Cardiac Sciences Program Learning Module

PFO/ASD Closures: Indications, Techniques and Complications

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Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closures

Anatomy

The septum is the muscular wall separating the heart into left and right sides. The atrial septum is the wall separating the atria and the ventricular septum is the wall separating the ventricles. The foramen ovale is a small hole located in the atrial septum that is used during fetal circulation to speed up the travel of blood through the heart.

An atrial septal defect (ASD) is a hole in the septum, or muscular wall that separates the two atria. An ASD occurs when part of the atrial septum does not form properly.

Within the broad category of ASDs, there are several types of defects. Atrial septal defects are classified by where they occur and their size.

- **Secundum ASD** – is a hold in the middle of the atrial septum, which lets blood flow from the left chamber to the right chamber, or from the right chamber to the left chamber, depending on pressures in the atria.
- **Patent foramen ovale (PFO)** – is a ‘flap’ that is present when the atrial septum does not close properly at birth. A PFO allows blood to flow from the right atrium to the left atrium. This type of defect generally only permits blood flow when there is more pressure inside the chest, such as straining during a bowel movement, coughing or sneezing. The prevalence of PFO is approximately 25% in the general population.
- **Sinus venosus or primum ASD** - are more complicated and rare types of ASDs that involve different parts of the septum and also involve abnormal blood return from the lungs (sinus venosus) or heart valve abnormalities (primum ASDs).
What Causes ASDs?

Secundum ASD is the most common congenital heart defect to present into adulthood. Approximately 10 percent of congenital heart problems are caused by specific genetic defects. Most congenital heart defects are likely due to maternal environmental factors combined with a genetic predisposition. Environmental factors during pregnancy include use of alcohol and street drugs, as well as diseases such as diabetes, lupus and rubella.

Atrial septal defects account for about seven percent of all congenital heart defects, making them the third most common type. In addition, ASDs are the most common congenital defect in adults and are more common among women than men.

What are the long-term effects of ASDs?

Normally, the right side of the heart pumps blood that is low in oxygen to the lungs, while the heart’s left side pumps oxygen-rich blood to the body. When there is an ASD, blood from the left and right sides mix, and the heart generally does not work at its most efficient level.

The risk of problems is greater when the defect is large (greater than 2 cm). Problems may include:

- Right heart enlargement (leading to right heart failure)
- Heart rhythm disturbances, including atrial fibrillation or atrial flutter, occur in 50-60% of all patients over age 40 with an ASD
- Ischemic stroke
- Pulmonary hypertension. Blood normally flows from the left side of the heart to the right, but in patients with an ASD and severe pulmonary hypertension, the blood flow across the ASD can reverse (flow right to left). As a result, oxygen levels in the blood will decrease, leading to a condition known as Eisenmenger syndrome (or tardive cyanosis, which is the process in which a left-to-right shunt caused by a congenital heart defect causes increased flow through the pulmonary vasculature, causing pulmonary hypertension, which in turn, causes increased pressures in the right side of the heart and reversal of the shunt into a right-to-left shunt)
- Leaking tricuspid and mitral valves as a result of the enlargement of the heart
What are the symptoms of ASD?

The severity of the symptoms often depends on the size of the hole. Large ASDs may cause fatigue, pulmonary hypertension, arrhythmia, and/or an enlarged heart.

Although ASDs are present from birth, there are usually no associated symptoms and the condition can go undetected until adulthood. In some patients, the defect is discovered incidentally during a chest X-ray that reveals enlargement of the right side of the heart. By age 50, an individual with an ASD may start having symptoms such as shortness of breath, fainting, irregular heart rhythms or fatigue after mild activity or exercise.

In people with a PFO, a stroke may be the first indication of the defect. More than 40% of people who have a stroke but do not have any other risk factors for a stroke are diagnosed with PFO.

How is an ASD diagnosed?

An assessment for an ASD may include:

- EKG
- Chest X-ray – to evaluate the size of the heart and the blood vessels that supply blood to the lungs
- Transthoracic echocardiography (TTE)/Doppler examination – an ultrasound image of the heart combined with measurements of blood flow to assess the heart’s structure and function
- Transesophageal echocardiography (TEE)/Doppler examination – an ultrasound image obtained via esophagus to provide a clearer image of the atria, more precisely define the defect’s size and shape and to evaluate the health of the heart valves. The use of TEE helps the physician easily distinguish a PFO from other types of ASDs
- Intracardiac echocardiography (ICE)/Doppler examination – an ultrasound image obtained by inserting a tiny camera (echo probe) into the chambers of the heart via a peripheral vein. The test can define the size and shape of the defect and the direction of the blood flow across it. This study often is used during percutaneous (nonsurgical) repair of the defect
- Cardiac Magnetic Resonance Imagin (MRI) – this test may be performed to assess the ASD and rule out other congenital heart defects. It can also be used to assess the amount of blood being shunted and look for right ventricular (RV) enlargement
• Right heart catheterization – a catheter is inserted into the heart via the peripheral vein. Pressures and the amount of oxygen in the blood (oxygen saturation) are measured in each chamber. The oxygen saturations determine how much blood is flowing across the ASD by measuring how much the oxygen level increases beyond the site of the ASD. The ASD also can be crossed using a catheter and sized with a balloon, or contrast dye can be injected into the left atrium to determine the size of the defect (atrial angiogram)
• Left heart catheterization – during this procedure, angiography can be performed to check for significant coronary artery disease

How is an ASD treated?

Treatment of an ASD depends on the type and size of the defect, its effect on the heart and the presence of any other related conditions, such as pulmonary hypertension, valve disease or coronary artery disease.

In general, when a patient has a large ASD that causes significant shunting (flow of blood through the defect) and right-sided heart enlargement, specialists recommend correcting the defect.

The size of the defect correlates with the degree of shunting – the more shunting, the greater the risk of long-term complications such as atrial fibrillation and pulmonary hypertension. The degree of shunting is determined by echocardiography, MRI or oxygen saturations measured during catheterization. The degree of right-heart enlargement, as measured by echocardiography or MRI, usually correlated with the degree of shunting.

ASD Repair – Nonsurgical Treatment

Nonsurgical, percutaneous (through the skin) is the preferred treatment for most secundum ASDs, but surgery may be needed to repair other types of ASDs. The procedure requires cardiac catheterization to guide placement of ASD closure devices. The catheterization procedure will typically take 1-2 hours to complete and may require the use of general anesthesia.

At St. Boniface patients there are 2 different brands of closure devices that may be utilized – the Amplatzer® Septal Occluder and the Gore HELEX® Septal Occluder. The closure devices differ in design, but the placement method and their function are similar. The device is attached to a catheter, which is inserted into a vein in the groin and advanced to the heart and through the defect, guided by X-ray and intracardiac echo (TEE). There may be the possibility that intracardiac echo (ICE) will be used and involves passing an imaging device up to the heart through the vein in the patient’s other leg. As the device is slowly pushed out of the catheter, it opens up to cover each edge of the defect, sealing it closed. The device will remain in the heart permanently to stop the abnormal flow of blood between the two atrial chambers of the heart. Over time, tissue grows over the implant and it becomes part of the heart.

For at least the first 6 months after the repair, the patient will need to take an anticoagulant such as aspirin, clopidogrel or warfarin to prevent clots from forming on the device.
The Amplatzer® Septal Occluder is a transcatheter closure device that consists of two Nitinol (nickel-titanium metal alloy) wire mesh discs filled with polyester fabric. The 2 discs are linked together by a short connecting waist, allowing free motion of each disc and matching the size of the defect. The discs and the waist are filled with polyester fabric to increase the device’s closing ability. The polyester fabric is securely sewn to each disc by a polyester thread.

The occluder is folded into a special delivery catheter, similar to the catheter used during catheterization. The atrial septum and the catheter is in the proper position, the device sit on each side sandwich. The double-disc oppose the septal wall on create a platform for tissue implantation.

The GORE HELEX® Septal Occluder is a disc-like device comprised of a nickel-titanium (Nitinol) wire frame covered with expanded polytetrafluorethylene (ePTFE). The ePTFE 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 is folded into a special catheter and using a guide wire, the device is advanced through the atrial septum. When the catheter is in the correct position, the device slowly is pushed out of the catheter until it covers the defect. The device bridges the septal defect.

**How does the body react to a permanent implant?**

The materials used in the occluders have a proven long-term safety history and have been widely used in heart surgery procedures. It is not likely that the body will have a negative reaction to these devices. Within a few days, the body’s own tissue will begin to grow over the device. By 3-6 months, the device is completely covered by heart tissue and at that point becomes a part of the wall of the patient’s heart.

The patient will not be able to feel the device. The implant will not be affected by airport or other security sensors, or by any household appliances, or medical imaging methods. These devices are approved in most conventional MRIs, however, the clarity of MRI or CT images may be slightly reduced because of the wire frame on the occlude devices. For this reason, patients will receive an identification card that should be carried with them to show to medical personnel or imaging technicians if necessary.

**Contraindications to Catheter-Based Repair of ASDs**

Surgical repair may be needed for large secundum ASDs and other types of ASDs. ASD closure devices cannot be used:

- If the ASD is too large to be adequately closed by a catheter-based closure device
- If the ASD is not a secundum ASD
- If the particular patient’s heart structure does not allow an ASD closure device to be used such as in the case where there is not enough atrial septal tissue left to secure the device
- If the particular patient’s blood vessels are too narrow to allow the catheter-based delivery system to be used
- If the patient has severely elevated lung or right heart pressures (the physician will determine eligibility)
- If the patient has blood clots in their heart
- If the patient needs surgery to fix other heart defects
- If the patient has a bleeding disorder, untreated ulcer, or is unable to take aspirin or clopidogrel
- If the patient has an active infection anywhere in the body (the device can be implanted after the infection is completely gone)
**Surgical Repair of ASDs**

The catheter-based procedure for ASD closure usually results in much shorter hospital stay, reduced scarring (limited to the leg area where the catheter is inserted), and an easier, more rapid recovery. With open-heart surgery, an incision in the chest is required to expose the heart. A heart-lung bypass machine is used to pump blood for the heart while the heart is stopped and the wall defect is being repaired. The defect is closed by sewing a patch in place (if the defect is large) or by stitches (if the defect is small). Surgical patients usually stay overnight in the cardiac intensive care unit and then 3-5 days in the hospital and 4 weeks of additional recovery time is necessary at home.

**Follow-Up Care**

Bed rest in the hospital for 4-6 hours after device placement is required. The patient will remain as an inpatient on the cardiology ward for a total of 3 days for observation. Within 24 hours after the procedure, a chest x-ray, EKG, and echocardiogram are conducted to make sure that the device is positioned correctly and to determine if any residual leak is apparent.

The patient may experience minor pain at the catheter incision site and a slight sore throat for a few days if an ultrasound probe (TEE) was used to check device placement. The patient will be instructed not to lift anything greater than 10 lbs for 1 week after the procedure. The physician will discuss when the patient can return to regular activities (usually within a week).

The patient usually returns to the cardiology specialist at 3 and 12 months after a procedure for a follow-up physical exam and echocardiogram, and once a year thereafter. After a secundum ASD is repaired, most people can return to their regular activities without any activity restrictions (other than those associated with all heart catheterizations). Patients usually take anticoagulants for 6 months to a year after the repair to prevent blood clots and help the health process. Patients who have had a stroke may need to take anticoagulants indefinitely.

Patients who have heart surgery to repair a defect or receive a transcatheter closure device will need to take preventive antibiotics for at least 6 months after the repair procedure to reduce the risk of infective endocarditis. The physician will provide specific guidelines about when to take antibiotics.
St Boniface Plan of Care for Percutaneous Closure of ASDs

- Patients have been referred to Drs Kass or Hussain for ASD closure from family physicians or Cardiologist
- A pre-procedure TEE will likely already have been ordered and completed by the patient’s family physician or Cardiologist during the work up and diagnosis of ASD
- Only secundum ASD closures to maximum of 25-30 mm will be done
- PFO <10 mm will be done
- All patients planned for secundum ASD closures will have a general anesthetic and will be seen in CPAC. The pre-angiogram order set will be ordered for admission to the hospital and will include an order for post-procedure limited echo on post-procedure day 1
- Presently PFO closures will also have a general anesthetic and will be seen in CPAC. In the future, PFO closures may potentially have local anesthetic in conjunction with Cardiac ICE (intra-cardiac echo) and will then be seen in pre-angio clinic for teaching in the future
- Patients will be admitted as an elective outpatient to the cardiac pre- and post-procedure area and be prepped for the cath lab. This will require the establishment of IV access and preparation of the right and left groin as per pre-angio routines. The wrist may also be used and should be prepped. The pre-angio order set will be used for care and preparation of the patient
- All ASD/PFO closures will occur in Cath Lab #2 with a dedicated anesthesia machine
- Anesthesia support will occur for general anesthesia (requiring endotracheal intubation of patient) and echo expertise
- In addition an echo physician will be present for trans-esophageal (TEE) support during the ASD closure in the initial cases
- Intracardiac echo (ICE) options may be used in the future
- Patients will have general anesthesia with anticipated time of sedation 20-30 minutes
- Typically 2 venous access sites are required (one in each groin) and are done with 8 French introducer/sheath. Arterial access for angiogram may be required if a patient has not had a pre-procedure angiogram and typical access site will be radial.
- TEE will be performed intra-procedure along with endotracheal tube to guide deployment of the ASD/PFO occluders
- The expected intervention time is approximately 30 minutes. Total time from beginning to end of case will be 2 hours each and aiming for a potential 3 cases per day.
- Once the occluder has been placed and the catheters removed, sheaths will be removed in the cath lab
- The patient will be extubated by the anesthetist prior to transfer of patient from the cath lab to PACU
- The patient will recover in PACU for a period of approximately 1 hour, or until deemed stable to be transferred to the cardiology in-patient unit
- While in PACU, anesthesia issues will be addressed by anesthetist and vascular issues address by interventional physicians
- The patient will admitted to the in-patient cardiology unit initially into an intervention/overnight bed and to be transferred to the teaching service with anticipated total stay of 3 days
- Within 24 hours of procedure, the patient will have a repeat limited echo performed with expected follow-up echo in 3 months and within 1 year to identify any residual leak
- Upon discharge the patient will have follow up with the interventional Cardiologist at 3 and 12 months for a follow-up physical exam and echocardiogram, and once a year thereafter.
• Upon discharge most people can return to their regular activities without any activity restrictions (other than those associated with all heart catheterizations)
• Patients usually take anticoagulants for 6 months to a year after the repair to prevent blood clots and help the health process
• Patients who have had a stroke may need to take anticoagulants indefinitely
• Patients will need to take preventive antibiotics for at least 6 months after the repair procedure to reduce the risk of infective endocarditis for all dental and relevant procedures you may have. The physician will provide specific guidelines about when to take antibiotics

Potential Risks

There are risks with cardiac catheterization procedures as well as additional risks that may be associated with the device. Potential risks include, but are not limited to:
• Erosion of device into other heart chambers or into the lining of the heart – risk 1/500. May manifest as chest pain, sudden cardiac death, or dizziness. This complication most commonly occurs in the 1st 72 hours, but has been reported to happen out to 3-5 years. This requires open heart surgery to correct.
• Arrhythmias - <1-2%.
• Device embolization or movement of device to unintended location during or after procedure – approximately 1%. Device may be retrievable with catheters or may need open heart surgery to retrieve the device and close the ASD.
• Vascular (blood vessel) complication or rupture – 1-2%. May require blood transfusion or surgical repair.
• Stroke or mini-stroke or clot formation on the device – 1%.
• Headaches/migraines – uncommon, but may occur or persist post device. These are generally treated conservatively.
• Fever/device infection - <1%.
• Allergic dye/contrast reaction - <1%.
• Hemolysis – breakdown of blood due to blood crossing the device - <1%. This is generally self-limiting.
• Cardiac perforation – may occur during procedure or later due to device erosion - <1%. This requires open heart surgery to correct.
• Heart valve damage - <1% (uncommon).
• Transient chest pain or small heart attack (MI), mini-stroke due to air escaping to the heart arteries or brain (air embolus) - <1%.
• Death - <1%.
• Bleeding or allergic reaction to aspirin or clopidogrel (Plavix) used to prevent clot outside the device
References


