

## *Transcript-Embolization of AMPLATZER® ASD Devices: From Prevention to Retrieval*

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### **Slide 1 & 2**

Hello and welcome. I have been asked to talk about device embolization with the AMPLATZER Septal Occluder devices. I firmly believe that, prevention is much better than cure, so, in this talk, I will discuss the causes of device embolization, ways to recognize defects which increase the risk of embolization, followed by review of cases where device embolization could have been prevented. The final part of my talk will discuss methods to retrieve embolized devices and instances where referral for surgical removal of the device should be preferred.

### **Slide 3**

This is a very important paper that was published in 2008 in the "Journal of the American Medical Association." A review of number of cases performed between 1998 through 2004 indicated that there was substantial increase in the percutaneous closure of ASD/PFO. The increase was 58 fold and in absolute percentage terms, the increase was 92 from 18%. However, the number of surgical cases during the same time period did not change. These findings suggest that these patients would not have gone to the OR if simplified percutaneous closure of ASD was not available. The only change that occurred during this review period was the FDA approval of ASO devices. So, as you can guess, these findings tell us that introduction of ASO device substantially increased the number of percutaneous cases. So, as the number of cases increased, the number of device related complications increased even though the complication rate remains very low.

*Please note the AMPLATZER® PFO Occluder is for investigational use only in the US*

*Opatowski et al. Trends in the Use of Percutaneous Closure of Patent Foramen Ovale and Atrial Septal Defect in Adults, 1998-2004. JAMA. 2008;299(5):521-522.*

### **Slide 4**

Lets look at the two devices from AGA that are approved by the FDA. Most of you are familiar with these two devices. There are, however, some features of these devices which some of you may not be familiar with. The Cribriform device is available in 4 different sizes. The size of the device is based upon the diameter of the disc not the waist - the waist diameter remains the same in all four available sizes. This makes the Cribriform device a non-self-centering device. In addition, both discs are of same diameter.

The size of the ASO devices, is based upon the waist. It is available in sizes that range from 4 through 38 mm. The size of the left disc for devices between 4 through 10 mm is 12 mm larger than the waist, for devices between 11 through 32 mm, the left disc is 14 mm larger than the waist and above 32 mm the left disc is 16 mm larger than the waist. The right atrial disc is 8 mm larger than the waist for devices that range from 4-10 mm and 10 mm for device 11 through 38 mm. The reason to have an array of ASO sizes is the self-centering nature of the device. The device sits like a peg in the ASD with the waist occupying the defect. Availability of array of sizes is to ensure that appropriate sizing techniques are employed to decrease the risk of complications.

Since the size selection of the device is based upon the waist, the ASO device has significant margin of safety as the discs are much larger than the waist. In addition, the margin of safety increases more so when the size of the device increases from 10 to 11 mm and for 32 to 34 mm.

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### **Slide 5**

Device embolization, as all of you know, is very much feared. In complex defects, this fear increase four fold, when it is difficult to ascertain optimal device placement we may sometimes make mistakes.

There are some anatomical features of the atrial septum and location of defects that will almost always increase the risk of device embolization. So we are to going to review atrial septal defect anatomy that is crucial to minimize device related complications; and, types of defects which increase the risk of device embolization in detail.

As I said earlier, final portion of the talk will be regarding embolized devices and methods to retrieve such devices.

### **Slide 6**

Now in order to minimize the risk of device embolization, we have to perform optimal echocardiographic evaluation of the defect and correct device selection. By correct device selection, I mean the size of the device plus the type of the device. Devices should not be undersized or over-sized. I know that the usual knee-jerk reflex is to over-size the defect when the operator is having difficulty in device placement. I believe that over-sizing is not conducive to safe procedure because it increases the risk of other complications and in some defects may not even prevent embolization. so, to me both, undersizing and over-sizing are two-edges of the same sword. In this talk we will touch base on why device over-sizing can be detrimental to a safe procedure.

### **Slide 7**

Lets start with atrial septal rims nomenclature. In the literature and in every day description - these rims have been named as anterior (toward the chest wall), inferior (toward the feet), posterior and superior. This nomenclature is confusing and in-accurate when patients posture changes, for example, if the person is standing up or lying down.

We recently proposed rims nomenclature based upon the proximity of the adjacent cardiac structures. For example, the atrial septal rim that is towards the aorta is referred to as the aortic rim. The atrial septal rim that is towards the superior vena cava is called SVC rim. The atrial septal rim towards the IVC should be the IVC rim and the atrial septal rim towards the atrio ventricular valve should be the AV valve rim.

This picture you see is from our recent article where we first proposed the classification.

*R Anderson and A Cook. The structure and components of the atrial chambers. Europace 2007; 9:vi3-vi9.*

*Z Amin. Transcatheter Closure of Secundum Atrial Septal Defects. Catheter Cardiovasc Interv 2006; 68:778-787.*

### **Slide 8**

There are two echocardiographic modalities used to close ASDs: TEE and ICE. Rarely TTE is also used in small children. By transesophageal echocardiography, there are three standard views to review six atrial septal rims. Whether you close a very small atrial septal defect, a PFO or a large atrial septal defect, all six rims should be documented. On the left side is the 4 chamber view to evaluate the AV valve rim and the superior rim. In the middle of this slide is the short axis aortic view by which you can evaluate the aortic rim and the posterior rim. And on the right side

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of the screen is the bi-caval view where you see the SVC rim and the IVC rims. The bottom frames are the color flow evaluation of the top frames.

**Slide 9**

This slide shows the intracardiac echocardiographic evaluation of the atrial septal defect and rims. On the left side of the slide is the home view or also known as the neutral view. You can visualize the right atrium, right ventricle and the tricuspid valve. The 2<sup>nd</sup> frame is the atrial view where the catheter usually sits in the mid-atrium in neutral position; you can see the right atrium, the left atrium and also the defect. The remaining two frames are to evaluate the four orthogonal atrial septal rims- AV valve, superior, SVC and the IVC rims.

**Slide 10**

This is a 3-D PDF of a patient who had a very complex atrial septal defect. He underwent CT angiography followed by creation the 3-D model. An oval shaped defect is identified. We will rotate the 3-D model, to position the aorta which is colored red on the right side of the screen. By doing so we have orientated the heart so that it simulates as if it is inside a patient who is standing up facing the right side of the screen. This patient has absence of the IVC rim. IVC deficiency makes the defect very close to the AV node. As you can expect, device placement will be difficult in this patient and the operator will end up significantly over-sizing the device. The primary issue in these patients is that the defect in short-axis view is much smaller than in the Bi-Caval view. Device over-sizing can lead to atrial arrhythmias and other important complications.

Another important issue that warrants a little more discussion is that, since the IVC rim is missing, the device can slowly slide towards the right atrium and embolize several hours after placement. So, optimal sizing is important and ideally in absence of IVC rim these cases should go to the operating room.

**Slide 11**

This is a specimen of a patient who has a small atrial septal defect. But, this defect is very close to the aorta as pointed out by the two white arrows. You also see the red dots making an arc above the defect. The red dots are to show that some defects can extend superiorly. With superior extension, the defects not only have deficiency of the aortic rim but also superior rim, this increasing the risk of device related complications substantially. If the device is oversized in these types of defects, the risk of device disc impinging upon the aorta and atrial free wall increases which in a small subset of patients may increase the risk of complications.

**Slide 12**

So, what is the incidence of device embolization? Well, it is in the vicinity of 1%. In the US pivotal trials that were conducted by AGA Medical Corporation, the risk of device embolization was 1.1%. The risk was 0.9% if all the trials conducted by AGA are combined. In our own series the risk is about 0.3%.

Device embolization is considered acute if it happens within 24 hours of the procedure. Acute embolization is the most common adverse event reported to AGA Medical Corporation and subsequently to the FDA. If the embolization occurs after 24 hours, or after the patient has been discharged home the next day, its termed late embolization. There are a few case reports of late embolization, but in general almost all embolizations are acute. I have cited a few published case reports from the literature. One was published in 2005, in this report; there were two cases of device embolization that were discovered about 4 months later. Unfortunately, these patients were discharged to home the day of the procedure without any studies. So, from my perspective, we cannot say or predict when these devices really embolized. In the second cited study, there

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was follow up documentation of device being in situ and later found to have embolized. To my knowledge, this is the only study, with documented late device embolization.

In my practice, I always perform a chest x-ray one week after the device procedure and compare it with post-discharge chest x-ray. May be we have been lucky but we have had no late device embolization in our case series of about 1,500 patients.

*Z Amin. Transcatheter Closure of Secundum Atrial Septal Defects. Catheter Cardiovasc Interv 2006; 68:778-787.*

**Slide 13**

So the risk of device embolization, as far as I'm concerned, depends on several factors. Most important of these is the complexity of the defect and we'll discuss more about it later. The second factor is the size of the defect and the type of device chosen to close the defect.

Device embolization may have some association with the experience of the interventionist.

Generally the manuscripts we read in reputable journals have a positive impact on our practice, sometimes; however, they may have negative impact. Here is a sited example of one article where they stated that closure of ASDs with IVC rim absence/deficiency is feasible. As I have stated earlier, absence of IVC should be considered contraindication to device closure.

*Physicians should follow the device Instructions for Use (deficient IVC rims is a precaution in the IFU) . The information stated during this slide is Dr. Amin's personal clinical experience and is not necessarily that of AGA Medical.*

*Remadevi et al. Catheter closure of ASD with deficient IVC rim under TEE guidance. CCI 2009;73:90-96.*

**Slide 14**

Lets define complex ASD. If I were to define a complex defect, I would define a complex defect as an oval defect. We know that nearly 80% of atrial septal defects are slightly oval in shape. A complex oval defect is significantly oval, .An example would be a defect that measures 10 mm by 20 mm in diameter. Second: Defects that have IVC rim deficiency or absence are a very difficult defect to close and have a very higher risk of device embolization. Third: defects where the atrial septal rim is thin, hypermobile and flailing are also a complex defect. Fourth: I would call a dynamic defect-meaning a defect where there is significant change in the size of the defect during atrial systole and diastole. Such defects, for example, may be only 8 mm in systole and in diastole the diameter increases to 16 mm. These are very difficult defects to balloon size and hence, very difficult to close. And finally, defects that are multiple and separated from each other by thin atrial tissue are complex defects. The usual problem when closing these defects is the inability of the interventional cardiologist to recognize two separate defects.

**Slide 15**

This is an example of a patient with no IVC rim. As you can see with the black arrow going towards the IVC, there is absolutely no rim. If you were to close this defect, you will have to oversize the device significantly because the oval nature of the defect. Second, we have to remember that with every cardiac cycle the left disc may start sliding towards the right atrium and ultimately embolize after several hours.

**Slide 16**

So what is the ideal defect size to device size ratio? Well, per AGA recommendations, the device size should be equal or 1-2 mm larger than the stop-flow diameter of the defect. But as I said before, if the defect is significantly oval, for example a 20 mm by 11mm defect, balloon sizing of this defect becomes very difficult because in one echocardiographic view the ASD is very small,

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and balloon sizing there will be no residual shunting, whereas in the other view there is some residual shunting requiring the interventionist to keep inflating the balloon. This leads to either use of significantly large ASD device for the defect or a smaller size device, which leads to embolization.

While closing such defects, I do some math in my mind. For example, average diameter of a 20 mm by 11 mm defect, will be about  $15\frac{1}{2}$  mm (which is  $20+1=31/2$ ). If the atrial septal rims are adequate, balloon sizing should give us a diameter of about 16 to 17 mm. If the atrial septal rims are thin, or the rims are deficient, the stop-flow diameter should be expected to be more than 16 or 17 mm. I believe that recognizing these subtleties will decrease the chance of embolization and even other complications.

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### **Slide 17**

We know you will never attain experience overnight. There is no question about that. Luckily, despite different levels of expertise amongst the interventionalists, the rate of embolization remains very low.

We rarely encounter complex defects. And we can always obtain 2<sup>nd</sup> opinion from our colleagues. In cases where there is a question whether device closure may result in a potential complication, contact the physician who proctored you or if he/she is not available find one thru AGA Medical Corporation; someone will be available.

### **Slide 18**

Lets start by reviewing some cases where device embolization occurred and try to deduce the cause of embolization. This is example A. Atrial septal defect closure was performed under intracardiac echo guidance. On the left side of the screen you see the home view; in addition, you see part of the atrial septum that appears mobile and thin. The frame on the right side of the screen is bi-caval view, you see atrial septal defect clearly, atrial septum and there appears to be a possibility of a 2<sup>nd</sup> defect.

### **Slide 19**

So the operator performed balloon sizing. An important thing to recognize is the presence of a good waist on the balloon and despite the presence of a good waist, residual shunt is seen. The balloon was inflated further to obviate the shunt.

### **Slide 20**

An appropriate sized device was then chosen and deployed. Stability test (which you also call Minnesota wiggle or pull-push maneuver) was performed and the device was released. After release the device was seen to be significantly mobile and it rocked back and forth. These findings then found that the septum was thin and redundant.

### **Slide 21**

This is a final picture after the device was released and the device looks in fairly stable position. Unfortunately this device embolized overnight.

### **Slide 22**

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So, why did this device embolize? The device embolized because of two or three very important reasons. One was that the operator did not recognize that the patient has more than one defect. Second, when the defect was crossed, they went through the smaller of the two defects. And third, because they went through the smaller of the two defects and inflated the balloon in the smaller defect, they stretched the septum that separated these two defects even further and made it weaker. So after the device was released, the mobility of the device, the redundancy of the septum, caused the septum to give in, if you will, and the device embolized.

Had the operator recognized that there were two defects separated by the rim of weak atrial tissue, and that he was through the smaller defect, he could have prevented this device embolization. So recognition of two defects, closing the larger defect would have absolutely prevented this device embolization.

**Slide 23**

Let's go to example B. This is an atrial septal defect closure under TEE guidance. The first video you see is on the left shows a 4 chamber view of a significantly large atrial septal defect, right atrium and right ventricle enlargement. The second video is a color flow, the pulmonary vein draining normally and dilated right ventricle. The other important observation is the deviation of the AV valve rim towards the left side.

**Slide 24**

This slide shows the echo loops of bi-caval view. This view is to evaluate the SVC and IVC rims. Although we see a good SVC rim, the IVC rim appears unstable and tends to go in and out of the picture. The defect was measured and then balloon sized.

**Slide 25**

This slide shows you the balloon sizing in short axis view. The aortic and the posterior rims are adequate. Device placement was attempted but the operator had difficulty placing the device. So, he chose a larger device.

**Slide 26**

This is the short axis view after the device was placed. The device position looks very stable. The aortic rim is sandwiched between the left and the right disks; the posterior rim looks good as well. The 2<sup>nd</sup> frame is the bi-caval view where you see the SVC is sandwiched between the two disks. And there's a suggestion that the IVC rim may also be in between the two disks, although it's very difficult to see.

**Slide 27**

This device embolized 4 hours after the procedure. The patient experienced significant ventricular ectopy. An echocardiogram was performed, and the device was found in the RV.

**Slide 28**

So in this case, what are the causes of the device embolization? I'm pretty sure that you have figured out that the IVC rim was very inadequate. With transesophageal echo, IVC rim deficiency may be very difficult to assess. So the take-home lessons in these type of cases are; A: normally the IVC is a very thin and frail rim, so it has to be adequate enough to be able to support the device. B: if a device is placed in such defects, it will always embolize to the right atrium or right ventricle. C: If the IVC rim adequacy is doubtful, a transthoracic echocardiogram or intracardiac echocardiogram can be performed to rule out IVC rime deficiency.

**Slide 29**

Let's move onto example C. This patient had atrial septal defect closure under ICE. The short axis view is on the left and the bi-caval views. The septum primum of the septum is very thin, it is significantly mobile and it appears it overlap the septum secundum, although this is an ASD with documented left to right shunt, the septal overlap makes it an PFO type ASD.

**Slide 30**

This slide shows the color flow with left to right shunt confirming it is an ASD. Balloon sizing was performed and then after balloon sizing, an atrial septal defect device was chosen to close the defect.

**Slide 31**

The left disc is in an optimal location, but the right disc is barely covering the limbus, or the septum secundum. With the pull-push maneuver, the right disk moves further toward the left side and barely covers the septum secundum. The device remains stable now.

**Slide 32**

This slide shows further migration of the right disc toward the left side of the septum secundum and the last frame here shows both discs on the left side of the septum secundum. The device in this scenario will not embolize initially because the device remains wedged in the tunnel. However, with time, it will keep sliding and subsequently embolize. The device will always embolize into the left atrium. From the left atrium it may further migrate into the left ventricle or even the aorta.

**Slide 33**

This slide shows the device in the descending aorta. It was retrieved percutaneously from the arterial side and a larger device placed in the ASD with excellent results.

**Slide 34**

So in the previous case, the device embolized because the right disk did not overlap the limbus or the septum secundum. Take home message in these types of cases is to ensure that the right disc of the device always covers the limbus.

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**Slide 35**

This is diagrammatic representation to further clarify and explain the why the right disc has to overlap the septum secundum. If the right disc does not sit astride the septum secundum, it will slide through this slit like opening and end up on the left atrium.

**Slide 36**

So what are the subtleties and nuances of device embolization? The risks of embolization can be minimized, by proper echocardiographic identification of the atrial septal rims. Always assess the IVC rim and its adequacy. Evaluate the consistency of the rims to see if the rims are strong enough to hold the device. Interrogate the septum thoroughly to rule out multiple defects. If there are multiple defects always assess the adequacy or the consistency of the septum that separate these defects.

Once you have placed a device and before you release the device, perform complete echocardiographic evaluation, look at all the septal rims. In atrial septal defects that have anatomic similarities to PFO, ensure that the right disk straddles the limbus.

**Slide 37**

If the device is undersized, it will embolize into the left atrium and from there it may go to the LV or the aorta as I said before. If the device is improperly placed it will embolize to the right or the left atrium, depending on the degree of tilting of the device. If the device was placed in the patient who had IVC rim absence, it will almost always embolize into the right atrium and ultimately may go the right ventricle or the pulmonary artery.

**Slide 38**

Let's go to the second part of this talk, which is when to retrieve device percutaneously. I personally believe that we can retrieve all devices percutaneously except in a few instances where we should not attempt to retrieve the device and I'll talk about this in the next few minutes.

Remember that the success of retrieving a device depends upon what kind of armamentarium you have in your catheterization laboratory and how comfortable you are in retrieving the device. The sites from where the embolized devices can be retrieved rather easily are the left atrium or the right atrium. They can also be retrieved rather easily from the main or the branch pulmonary arteries or even the aorta. It can be cumbersome and very difficult to retrieve them from the left ventricle and sometime even from the right ventricle especially if it's entangled in chordae of the mitral or tricuspid valve.

**Slide 39**

What to do when it is discovered that the device has embolized? Well, first thing I usually do is I NPO the patient. Second thing you should do is call your surgeon, notify him even if you are going to try to retrieve the device percutaneously. If the device is in the left atrium or the left ventricle always Heparinize the patient. If general anesthesia is available and you have a biplane lab also available I prefer using both.

The femoral sheath size that you want to use to retrieve the embolized device should be at least 2 Fr sizes bigger than the sheath that was used to deliver the device. For example, if you used a 10 Fr sheath to place the device, you should place at least a 12 Fr or larger sheath to retrieve the device.

**Slide 40**

In your cardiac catheterization laboratory always have the Amplatzer bail-out delivery sheath available; these sheaths can be very helpful in exchanging a kinked or damaged sheaths. Always have Amplatz Goose-neck snares, which are manufactured by EV3 available. You should have snares available from 10 to 30 mm in diameter although a majority of the time you will only use a 20 to 30 mm snare. Some physicians advocate the use of bioptomes. I don't think that bioptomes are ideal for device retrieval. But, nevertheless, the bioptome can be used to reorient the embolized device.

Other important pointers are to cut the retrieval sheath in oblique fashion, to increase the chances of pulling the device inside the sheath. An important point to remember is that when the device has embolized in the pulmonary artery, the retrieval sheath has to be in the pulmonary artery to retrieve the device in the sheath, because if you try to pull this device through the right ventricle, it may get tangled in the tricuspid valve chordae.

**Slide 41**

Here's a nice example of a standard sheath whose area of capture can be increased by cutting it obliquely. These are examples of the Amplatzer goose-neck snares on the right side of the screen.

**Slide 42**

Like I said before, always try to snare the device on the female screw side, which is the right atrial disc. This is the larger of the screws so you can grasp the screw rather easily. Now if it is facing away from where your snare is, you can re-orient it by using Judkins catheter, modified Pigtail catheter or any other catheter. Sometime you can use wires, biopptome as well. I have, in one case used a balloon to flip the device 360 degrees and later on I was able to capture it.

Once you have grasped the device and you cannot pull it inside the sheath, pull it in the IVC. Since the device is almost always larger than the IVC, you can let go of the device there and then put a larger sheath for retrieval.

**Slide 43**

If you still cannot capture the device in the sheath, you can pull it all the way into the femoral vein and then perform a cut-down. You can also call your surgeon to perform a cut-down.

The most important part of the retrieval process is to know your limits and have a cardio thoracic surgeon available.

**Slide 44**

Here's an example of an 18-kilogram patient who had closure of large ASD but unfortunately the device embolized overnight.

**Slide 45**

The device was grabbed at the female screw but we were not able to retrieve the device into the sheath.

**Slide 46**

So we pulled the device into the inferior vena cava...

**Slide 47**

And exchanged the sheath for a larger sheath. We were then able to capture and pull all the device into the sheath. We then placed a larger device in the ASD during the same procedure and placed a larger device. The patient was discharged to home without any complications.

**Slide 48**

These are a couple examples of difficult device retrieval. Although I won't show you the entire process, on the left you see the device that has embolized in the left ventricle and on the right you see the device that has embolized in the right ventricle. The device that was in the right ventricle did not entangle the tricuspid valve cordae, so it was removed percutaneously. The device in the left ventricle was stuck under the mitral valve and hence the patient went to the operating room for device removal and closure of atrial septal defect.

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In conclusion, the incidence of device embolization is low and can be further minimized by optimal patient selection, EKG interrogation and correct balloon sizing. A majority of these defects can be retrieved by using transcatheter techniques. When attempting to retrieve a device the patient's safety should be our main concern. So we should know when to quit the retrieval process.

One very important characteristic of AMPLATZER device is that it does not seem to obstruct or compromise the circulation after embolization. This excellent characteristic of the AMPLATZER device indicates that we do have time to retrieve the device percutaneously, should we choose to do so. Thank you.