## REVIEW

## ECHOCARDIOGRAPHIC EVALUATION OF ATRIAL SEPTAL DEFECT DEVICE CLOSURE

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With further development of transcatheter techniques and improved occlusion devices, percutaneous closure has become the treatment of choice for secundum ASD. The Amplatzer septal occluder device is frequently used for ASD occlusion due to its straightforward implant technique and efficacy in occluding a wide range of ASD sizes. TEE is vital in the recognition of morphologic variations of the ASD and patient selection. It allows clear visualization of the defect and the device during the procedure, precise measurements of stretch diameters, guiding of deployment, and stable positioning of the device. This is especially important in patients with large ASDs or multiple ASDs and those with atrial septal aneurysm. With TEE, incorrect positioning of the device can be detected while it is still screwed to the delivery cable, which allows its early redeployment, before any complications occur. Compared with the patients undertaken surgical repair, the left ventricular function using strain rate imaging was preserved after the device closure. Echocardiographic evaluation for ASD device closure is essential in patient selection, during procedure, after occlusion, and long term follow-up.

KEY WORDS : Echocardiography · Atrial septal defect · Device closure.

### **INTRODUCTION**

Secundum atrial septal defect (ASD) accounts for 10% of congenital heart disease at birth and as much as 30% to 40% in adults who present with congenital heart problem. Surgical repair of an ASD is a safe and widely accepted procedure with negligible mortality. However, it is associated with morbidity, discomfort, longer stay in hospital, and a thoracotomy scar.<sup>1)</sup> Therefore transcatheter closure of ASD has been developed as an alternative to surgery. The first reports of transcatheter device closure of secundum ASD in humans were published in 1976 by King and Mills<sup>2)</sup> and in 1983 by Rashkind.3) Since then, a variety of devices including of Cadioseal, Angel Wing etc.<sup>4-11)</sup> have been developed, but none has gained wide acceptance. Previous techniques had some limitations like large delivery sheaths, difficult implantation techniques, inability to recapture, and structural failure causing damage to neighboring structures, dislodgment, and embolization.<sup>12)13)</sup> With further development of transcatheter techniques and improved occlusion devices, percutaneous closure has become the treatment of choice

#### DEVICE (FIG. 1)

The Amplatzer ASD Occluder consists of a nitinol (Nickel + titanium) wire mesh(0.004-0.005") in a double-disk design. The left and right atrial disks are joined by a central connecting waist. Each disk, as well as this central waist, is filled with polyester fabric to increase occlusion by promoting thrombogenesis. The size of the device chosen for implant corresponds to the diameter of the central connecting waist, measured in millimeters, ranging from 4 to 40 mm. Currently, devices

Received : March 20, 2007
 Accepted : March 30, 2007

for secundum ASD. The Amplatzer septal occluder<sup>®</sup> (ASO<sup>®</sup>) device (AGA Medical, Golden Valley, MN) is frequently used for ASD occlusion due to its straightforward implant technique and efficacy in occluding a wide range of ASD sizes.<sup>13-15)</sup> There is clinical evidence that the Amplatzer is a preferable choice among the other devices. It produces significantly higher occlusion rates and is much easy to apply.<sup>16</sup> I would review the echocardiographic evaluation of Amplatzer device in transcatheter closure of ASD in children and adults.

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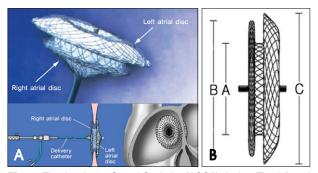
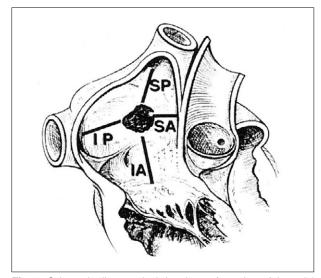


Fig. 1. The Amplatzer Septal Occluder (ASO®) device. The left and right atrial disks are joined by a central connecting waist. Each disk, as well as this central waist (A), is filled with polyester fabric. LA disk<sup>®</sup> is larger than RA disk (B).



**Fig. 2.** Schematic diagram depicting the en face view of the atrial septum. Suitable septal rim of at least 5 mm from the right pulmonary veins, coronary sinus, superior caval vein, inferior caval vein, and mitral valve were considered suitable except SA rim. SP (supero-posterior) rim : between SVC-ASD, SA (supero-anterior) rim : between Aorta-ASD, IA (infero-anterior) rim : between ASD-TV, IP (infero-posterior) rim : between IVC-ASD.

with waist diameters from 4-38 mm are available in Korea. The central waist produces a radial force against the ASD rim, while the atrial disks flatten against the atrial septum. The ASO device is self-expanding, self-centering, retractable, and repositionable. A 3-4 mm short, cylindrical waist connects the two discs. The diameter of the left atrial disc is 12 mm larger than the conjoint waist in devices up to 10 mm (that is, 6 mm rim), 14 mm larger than the conjoint waist in devices greater than 10 to 32 mm (that is, 7 mm rim) and 16 mm larger than the conjoint waist in devices greater than 34 to 38 mm (that is, 8 mm rim). The right atrial disc is 8 mm larger than the waist in devices up to 10 mm (that is, 4 mm rim) and 10 mm larger than the waist in devices greater than 10 mm (that is, 4 mm rim) and 10 mm larger than the waist in devices greater than 10 mm (that is, 5 mm rim).

The ASO is available in sizes with 1 mm increments from 4 to 20 mm, and then in 2 mm increments until the current largest device of 38 mm. The left disk is slightly larger than the right, because of the higher left atrial pressure. The prosthesis is filled with Dacron fabric to facilitate thrombosis. The waist of the device is designed to stent the ASD. In order to stent, the diameter of the waist has to correspond to the stretched diameter of the defect. The device is connected to a delivery cable by a microscrew fixed to the right atrial disc and loaded into a 6-12 French long sheath<sup>13-16</sup>. Balloon stretched diameter (BSD) has long been regarded as the standard way of measuring ASD size.<sup>17</sup>

## PATIENT SELECTION FOR THE ASO DEVICE CLOSURE<sup>17-23)</sup> (FIG. 2)

All patients with a clinically significant fossa ovalis ASD. Initial selection was based on transthoracic (TTE) and/or transesophageal (TEE) echocardiographic assessment. Ideally ASD with a maximum TEE diameter of 30 mm or less, sometimes to 34 mm or less with a suitable septal rim of at least 5 mm from the right pulmonary veins, coronary sinus, superior caval vein, inferior caval vein, and mitral valve were considered suitable. Typically, the ASO device size(=waist size) selected is equal to or 1-2 mm larger than the balloon-sized ASD diameter. The diameter of the left atrial disc is 12-16 mm larger than the conjoint waist in devices. Total length of atrial septum covered by ASO has to be considerd. Occasionally, a larger device is selected in an attempt to cover fenestrated defects, to simplify placement, or when septal rims are deficient, particularly the superoanterior septal rim (retroaortic). To ensure optimal position of the ASO and closure of the ASD, echocardiographic (echo) imaging, either by TEE or intracardiac (ICE) methods, is used during device positioning, deployment, and release.

Maximal criteria for transcatheter closure with ASO device were (1) ASD secundum with a maximum TEE diameter of 34 mm, (2) rims, except the anterosuperior rim, of at least 5 mm, and (3) the dimensions of the total length of the atrial septum were not smaller than the left atrial disk of the chosen device. Patients meeting the above criteria can be tried with transcatheter closure of ASD using ASO.

## MEASUREMENT OF THE DEFECT AND MARGINS<sup>16-19)24)25)</sup> (FIG. 2 AND 3)

The dimensions of the defect were measured in the standard horizontal and longitudinal TEE views. We used the maximal measured value as the diameter of the defect. The longitudinal diameter of the defect was measured in the longitudinal view of the caval right atrial and atrial septal view. The horizontal

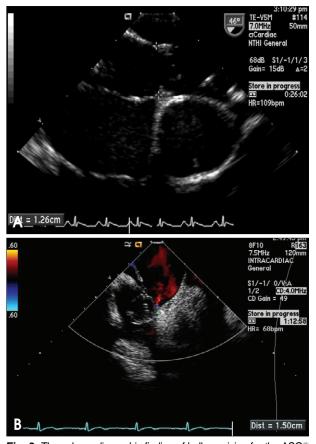


Fig. 3. The echocardiographic finding of balloon sizing for the ASO<sup>®</sup> device. A: The TEE finding revealed the stretched balloon diameter with "waist" across ASD measured. Sometimes this method had the risk of oversizing. B: The ICE finding revealed the occlusive balloon diameter without waist across ASD measured. When color Doppler was disappeared by the occlusive balloon, the balloon size was measured.

diameter was obtained in the TEE 4-chamber view with use of slight anterior or posterior flexion of the transducer to obtain the maximal diameter of the defect. All measurements were performed without color flow or electrocardiographic gating. The longitudinal and horizontal diameters were used for calculation of the ovality index. The rim diameters of the defect were obtained in the standard TEE views. The superoanterior rim was measured in the horizontal plane as the distance between the aortic annulus and the defect. The posterior rim represents the distance from the defect to the coronary sinus and posterior atrial wall, and the inferoanterior rim was measured in the 4-chamber view as the distance from the atrioventricular valves. The longitudinal planes were used to determine the superoposterior rim as the distance from the defect to the superior vena cava (SVC) and the inferoposterior rim as the distance from the defect to the inferior vena cava (IVC). The total atrial septal lengths

were obtained by TEE 4-chamber view and the caval right atrial and left atrial septal views. The balloon stretched diameter of the ASD has been determined by using a compliant sizing balloon, which is filled with dilute contrast, placed across the ASD, and inflated until a waist in the balloon is visible on fluoroscopic imaging. The balloon was gradually inflated until shunting was eliminated on the color Doppler evaluation. The balloon stretched diameter was determined by fluoroscopy/TEE/ICE. The ASO device size was selected and implanted with the standard procedure using TEE/ICE guidance. Many of these major complications may be related to the size of the ASO. Specifically, oversized devices, though easier to implant in the ASD, may be more likely to exert pressure against other intracardiac structures, leading to an increased potential for complications. In addition, oversized devices can mushroom rather than flatten against the septum; this device deformation may increase the risk of embolization, residual leak, thrombus formation, or perforation. Sometimes large sizes of ASO are implanted directly without any balloon measurement in several institutions concerned about balloon related oversizing.

As recommendation, the inflating a compliant sizing balloon only until shunting is eliminated by color Doppler imaging, and not continuing to inflate the balloon until an obvious waist is created. The ASO device size should be selected equal or up to 2 mm greater than this balloon size. This should result in less oversizing of the ASO device, a potentially lower complication rate, yet still achieve effective ASD closure.

The BSD has long been regarded as the gold standard for the measurement of maximal ASD size. However, the ASD size could be overestimated because of oblique passage of the balloon through the ASD. The accuracy of ASD size measurement by 3-D TEE has been proved by both in vitro and in vivo studies. Therefore, the issue of measuring the size of ASD by 3-D TEE versus the SBD remains controversial. Magni et al.<sup>26)</sup> found that the SBD was larger than 3-D measurement and speculated that it could result from the easily distended pliable rim tissue, but they did not validate this finding. In the process of balloon sizing with 2-D TEE, to ensure that the balloon was perpendicular to the septum during pullback through the septum. Thus, the oblique view for measuring the balloon size was prevented. Because the ASD was not always round,<sup>26)</sup> the minimal diameter of the ASD was first reached by the balloon that was being inflated. However, there was still residual shunt across the septum. Only when the maximal diameter was reached by the balloon could no residual shunt be seen. Balloon sizing was always larger than 2-D TEE and 3-D TEE measurement.

The SBD was roughly 4 mm larger than 2-D TEE and 2 mm larger than 3-D TEE measurement.<sup>27)28)</sup>

## PROCEDURE<sup>18, 19, 23)</sup> (FIG. 3 AND 4)

During transcatheter closure TEE or ICE was used for (1) measurement of balloon stretch diameter of the ASD, (2) detection of leaks around the balloon, (3) guidance for correct device placement, (4) controlling the position and stability of the ASO, (5) guidance for the release of the device, and (6) assessment of leaks across the device immediately after implantation.

Vascular access was obtained through the femoral vein. The stretched diameter of the ASD was determined by a sizing balloon catheter, which was inflated in the left atrium with diluted contrast to the diameter that could be pulled into the right atrium with slight resistance and at the same time prevent the TEE or ICE detecting color flow leaks across it. The stretched diameter of an ASD was determined by TEE or ICE and the sizing plate. The device was then fixed to the delivery system with a microscrew and introduced through the loader into the 7-12F delivery sheath. Under TEE or ICE and fluoroscopic control the left atrial disk and waist were deployed in the left atrium and then pulled back to the septum, resulting in self-centering of the device, after which the right disk was deployed in the right atrium. Before the device was unscrewed, its correct and stable position was confirmed by TEE or ICE by demonstrating unobstructed flow from the coronary sinus, pulmonary veins and superior and inferior caval veins and competence of the atrioventricular (AV) valves. Immediately after closure, residual leaks across the ASD were sought.

During follow-up studies, TTE allows the detection of residual shunts and complications such as device embolization, wire fractures, heart penetration or perforation with pericardial effusion, erosion, laceration, thrombus formation and etc.

# THE ROLE OF TEE OR ICE FOR ASD CLOSURE<sup>22-24</sup> (Fig. 3, 4 and 5)

TEE is essential for ASD closure with ASO. TEE is vital in complete and accurate assessment of the morphologic variations of the ASD and patient selection without interfering with the sterility of the operative field or obstructing fluoroscopy. It allows clear visualization of the defect and the device during the procedure, precise measurements of stretch diameters, guiding of deployment, and stable positioning of the device. This is especially important in patients with large ASDs or multiple ASDs and those with atrial septal aneurysm. With TEE, incorrect positioning of the device can be detected while it is still screwed to the delivery cable, which allows

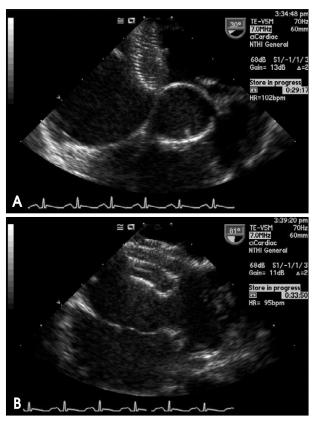


Fig. 4. The TEE finding of the ASO<sup>®</sup> device. A: LA disk was deployed in LA cavity. B: Both disks were deployed in each atrial cavities.

its early redeployment, before any complications occur. Following deployment of the device, TEE was used to assess device position, its relation to the surrounding structures, and its stability. Residual shunts are also best demonstrated.

Two-dimensional TEE imaging is superior to fluoroscopy because it provides more information regarding the anatomy of the defect, surrounding structures, and the relationship between the device and the septum. However, only limited structure is shown and the maximal ASD size tends to be underestimated if the probe is not on the line between the longest diameter. Three dimensional TEE provides en face ASD imaging, thus presenting the overall anatomy of ASD.

As comparison of ICE versus TEE guidance for percutaneous transcatheter closure of ASD, TEE requires general anesthesia in most cases. Using a ICE catheter may avoid endotracheal and esophageal intubation while using only local anesthesia. Echocardiographic visualization of the septal defect and deployment was adequate by both methods. Catheterization laboratory time and interventional procedure length were shortened using ICE. Patient's defects that were closed using ICE guidance remained awake during the procedure; they required minimal sedation, and afterwards, only the bed rest necessary for a safe venous sheath removal, with a recovery time not much longer than that needed for regular right-sided cardiac catheterization. The patient being awake during the procedure is also advantageous in evaluating the effects of Valsalva maneuvers and coughing on shunt hemodynamics. Using ICE avoids the need for another physician to maneuver the TEE probe because the operator doing the closure manages the ICE catheter simultaneously. This allows precise and more rapid determination of the views needed for closure by the primary operator, in addition to reducing the need for the availability of another cardiologist during the procedure.

ICE guidance offers equivalent echocardiographic views compared with TEE and similar rates of closure. ICE offered better quality images and required less manipulation due to its favorable position in the right atrium with respect to the interatrial septum and the possibility of a wider range of motion in the atrium. Due to these technical advantages, ICE can overcome some of the important near-field limitations of TEE, especially in patients with small left atriums.

An AcuNav-ICE catheter (Acuson, Mountain View, California) was used for imaging. The ICE catheter was introduced through an 11 Fr, 10-cm hemostatic valve sheath in the right common femoral vein. This catheter is a disposable FDAapproved 8, or 10 Fr multiplane ICE imaging ultrasoundtipped catheter (5 to 10 MHz) that has a 64-element vector phased-array transducer, which provides orthogonal imaging with a tissue penetration up to 12 cm and full color and spectral Doppler capabilities. The cost of the ICE catheter for disposable use may be an important limitation to its use. It might be possible to safely resterilize these probes which will greatly improve their cost effectiveness.

### FUNCTIONAL CHANGES AFTER ASD DEVICE CLOSURE<sup>29-39)</sup>

Cardiac function using the assessments with new echocardiographic parameters was improved rapidly after ASD device closure.<sup>29)30</sup> The functional restoration depends on the age of occlusion.<sup>31)32</sup> And strain rate imaging is the most sensitive parameter for functional assessment after the device closure.<sup>37)</sup> Septal function was affected than other segments of ventricle after closure.

Device closure of ASDs in adult leads to improvement of both RV and LV function as well as reduction in LA volume.<sup>30)</sup> Measurements of RV and LV Tei index and LA volumes were made in patients underwent transcatheter closure of ASD. There was statistically significant improvement in RV Tei index, LV Tei index, and LA volume index after closure of ASD.

In adults, there are differences in right and left ventricular

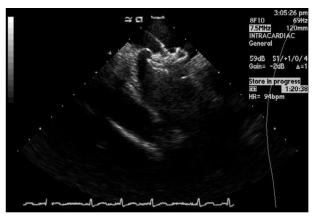


Fig. 5. The ICE finding of the ASO<sup>®</sup> device. Before the ASO was unscrewed, the device was located at interatrial septum.

remodeling after transcatheter closure of atrial septal defect. Echocardiographic assessment including LV and RV myocardial performance indices, or Tei indices, and plasma brain natriuretic peptide (BNP) sampling was performed before closure of the ASD, and 1 day, 1 month, and 3 months after closure. (1) LV end diastolic diameter increased, and RV end diastolic diameter decreased markedly after the closure; (2) differences existed in LV and RV adaptation. While LV Tei index improved soon after the procedure, RV Tei index worsened until 1 month after the procedure, then recovered by the 3 month follow-up visit; and (3) BNP elevated 1 day after closure of the ASD and declined by the 1-month followup visit. "Shrinkage" of the RV and "expansion" of the LV occurred soon after the procedure, even in elderly patients. Device closure of ASDs caused rapid improvement of LV function, but RV function underwent transient deterioration, probably due to delayed changes in RV ventricular mass in the face of acute volume reduction.

Device closure of ASD results in an acute transient decrease of regional myocardial velocities in the LV and RV, whereas the load-insensitive marker, isovolumic acceleration remained stable. Therefore, the velocity changes may represent a response to altered left and right ventricular loading conditions. Compared with pre-, immediately and post- 1 day after occlusion, fractional shortening and left ventricular enddiastolic diameter was unchanged. The findings on regional myocardial velocities at the 3 periods, the peak systolic velocities of the RV and LV fell by approximately 30% compared with baseline values. In the basal right ventricular and septal and lateral left ventricular segments, the greatest drop occurred for the left ventricular longitudinal velocities, and the fall in the right ventricular and basal posterior segments was smaller but still significant. Diastolic velocities also decreased significantly in the left ventricular longitudinal segments. These remained unchanged for the RV and posterior basal segments. The significant acute fall of velocities after the procedure had reversed to baseline values on the second follow-up study on day 1. Statistical comparison of myocardial velocities revealed a significant increase from post-ASD closure to day 1 but no difference between pre-ASD closure and day 1 for either the LV or RV.

Isovolumic contraction velocity and isovolumic acceleration (IVA) were also measured before, immediately after, and 1 day after the procedure in all 6 segments. In the RV, IVC velocity increased after the procedure and on follow-up at 24 hours. In the LV, the baseline differences between patients with ASD and normal controls had disappeared by day 1. In contrast to myocardial velocities, IVA was essentially unchanged after ASD device closure without significant differences among the initial, early, and late follow-up studies in the longitudinal left ventricular segments. In the RV, IVA increased slightly but significantly on the day after ASD device closure. A similar small change occurred in the radial LV segment, the basal posterior wall.

Strain rate imaging was applied for evaluating ventricular function in patients late after the successful closure of ASD. After the surgical closure of ASD, RV and LV longitudinal function was impaired, suggesting a major susceptibility of longitudinal fibers to intraoperative injury and a compensatory response by circumferential fibers.

After device closure, although global LV longitudinal function was comparable with that in controls, there were regional abnormalities in the septal wall. LV global longitudinal function, assessed by annular excursion, only reflects motion and can be influenced by global heart motion, rotation, and tethering effects, whereas regional strain ratc (SR) is strongly related to contractility. Radial function in the surgical repair group was comparable with that in controls and, although not significantly, was greater than that in the device closure group. There was a significant reduction in longitudinal regional deformation properties on the basal and mid segment of the interventricular septum, whereas deformation properties of the LV inferior wall were normal in each studied segment. This may be due to the imposition of a noncontractile element within the interatrial septum, affecting the shortening of the basal and mid segments of the septal wall. The extension of reduction in septal longitudinal function is related also to the device size, localization, distance between the device and the mitral annulus, and other device characteristics such as stiffness or spatial profile.

After the repair of an ASD using surgery or percutaneous closure, echocardiographic assessment demonstrated a persistence of RV dilation. Despite the presence of normal global RV longitudinal function, after device closure, the myocardial deformation properties of the basal segment of the RV free wall were significantly reduced compared with controls.

SR imaging indicies could provide new, noninvasive, clinically relevant insight on regional changes in atrial function for patients with ASD. In the surgical group, the peak systolic and SR values were significantly reduced in both RA and LA when compared with control and device groups. In the device group there was no significant difference in both LA and RA deformation properties when compared with control subjects.

### CONCLUSION

Transcatheter closure of ASD has been developed as an alternative to surgery. With further development of transcatheter techniques and improved occlusion devices, percutaneous closure with Amplatzer Septal Occluder has become the treatment of choice for secundum ASD.

The role of TEE or ICE is essential for ASD closure with ASO. It provides for complete and accurate assessment of the morphology and patient selection. During and after the procedure, it allows the procedure was safe without complication.

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