F for devices 16–19 mm, 9-F for devices 20–26 mm, 10-F for devices 28–34 mm, 12-F for 36–38 mm, and 14-F for the 40 mm device.

The Amplatzer multifenestrated septal occluder “Cribriform” is designed for use in multiple ASDs. It has a narrow waist to place it through one of the central holes in the septal wall with the disks covering the surrounding holes. The LA and RA disks are equal in size. The device is available in 18, 25, 30 and 35 mm sizes (Fig. 11B).

The ASO devices are delivered through long sheaths that are manufactured by AGA (now part of St. Jude Medical). The delivery system contains all the necessary equipment needed to facilitate device deployment. It consists of a delivery sheath of specified French size and length and appropriate dilator; a loading device, used to collapse the device and introduce it into the delivery sheath; a delivery cable (internal diameter, 0.081 inch); a plastic pin vise which facilitates unscrewing of the delivery cable from the device during device deployment; Tuohy-Borst adapter with a side arm for the sheath to act as a one-way stop-bleed valve; and the device is screwed onto its distal end and it allows for loading, placement and retrieval of the device.

Figs 9A to D  ICE and fluoroscopic views during passage of (A and B) catheter and (C and D) guidewire through the ASD
Figs 10A to E  (A) Fluoroscopic image showing the balloon size.  
(B to E) Corresponding ICE images during stop-flow measurement by a balloon
All delivery sheaths have a 45° angled tip. The 6-F sheath has a length of 60 cm, 7-F sheath is available in lengths of 60 and 80 cm, and the 8-F, 9-F, 10-F and 12-F sheaths are 80 cm long.

**Gore HELEX Septal Occluder**

[WL Gore, Flagstaff, AZ (Arizona)]

The Gore HELEX device is a nonself-centering double disk device made of nitinol and expanded polytetrafluoroethylene (ePTFE) (Fig. 11C). The construction of the device consists of a curtain of ePTFE bonded to a single-piece wire frame of 0.012 inch nitinol. When deployed, the occluder has double disk shape that bridges the septal defect and held in position utilizing tension created by the wire frame and the blood pressure that pushes the ePTFE patch against the atrial septum. The ePTFE material has proven longevity and biocompatibility with rapid endothelialization characteristics. The ePTFE material is micro porous and will become attached to the atrial septum by cellular penetration through the membrane micropores. Over time, the endothelialization process will maintain the occluder in position and create a permanent defect closure. The delivery system consists of three components: a delivery catheter, a control catheter and a mandrel. The control catheter has a retrieval cord to retrieve the occluder. The HELEX is available in 15, 20, 25, 30 and...
35 mm diameters. The devices are delivered through a short 10-F sheath, although if using the monorail technique, a short 11–12 F sheath is required.

The Gore Septal Occluder (GSO) is a new device that is the result of the extended development and improvement of the HELEX septal occluder (Fig. 11D). Major changes have been made to the device and delivery system resulting in simplified implantation and retrievability steps. The new design of the GSO has improved the device apposition ability and tissue response whilst keeping its atraumatic design, low septal profile with minimal septal distortion and long-term biocompatibility. The GSO consists of a frame of five nitinol wires with platinum core that is covered by a tube of ePTFE. The platinum core enhances visibility on fluoroscopy. Similar to the HELEX device, the GSO is fixed in place by an intrinsic locking mechanism which passes through the center of the device from the LA to RA disk. The recommended device to defect size ratio is 1.7 and the device is currently available in 15, 20, 25 and 30 mm diameters.

Bioabsorbable Devices

(Biostar, Biotrek) (NMT, Boston, MA)

Biostar and Biotrek are unique in using bioabsorbable materials to optimize the biological response of the defect closure and reduce the burden of prosthetic material that remains in the heart once the closure is achieved. The Biostar has an engineered porcine intestinal collagen layer scaffold mounted on the STARFlex double umbrella metallic framework (Fig. 12E), while the Biotrek uses the synthetic polymer poly-4-hydroxybutyrate. The manufacturer of these two devices ceased to exist.

Cera ASD Occluder

(Lifetech Scientific, Shenzhen, China)

The Cera ASD occluder is a self-expandable double disk device similar in design to ASO device with less material on the left atrial side to minimize thrombotic complications. It consists of nitinol wire mesh coated with titanium nitride that enhances smooth antithrombotic endothelial covering and minimizes systemic nickel ion release. It is available in 6–40 mm size, requiring 8–14 F sheaths. The newer generation Ceraflex ASD occluder features a unique delivery system that provides maximum flexibility with 360° rotation to allow for accurate and controlled positioning and minimizes unwanted drag or pull on the implant (Fig. 12F).

Cocoon ASD Device (Vascular Innovations, Nonthaburi, Thailand)

The Cocoon ASD device is a self-expanding platinum-coated nitinol device that prevents systemic nickel ion release. It has two circular disks with a central connecting waist similar to ASO device. The disks are filled with 3 circular polypropylene sheaths (sewn at the right atrial disk, the central waist and the left atrial disk) to enhance thrombogenicity.

Pfm NitOcclud ASD-R

(pfms medical, Koln, Germany)

This is a double-disk device made from a single nitinol wire resulting in a very low profile design; a double-layer right atrial disk and a single-layer left atrial disk, reducing the metal used in the left atrium by 50% thus reducing the risk of clot formation. Furthermore, the left atrial side is completely covered by a polyester fabric sutured to the borders, minimizing contact between the metal and blood in this side, thus reducing the chance of clot formation. The device is available in 8–30 mm sizes and is easily retrievable and repositionable (Fig. 12G).

OTHER DEVICES

Occlutech Figulla Flex II ASD Device

(Occlutech GmbH, Jena, Germany)

The device is made of braided nitinol threads consisting of two disks and an intermediate waist. Inside each disk, there is polyethylene patch to facilitate immediate closure as this prevents blood flow through the device meshwork. The unique braiding technology allows the device to be manufactured without a left sided hub, minimizing both the risk of thrombus formation and damaging the distal wall of the left atrium during implantation. The device is fully recapturable and repositionable, available in 6–40 mm size, and utilizes a unique biopsy-forceps delivery cable mechanism that allows pivoting of the device, a feature that is advantageous in challenging large defects (Figs 12A and B).

CardioSEAL/STARFlex

(NMT Medical, Boston, MA)

The CardioSEAL/STARFlex family of devices consists of two square patches of polyester fabric hand-sewn to a stainless-steel skeleton. The CardioSEAL was a modified version of the initial Clamshell device. It consisted of two square Dacron patches, mounted between four spring arms composed of a nonferrous alloy (Fig. 12C). The device was available in diameter sizes from 17 mm to 40 mm. The STARFlex septal occluder represented a further revision of the CardioSEAL with the addition of small microsprings attached at the end of each opposing arm (Fig. 12D). These devices have been discontinued and the manufacturer of these devices (Nitinol Medical Technologies) ceased to exist due to financial problems.
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Figs 12A to F
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Figs 12A to I Various atrial septal defect closure devices. (A and B) Occlutech Figulla Flex II ASD occluder (Occlutech GmbH, Jena, Germany); (C) Cardioseal; (D) StarFlex (NMT Medical, Boston, MA); (E) Biostar (NMT Medical, Boston, MA); (F) Cera ASD occluder (Lifetech scientific, Shenzhen, China); (G) PFM NitOcclud ASD-R (pfm medical, Koln, Germany); (H) Transcatheter patch device (Custom Medical Devices, Athens, Greece); (I) Solysafe septal occluder (Swiss Implant, Solothurn, Switzerland)

**Transcatheter Patch Device**  
(**Custom Medical Devices, Athens, Greece**)  

The Transcatheter Patch utilizes a balloon-mounted, porous, polyurethane patch in combination with a defect bridging system for device apposition and immobilization until patch integration into adjacent tissue occurs. This device is flexible, biodegrades in situ and eventually will be replaced with native tissue (Fig. 12H).

**Solysafe Septal Occluder**  
(**Swiss Implant, Solothurn, Switzerland**)  

This is a self-centering ASD closure device consisting of two synthetic patches that are attached to wires made of a cobalt-based alloy called Phynox which has similar characteristics to nitinol by virtues of elasticity and memory retention (Fig. 12I). The wires are maintained in place by two wire holders on each side of the atrial septum. A major advantage of this system is the delivery over a guidewire instead of a long transseptal sheath. The device is fully retrievable up to the point that the guidewire is removed. Distribution of this device ceased in August, 2010, partly due to the high rate of wire fracture.

**CLOSURE TECHNIQUE**

**Amplatzer Septal Occluder**

**Device Delivery**  

Once the device size is selected, the proper size of delivery sheath is advanced over the guidewire to the left upper pulmonary vein. Once the dilator is advanced into the left
atrium, the sheath is advanced into the pulmonary vein holding the dilator steady. Both dilator and wire are removed carefully so as not to cause vacuum and introduce air into the sheath. This can be done during simultaneous flushing of the sheath. The sheath is aspirated carefully and slowly until there is no air in the sheath. To set up the device for loading, the delivery cable is passed through the loader and Tuohy-Borst adapter and is attached to the septal occluder by turning the device in counterclockwise direction while the cable is fixed in position. It is recommended to back off the device in a clockwise direction for ¼ turn to prevent too-tight attachment. The device is soaked in a flush solution and the delivery cable with the attached device is pulled into the loader while keeping the device under the surface of the fluid and under continuous flushing. The loader containing the device is then connected to the proximal hub of the delivery sheath. The cable with the ASO device is advanced to the distal tip of the sheath. Both cable and delivery sheath are pulled back as one unit to the middle of the left atrium.

Device Deployment

The left atrial disk is deployed first under fluoroscopic and echocardiographic guidance by retracting the sheath over the delivery cable. Since the mechanism of ASD closure using the ASO is stenting of the defect, the connecting waist is deployed partially prior to the LA disk reaches the septum. Once the LA disk sits in the appropriate position with the connecting waist stenting the defect itself, the right atrial disk is deployed. After deployment, the position of the ASO is carefully evaluated using echocardiography. A very gentle push-pull motion “Minnesota wiggle” on the delivery cable may facilitate better disk separation and assist the echocardiographic assessment to confirm that all rims have been captured. Color Doppler flow may show some residual flow through the device but should not show residual flow around it. If needed, an angiography can be performed in the hepatocavricular projection to profile the septum using either the side arm of the delivery sheath or a separate catheter inserted via the ICE sheath. Good device position manifests by opacification of the RA disk alone when the atrial septum using the ASO is stenting the defect, the connecting waist is deployed partially prior to the LA disk reaches the septum. Once the LA disk sits in the appropriate position with the connecting waist stenting the defect itself, the right atrial disk is deployed. After deployment, the position of the ASO is carefully evaluated using echocardiography. A very gentle push-pull motion “Minnesota wiggle” on the delivery cable may facilitate better disk separation and assist the echocardiographic assessment to confirm that all rims have been captured. Color Doppler flow may show some residual flow through the device but should not show residual flow around it. If needed, an angiography can be performed in the hepatocavricular projection to profile the septum using either the side arm of the delivery sheath or a separate catheter inserted via the ICE sheath. Good device position manifests by opacification of the RA disk alone when the contrast is in RA, and opacification of the LA disk alone on levophase return. If the position is deemed unsatisfactory, the sheath is advanced while retracting the delivery cable to recapture the device.

Once the device position is verified, the device is released by counterclockwise rotation on the pin vise attached to the cable. The delivery cable should be pulled back into the delivery sheath immediately after it detaches itself from the device to avoid injury to the atrial wall. The device typically reorients itself into a more appropriate position once the tension of the delivery cable has been removed. Final echocardiographic and/or fluoroscopic assessment is performed after device release (Figs 13 and 14).

HELEX Septal Occluder

Device Delivery

Once the appropriate device size is selected, loading of the occluder into the green delivery catheter is accomplished with the catheter tip submerged in a heparinized saline bath. A large volume syringe is attached to the red cap to flush the catheter. When the initial flushing is completed, the gray control catheter is pulled back with the attached syringe until only about 3 cm of the occluder remains outside the delivery catheter and the tan mandrel appears slightly curved. At that point, the mandrel luer is loosened while continuing to draw back on the gray control catheter hub until the entire occluder has been withdrawn into the green delivery catheter. The control catheter is then flushed into the bowl and the flushing syringe kept attached to the red cap to prevent air from entering into the delivery system until the catheter tip is placed inside the introducer sheath (Figs 15A to D). A 0.018” or 0.035” guidewire is loaded into the delivery catheter through the guidewire port with special attention that the occluder is sufficiently withdrawn into the green delivery catheter to avoid interference with the guidewire. The delivery system is then advanced through the introducing sheath and across the atrial septum until the radiopaque marker at the tip of the green catheter is positioned within the LA. The guidewire is removed at this time.

Device Deployment

The LA disk is deployed using “push-pinch-pull” method. The gray control catheter is pushed resulting in the device leaving the sheath and entering the left atrium. Next, while holding the green delivery catheter, the gray control catheter is pinched. Then the tan mandrel is pulled back approximately 2 cm, thereby gradually forming the left atrial disc. This sequence is repeated until the central eyelet exits the green delivery catheter tip demarcated by the radiopaque marker. Once the LA disk is deployed, the entire system is pulled back as one unit until the LA disk is in contact with the atrial septum under echocardiographic and fluoroscopic guidance. This is followed by deployment of the RA disk by holding the gray control catheter in a fixed position and gently exposing a portion of the RA side by withdrawing the green delivery catheter until the mandrel luer stops on the Y-arm hub at which time it is tightened. This is followed by pushing in the gray control catheter and then tightened at the hub. Proper device position is then confirmed using echo. If the position is acceptable, the red retrieval cord cap is completely removed and the mandrel luer is loosened. While holding the green delivery catheter in a fixed position, the lock is released by sharply pulling the tan mandrel at least 2 cm. At the completion of the lock and release step, the occluder
Figs 13A to F  Fluoroscopic steps in ASO device deployment and evaluation postdeployment
Figs 14A to E  Echocardiographic steps in ASO device deployment and evaluation postdeployment in the previous patient
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Figs 15A to C
is still loosely attached to the gray control catheter by the retrieval cord. If the position is unacceptable, the occluder can be removed by taking up any slack in the retrieval cord and securely reattaching the red retrieval cord cap and withdrawing the gray catheter while pulling the occluder into a linear form back into the green delivery catheter and the entire system is removed. If the device position is acceptable, the green delivery catheter is advanced to abut the device followed by removing the gray catheter gently (Figs 16A to I). Once the delivery system is withdrawn, the occluder cannot be removed using the delivery system and only can be recaptured using snare device. A long sheath (10 F or greater) positioned close to the device is recommended for recapture.

COMPLEX ASDs

**Closure of Large Defects**

There is no universal definition of a large ASD. However, ASDs requiring devices more than 26 mm are generally regarded as being large and complex and frequently associated with deficient rims. Closure of such defects is challenging with prolapse of the device into the right atrium because of the perpendicular orientation of the LA disk to the plane of the atrial septum. One approach to overcome this problem is by using a device that is 4 mm larger than the stop-flow diameter. If this is not possible or does not work, other maneuvers can be attempted. Several techniques have been described to overcome such difficulties in aligning the left atrial disk parallel to the septum, allowing successful deployment. These techniques are discussed here.

**Hausdorf Sheath Technique**

Hausdorf sheath (Cook, Bloomington, IN) is a specially designed long sheath with two posterior curves at its end, allowing for a better alignment of the left atrial disk to the interatrial septum (Fig. 17). It comes very helpful in cases of large ASDs with deficient retroaortic and/or anterosuperior rims, as the aortic edge of the disk is kept posteriorly and parallel to the septum, hence away from the aortic rim, preventing the LA disk from prolapsing into the right atrium (Figs 18A to H). The Hausdorf sheath now is available in sizes from 8–12 F with a length of 75 cm. The correct orientation of the distal tip of the sheath in the LA can be guided by the site where the side port comes off which should be towards the side of the operator and parallel to the table.

If the Hausdorf sheath is unavailable, same technique can be employed using a modified Mullins trans-septal sheath (Straight Side-Hole (SSH) technique). A Mullin’s sheath (Cook, Bloomington, IN), that is 1–2 F sizes larger than the minimum recommended diameter intended for the ASO, is cut with scissors in a direction parallel with the proximal straight length of the shaft at the base of the pre-existing curve. This results in an elongated opening that is at the side of the sheath (Figs 19A to D). The cut edges of the sheath are sharp so extreme caution is required while maneuvering the sheath inside the body. Further steps follow as for ASD closure with the LA disk essentially parallel to the septum.

**Pulmonary Vein Technique**

For large ASDs with deficient anterior rim, left upper pulmonary vein technique works well. The delivery sheath
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Figs 16A to F
is positioned in the left upper pulmonary vein (LUPV) with enough depth to ensure that the device will temporarily stay in the pulmonary vein while the sheath is being withdrawn. While the delivery cable is kept fixed, the sheath is withdrawn swiftly all the way to the RA. With partial deployment of the LA disk, an American football-like appearance is created. With further withdrawal of the sheath, the disk springs out of the pulmonary vein and slaps parallel onto the septum. If the device does not jump out of the pulmonary vein, gentle traction on the cable helps in withdrawing the device (Figs 20A to F). Extreme caution should be exercised to avoid injury to the pulmonary vein.

In case the technique fails, deployment of the device from the right upper pulmonary vein (RUPV) can be attempted (Figs 21A to E). Similar to LUPV technique, the LA disk is partially deployed in the RUPV followed by quick retraction to deploy the remainder of the LA disk, resulting in the disk jumping parallel to the atrial septum. Successive deployment of the connecting waist and RA disk should follow quickly before the sheath changes its position or the LA disk prolapses into the RA. In case the posterior rim is deficient, the RLPV approach can be tried.

**Dilator-assisted Technique (Wahab Technique)**

This technique can be well used for large ASDs with deficient anterior, anterosuperior or posterior rims. Basically, a long dilator from the contralateral femoral vein is advanced to the LA to hold the superior/anterior aspect of the LA disk while the assistant deploys the remainder of the device. Once the
RA disk is deployed in the RA, the dilator is pulled back to the RA (Figs 22A to H). Potential problems using this technique include: damage to the LA disk from the stiff dilator and disturbance of the fabric layers of the device.

**Balloon-assisted Technique**

This technique is similar in concept to the dilator-assisted technique, where a balloon catheter is used to support the LA disk during device deployment. This technique is used in large ASDs with deficient rims even if it is the posterior inferior rim. A second wire is advanced from the contralateral femoral vein and placed in the LUPV. A Meditech or Equalizer sizing balloons (Boston Scientific, Natick, MA) is inflated in the RA and pushed over the guidewire to abut the atrial septum from the RA side. The LA disk is deployed in the LA and then pulled back along with the delivery sheath towards the atrial septum so that the inflated balloon could support the LA disk. The waist and RA disk are then deployed. The balloon is deflated and pulled out along with the wire (Figs 23A to D).

**Right Judkins Guide Catheter Technique**

This technique described by Hijazi involves the use of a right Judkins guide catheter with inner lumen of 0.089” (Cordis, Miami, Florida). The guiding catheter is advanced inside a sheath into the mid-LA followed by withdrawal of the sheath into the IVC leaving the guide catheter in LA. Retracting the cable over the guide catheter deploys the LA disk in an orientation parallel to the septum, followed by deployment of the waist and RA disk.

**Closure of Multiple or Fenestrated Defects**

Multiple or fenestrated defects are not uncommon accounting for about 13% of total secundum ASDs. These are also frequently associated with aneurysm of the interatrial septum. Our approach to closing such defects depends on the distance between these defects on multiple planes by echocardiography. Most defects within 7 mm of each other can be closed successfully using single device deployed in the larger defect. Use of non-self-centering device like Amplatzer...
Figs 18A to H  (A to D) Closure of a large ASD with deficient anterior rim with the standard delivery sheath resulting in less optimal alignment of the device with the septum and prolapse into the right atrium (arrow); (E to H) Closure of the same ASD using Hausdorf sheath resulting in proper alignment of the device with the septum.
Cribriform or HELEX in the central defect is appropriate in these cases. Echocardiographic evaluation while occluding the larger defect with a balloon is also helpful in deciding whether one or two devices are needed. This would decrease the distance between the two defects or even compress the smaller defect. On the other hand, if the defects are in remote locations, residual shunting will persist and more than one device is needed. After crossing each defect separately, simultaneous balloon sizing for the defects is performed followed by positioning a delivery sheath in each defect. It is recommended that wire access be maintained through both defects as closure of one defect may make re-accessing the second defect difficult. Initially, the smaller device is deployed followed by the larger one. After verifying good position of both devices, release of the smaller device should precede the release of the larger device (Figs 24A to G).

**Pulmonary Hypertension**

Pulmonary arterial hypertension (PAH) is a rare but serious complication of unrepaired atrial septal defect, and the decision to close such defects in this patient
Figs 20A to F  Left upper pulmonary vein approach for deployment of ASO. (A to D) Delivery sheath placed in the left upper pulmonary vein and withdrawn to deploy both disks simultaneously; (E and F) Once the left disk springs out of the pulmonary vein, the cable is pushed to form the right disk. Device deployed and released.
Figs 21A to E Right upper pulmonary vein approach for deployment of ASD. (A to C) Delivery sheath placed in the right upper pulmonary vein and withdrawn to deploy both disks simultaneously; (D and E) Once the left disk springs out of the pulmonary vein, the cable is pushed to form the right disk. Device deployed and released.
Section 4: Interventional Techniques for Shunt Lesions

Figs 22A to F
population should be approached with caution and careful consideration. PAH is defined as a mean pulmonary arterial pressure more than 25 mm Hg in the setting of normal left atrial pressure less than 15 mm and a normal resting cardiac output, corresponding to PVR of more than 3 Wood units. No validated guidelines have been established regarding the closure of ASDs in patients with PAH. Some have suggested that ASD closure should only be considered if the peak pulmonary artery pressure is less than 2/3 of the systemic pressure and the PVR is less than 5 wood units/m². ASD closure is indicated in all symptomatic patients with net left-to-right shunt and resting O₂ saturation more than 92%. If there is a bidirectional shunt, then pulmonary vasodilator testing should be performed. If there is a net left-to-right shunt on vasodilation, or balloon test occlusion of the ASD shows a favorable response with a fall in mean pulmonary artery pressure and no drop in cardiac output or increase in right atrial pressure, then the ASD should be closed. In the absence of favorable response, the patient can be placed on pulmonary vasodilators and reassessed in the cardiac catheterization lab after 6 months. Borderline cases may benefit from fenestrated ASD device closure; although no studies to document survival with this approach is available.

**POSTPROCEDURAL CARE AND RESULTS**

Once the procedure is compete, ACT is checked and if appropriate sheaths are removed. We use a figure-of-eight suture to achieve hemostasis. Protamine sulfate can be used to reverse anticoagulation effect if ACT more than 250 seconds. Patients are asked to take endocarditis prophylaxis when necessary for 6 months after the procedure, as well as aspirin 81 mg daily for 6 months and clopidogrel 75 mg daily for 2–3 months. We have observed that the incidence of postclosure headache is much less in patients taking clopidogrel. Full activity, including competitive sport, is usually allowed after 4 weeks of implantation. The devices are MRI compatible.

Patients are typically observed overnight in telemetry wards. The following day, ECG, PA/lateral chest X-ray and TTE should be performed to assess the position of the device and the presence of any residual shunt. A repeat chest X-ray after 1 week is recommended to look for device position but not mandatory. Recheck ECG, chest X-ray and TTE at 6 months postprocedure for full assessment. If device position is good with no residual shunt or effusion, follow-up can be annual for the first 2 years, then every 3–5 years.

The ASO device has low device-related complications. Closure rates at 12 months post procedure are 98-100% and device embolization is rare (< 1%). Rhythm disturbances are often seen in the first 24 hours consisting of ectopic atrial beats and atrial tachycardia with very few patients requiring long term medical therapy. Release of nickel from the device with a peak at 1 month postimplantation has been described but clinical significance is questionable. A rare but serious complication is the erosion of the device through the anterior atrial wall and into the aortic root. Its incidence is estimated at approximately 0.1–0.3%. Although oversizing the device has been implicated as a potential causal factor, this could not be documented in all affected patients and therefore the exact etiology of this complication remains unclear.
Figs 23A to D  Balloon-assisted technique. (A) The left atrial disk is opened in the left atrium and pulled back towards the atrial septum. The inflated balloon in the right atrium is pushed against the septum; (B) Waist and right atrial disk are released with inflated balloon in position; (C) Balloon deflated and withdrawn back, right atrial disk pushed towards the left atrial disk; (D) Balloon and guidewire removed, final device position

Serious complications following HELEX closure are rare with 98.1% successful closure rate at 12 months post implantation. Cardiac perforation and tamponade have not yet been reported. Embolization occurs, but the device can be retrieved using a snare device and a long 10-F sheath. Wire fractures have been seen in a small percentage of patients (about 5–6%) and are usually of no clinical consequence as the wire is held secure by the fabric of the device and its comprehensive endothelialization.

**TROUBLESHOOTING AND COMPLICATIONS**

**Cobra Head Formation**

This describes the situation when the left disk is extruded from the delivery sheath assuming the shape of cobra head (Fig. 25). This is recognized by a distortion of the left atrial pin away from the axis of the left atrial disk and by failure of the
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Figs 24A to F

A

B

C

D

E

F
left atrial arm to flatten as it is pulled into the septum. This can occur if the left disk is opened in the pulmonary vein or the left atrial appendage, or if the LA is too small to accommodate the device. It can also happen if the device is defective or has been loaded with unusual strain on it. The general recommendations when this happens are to recapture the device, remove it from the delivery sheath, and expand it outside the body to see if the phenomenon reoccurs. If the cobra head forms again, a different device should be used. If the disk forms normally, the same device can be advanced and redeployed. A device with cobra head deformity should not be released.

Device Embolization

Device embolization is the most common complication encountered with ASD transcatheter closure, and all operators who are involved in such procedures should be prepared to perform percutaneous device retrieval in the event of device embolization. The risk has ranged from 0.5% to 3%.24 Device embolization usually occurs during the procedure or within the first 24 hours, however late embolization has been described.25 There are various causes of device embolization. This might be due to large and eccentric defect, defect with inadequate rims, adequate rims without enough oomph to hold the device, improper sizing of the defect, or improper implantation process. The IVC rim by far is the most common cause of device embolization. Even with the presence of adequate IVC rim, the septum is thin in this location. Furthermore, interrogation of the IVC rim before and after device deployment is limited echocardiographically making it difficult to determine if the two disks have sandwiched the thin septum. A typical scenario that should raise the suspicion of deficient IVC rim is the prolapse of the left atrial disk into the right atrium despite sufficient aortic rim. The most common site of embolization appears to be the left atrium, followed by the aorta, right ventricle and pulmonary artery.26 In the event of device embolization, the first objective is simply to get the device into a position in which it will not cause harm. Devices which have embolized to the atria should be stabilized with a snare or a bioprost to prevent migration to the ventricles. If the device is entangled in the AV valve apparatus, it is strongly recommended to refer the patient for surgical retrieval of the device as valvular injury might occur from aggressive attempts to retrieve the device.27 Every catheterization lab should be equipped with large Mullins-type sheaths (12-16 F) and should have various sized snare
catheters. To snare a device, we usually use a long sheath that is 2-F sizes larger than the delivery sheath. Amplatzer Goose Neck Snare (ev3, Plymouth, MN) or Ensnaire (Merit Medical, Salt Lake city, UT) is then used to snare the female screw site of the right atrial disk. A 15–20 mm snare, regardless of device size, is usually preferable as larger snares are not helpful. A bioptome cannot pull the right atrial disk screw with enough force back into a sheath but may aid stabilization as described above. A snare may be advanced through the long sheath alongside the bioptome. Once the microscrew is snared, the bioptome is removed and the device is pulled into the sheath. Some operators recommend pulling the device back from the right atrium to the IVC to elongate the device and limit the migration. Once in the low IVC, a stiff wire is advanced through the device and stabilized in the SVC to limit the device’s ability to migrate followed by snaring the device out through the sheath. On rare occasions, the LA fails to collapse inside the sheath. In this scenario, another snare or bioptome is introduced from the right internal jugular vein to hold the stud of the microscrew of the LA disk and stretch it toward the internal jugular vein while the assistant pulls the device with snare toward the femoral vein. This allows the device to collapse further and come out of the sheath in the femoral vein. If the device is in the pulmonary artery, attempts should be made to capture and retrieve the device by advancing the sheath into the pulmonary artery over a wire that was placed through a balloon-tipped catheter.

The HELEX device has a retrieval cord that allows for easy retrieval of a device that does not lock appropriately. Similarly, a device that is not locked can also be snared easily back into the HELEX delivery sheath. Devices that are locked are much more difficult to retrieve. Snaring of the left atrial eyelet, which is attached to the locking loop, is necessary for successful retrieval. The locking loop that holds the device together originates from the left atrial side, thus pulling the device from this side unlocks the lock mechanism and permits the device to unravel. The right atrial eyelet is then pulled back into the rescue sheath.

Device Recapture

To recapture an ASO device prior to release, the operator should hold the sheath at the groin with the left hand and pull the delivery cable forcefully inside the sheath using the right hand. If the sheath is damaged or kinked, the exchange (rescue) system to change the damaged sheath is needed. The system components consist of a delivery sheath, delivery cable and a dilator, which incorporates an enlarged inner lumen for passage over an amplatz delivery cable. First, the rescue cable is attached to the proximal end of the delivery cable to extend the length of the cable. The sheath is then exchanged, or if it is larger than 9-F, the dilator of the rescue system is introduced over the cable and advanced inside the sheath until it is few centimeters from the tip of the sheath. This will significantly strengthen the sheath, allowing the operator to pullback the cable and the dilator as one unit inside it.

Release of the Device with a Prominent Eustachian Valve

To avoid the possibility of cable entrapment during release, the sheath is advanced towards the hub of RA disk. The cable is then released and drawn back quickly into the sheath before the sheath position is changed.

Air Embolism

Air embolism is rare but potentially lethal complication. Meticulous technique must be followed to prevent air entry, especially in the sedated patient with obstructive sleep apnea causing high negative inspiratory pressure in the LA. Such patients might need continuous positive airway pressure or bilevel positive airway pressure during the procedure to prevent this complication. Forceful negative pressure should not be applied to aspirate the sheath. We routinely tend to create small side holes at the tip of the sheath to facilitate blood withdrawal. Most commonly embolization involves the coronaries but also can involve the central nervous system. Air embolism is more likely to the right coronary artery due to the anterior and superior location of the right coronary sinus in the supine patient. The most common manifestations of air embolism include inferior ST elevation, chest pain, sinus bradycardia, heart block and other arrhythmias. Fortunately permanent sequelae are rare. If coronary embolism occurs, a catheter is inserted to engage the right coronary sinus followed by forceful injection of saline or contrast to displace the air. Alternatively, air embolectomy can be performed using an end-hole catheter.

Arrhythmias

New onset arrhythmias tend to be more common in adult patients with the most common complication being new-onset atrial fibrillation (incidence 4.3%).28 Exact etiology remains unclear but marked foreign body reaction or thrombus formation might be related.29 Large device to defect ratio and in general large devices seem to increase the risk of arrhythmias. Management of atrial arrhythmias is routine and may include medications or cardioversion to control ventricular rate and maintain normal rhythm. Rarely, complete heart block might occur.30 In the majority of cases, this resolves after device removal. It is strongly recommended to electively remove the device even if intermittent complete heart block is seen. Steroids do not seem to help as the complete heart block is secondary to mechanical compression of the disk.
Device Erosion

In a recent presentation at the April 2012 Pediatric Interventional Cardiac Symposium (PICS), data review from multiple databases identified a total of 97 worldwide erosion cases (48 in the US) associated with the on-label use of the ASO device from December 1998 to March 2012 (Table 2). The incidence of device erosion worldwide was 0.04–0.17% and in the US was 0.07–0.11% (based on number of devices sold or implanted, respectively). Most of the erosions occurred at the roof of the atria, near the aortic root: 47 involved perforation of the roof of the left atrium (with 28 involving the aorta), 26 involved perforation of the roof of the right atrium (with 22 involving the aorta), 9 involved both atria and in 15 the site was unknown. Although the mechanism of erosion was not pinpointed, it was noted that the most frequently observed relationship to erosion was oversizing and deficient anterior/superior rim. Oversizing was noted in 40% of cases: 31% of the pediatric cases and 46% of the adult cases; deficient anterior/superior rim was noted in 90% of cases: 100% of pediatric cases and 46% of the adult cases; deficient anterior/superior rim or were oversized, or both.32

Most of the cardiac perforations occurred within the first year of implantation and none occurring in patients younger than 15 years. Of note, all death cases were considered to have deficient anterior/superior rim or were oversized or both.32 To minimize the risk of erosion, the defect should not be overstretched during balloon sizing, patients with aortic rim deficiency spanning 30º or more and those with septal malalignment in the absence of adequate rim should not be selected for device closure.22

CONCLUSION

Transcatheter closure of secundum ASD has evolved into a very safe procedure with comparable results to surgical closure and excellent long-term outcomes. Patient selection and operator experience are very important for the success of the procedure. Future improvements in percutaneous technology may ultimately allow transcatheter closure of the other ASD types.

The physician should not treat the disease but the patient who is suffering from it.

—Maimonides

REFERENCES


