

AMPLATZER® Sizing Balloon II Case Study

Use of the AMPLATZER Sizing Balloon II during the closure of multiple secundum atrial septal defects in a child with a multi-fenestrated atrial septum



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Diagnosis

A five year-old female weighing 18.7kg was referred for the evaluation of a heart murmur. Cardiac examination confirmed the presence of a systolic flow murmur and a fixed split second heart sound. A transthoracic echocardiogram (TTE) was performed which demonstrated right heart chamber enlargement with an atrial septal aneurysm and a moderate to large secundum atrial septal defect. Left to right shunting was demonstrated by color Doppler. The tricuspid regurgitation Doppler velocity estimated the right ventricular pressure to be normal. A pre-procedural interventional catheterization consultation confirmed that the patient was a favorable candidate for trans-catheter device closure of her ASD. Her parents wanted for her to avoid open-heart surgery and gave informed consent for catheter-based device closure.

Procedure

Under general endotracheal anesthesia, the patient underwent a complete hemodynamic catheterization with upper limit normal right heart pressures and a 2:1 left to right shunt found by oximetry. Heparin was administered (ACT >300sec) and an intracardiac echocardiogram was performed using the 8 French AcuNav™ Intracardiac Echocardiogram (I.C.E.) catheter. Although the pre-procedural TTE suggested a single secundum ASD, the presence of an atrial

smaller device was released from its delivery cable, followed by release of the larger device. Final device orientation in orthogonal planes and I.C.E. imaging shows adequate coverage of the multiple defects with no significant residual acute atrial level shunting shown (Figure 7).

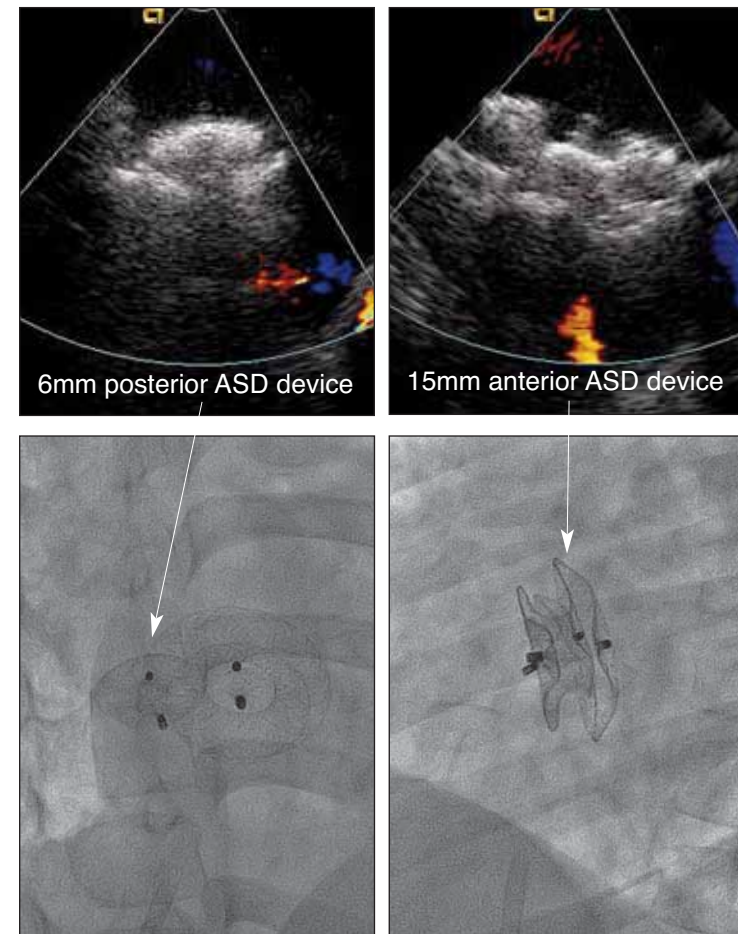


Figure 7: I.C.E. and corresponding fluoroscopic images of two AMPLATZER Septal Occluders used to close a multi-fenestrated ASD. Note: the smaller 6 mm device partially overlapped by the larger 15mm device. No significant residual ASD shunting is seen by color Doppler after release of both devices.

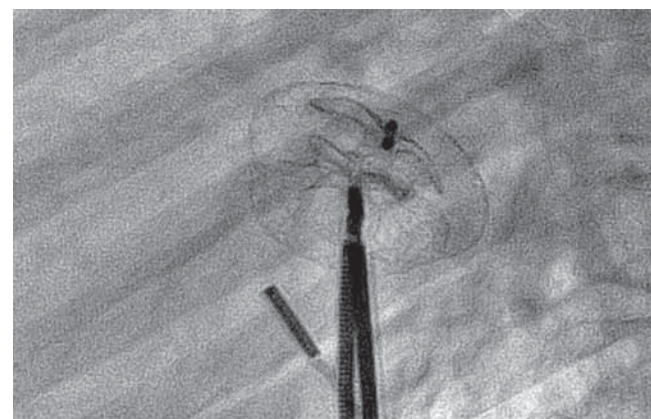
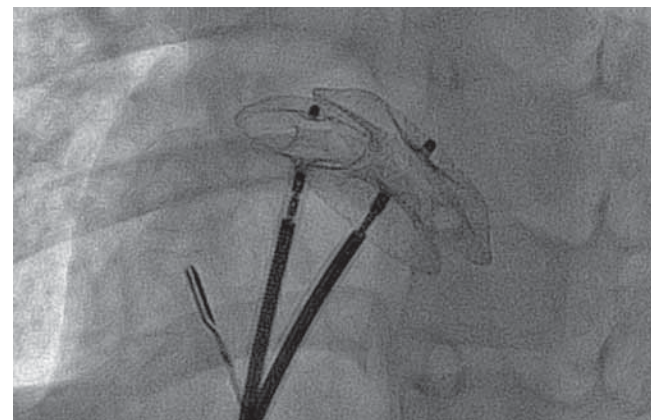


Figure 6: I.C.E. image and corresponding LAO-cranial & lateral fluoroscopic images of two AMPLATZER Septal Occluders implanted covering multiple ASDs prior to cable release. Note: smaller device (6mm) is implanted first so that it can be "nested" inside the discs of the larger device (15mm) resulting in minimal distortion of either device.



Figure 1A: Intracardiac echocardiographic (I.C.E.) imaging showing aneurysmal septum (arrow) with moderate sized defect in antero-superior septum

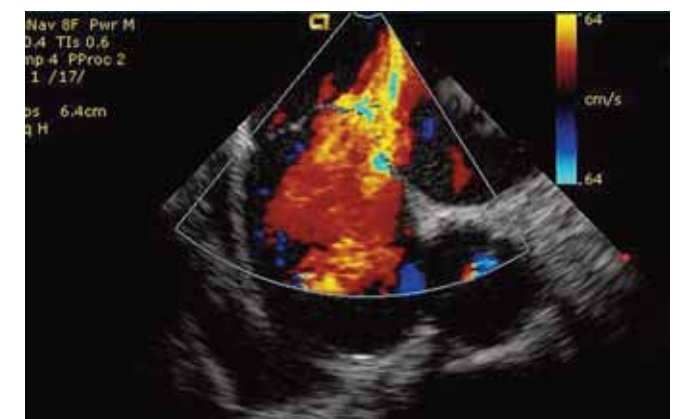


Figure 1B: Corresponding color Doppler image

septal aneurysm raised the possibility of a multi-fenestrated defect and, in fact, the I.C.E. images confirmed the presence of multiple defects (Figures 1A-C). There was a moderate sized defect in the antero-superior septum measuring approximately 12.8mm in diameter with at least one satellite defect immediately adjacent to the defect oriented towards the center of the septum. Additional I.C.E. imaging also demonstrated two additional defect closely spaced but located toward the posterior portion of the atrial septum. Each of these two

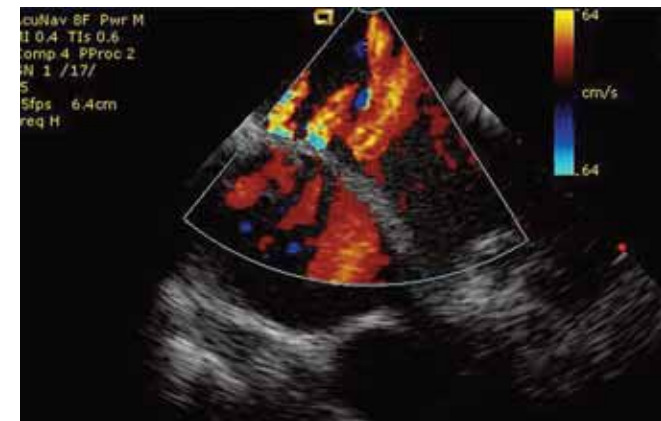


Figure 1C: Additional ASDs in the posterior septum shown by I.C.E. with color flow Doppler showing two additional defects with left to right shunting

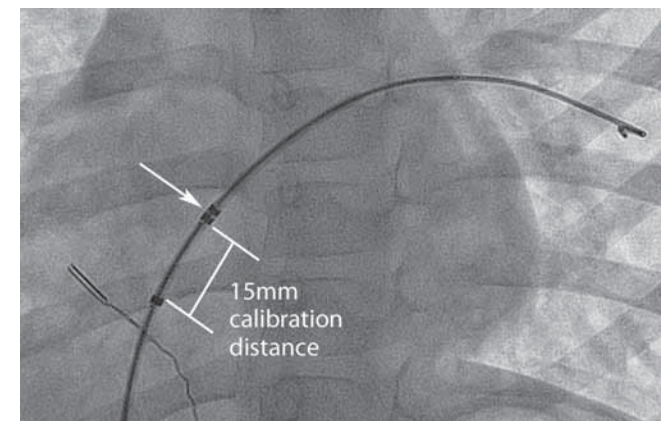


Figure 2: LAO-cranial view fluoroscopic view showing 18mm SBII over a guidewire positioned in the left upper pulmonary vein in preparation for stop flow balloon sizing of a secundum ASD. The x-ray tube is positioned such that the 0.4mm separation between the alignment markers (white arrow) is maximized, confirming the proper alignment to assure accuracy when measuring between the 15mm calibration markers. (Note: 8 French AcuNav™ intracardiac echocardiogram catheter in position for viewing balloon during inflation)

defects measured approximately 4mm in diameter. The larger anterior defect was first crossed using a 6 French woven Dacron catheter using I.C.E. guidance to ensure crossing of the main defect. The C-arms of the biplane x-ray system were positioned so that at least one was oriented in an orthogonal plane to the shaft of the sizing balloon catheter. The 0.4mm space marker bands on the catheter (inside the balloon) were used to confirm optimal positioning which in this case was LAO 23° and cranial 2° (Figure 2). The orientation markers, seen in the lateral plane, confirm that a lateral view should not be used to calibrate/measure.

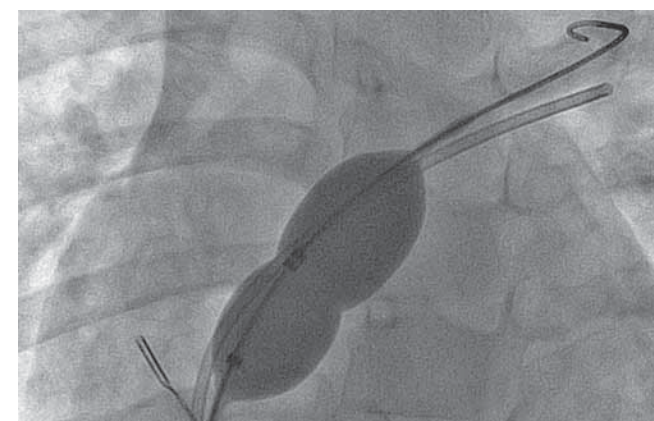


Figure 3: 18mm SBII inflated to stop flow diameter as confirmed by color Doppler on I.C.E. imaging showing the point of cessation of shunting across the defect. The residual color flow, just beyond the septum on the inferior side (9 o'clock) of the balloon, is flow from the additional defects in this multi-fenestrated septum. Note: On simultaneous fluoroscopy a "waist" is seen in the balloon, however, this does not necessarily correspond to the point of balloon stop flow. The marker bands inside the inflated balloon are easily seen for calibration and measurement when a 3:1-4:1 mixture of contrast to saline is used.

An 18mm AMPLAZER Sizing Balloon II (SB II) was then used to measure the balloon stop flow diameter of the larger anterior defect (Figure 3). Similarly, a second 6 French woven Dacron catheter, was advanced to the right atrium from a second venous sheath. Again, using I.C.E. imaging, the second catheter was directed across one of the posterior defects located closer to the center of the septum, in order to allow a device to span across the most posterior adjacent defect without becoming distorted against the posterior wall of the atrium.

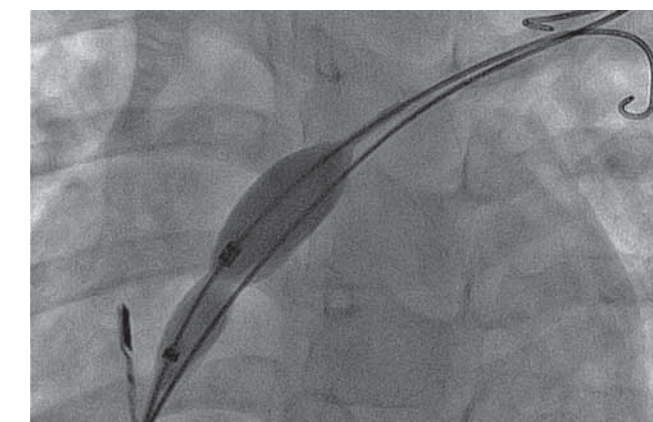


Figure 4: 18mm SBII used to size smaller posterior ASD. I.C.E. imaging confirming the point of balloon stop flow on color Doppler. Note: on the fluoroscopic image the intra-balloon alignment & calibration markers are easily seen. Importantly, the point of balloon stop flow is confirmed echocardiographically, before a significant "dumbbell" shape deformity in the balloon occurs. Inflating the balloon only to the point of stop color flow prevents defect over-sizing with potential oversized device implantation.

The balloon stop flow diameter of this defect was then determined also using the 18mm AMPLAZER Sizing Balloon II (Figure 4). After the main defects were balloon stop flow sized, the appropriate sized delivery sheaths were advanced across each of the two main defects (Figure 5).

Then a 6mm AMPLAZER Septal Occluder was implanted into the smaller posterior defect followed by implantation of a 15mm AMPLAZER Septal Occluder in the anterior larger defect (Figure 6). After ensuring secure placement and device seating against the septum and each other, the

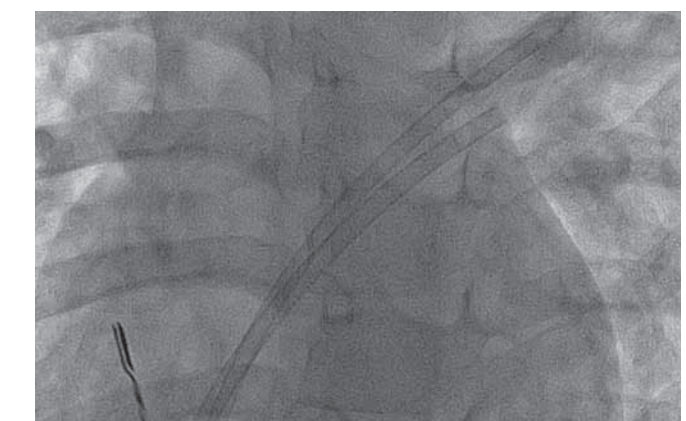
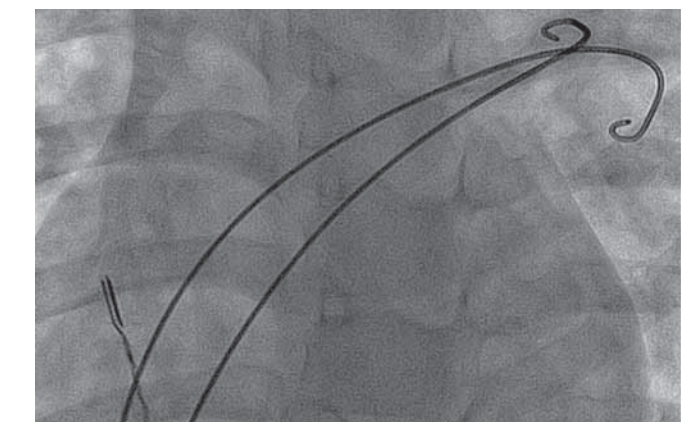


Figure 5: Following balloon sizing using the SBII, two delivery sheaths (6 French & 7 French) are advanced over the respective wires across the ASDs in preparation for device implantation.