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Clinical Investigations

Transcatheter Closure of Large Atrial Septal Defects in 18 Patients

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Summary

Purpose: This study was designed to evaluate the efficacy and safety of transcatheter closure of large atrial septal defects (ASD).

Methods: Eighteen patients diagnosed as ostium secundum defect with a diameter of 30-40 mm were enrolled in this study. With the guidance of echocardiography and fluoroscopy, the Amplazter occlusion devices were implanted percutaneously through the femoral vein.

Results: A small residual left-to-right shunt was detected with echocardiography immediately postprocedure but resolved after 1 week. The occlusion devices remained in proper position, and there was no residual shunt at 1- and 29-month follow-ups. Cardiac function and atrial sizes improved significantly as compared with the preclosure states.

Conclusions: Transcatheter closure of large atrial septal defects with the Amplazter occlusion device is feasible, safe and effective.

Key words: atrial septal defect, transcatheter occlusion, occlusion device

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Introduction

Although the mortality and morbidity associated with surgical closure of an atrial septal defect (ASD) is low, transcatheter closure is becoming a more attractive alternative because it eliminates or reduces the risks and morbidity inherent to surgery. From the literature, almost all transcatheter occlusions were performed in patients with ASD with diameters less than 30 mm.[1–8] Surgery is still the method of choice for a large ASD with diameters greater than 40 mm. We have observed that most large ASDs have a sufficient amount of residual septum that can facilitate the use of transcatheter occlusion (data not shown). So, we hypothesize that it is feasible to perform transcatheter closure of large ASDs in a safe and reliable manner. In this study, we present our data of transcatheter-based closure of a large ASD using the Amplazter device in 18 patients. The ASDs have diameters ranging from 30 to 40 mm as measured by fluoroscopy and echocardiography.

Methods

Patients

Eighteen patients (4 males, 14 females) with large secundum ASDs were referred for transcatheter closure. Patients' ages ranged from 12 to 53 years (mean 31.8 ± 12.96). All patients underwent physical examination, X-ray, electrocardiogram (ECG), transthoracic echocardiography (TTE) to confirm the diagnosis of ASD and to assess the size of the ASD. One patient had a recurrent ASD after surgical repair. The distance from the edge of the ASD to the pulmonary vein, caval vein, coronary sinus and atrioventricular valves was $\geqslant 5$ mm except 1 patient who had 3 mm of residual septum from the upper edge of ASD. The ECGs showed sinus rhythm in 14 patients, atrial flutter in 1 patient and atrial fibrillation in 3 patients. The cardiac functions of all patients were New York Heart Association (NYHA) class I except 2 patients with class IV and 1 with class III.

Devices and Procedures

The Amplazter septal occluding device (AGA Medical, Golden Valley, Minn., USA) was used in this study. A TTE was performed to evaluate the size, shape and location of ASD and the distance from the superior and inferior caval veins, right pulmonary vein, aortic root, atrioventricular valves and coronary sinus to the edge of the ASD. With the guidance of fluoroscopy, a pigtail catheter was inserted into the right ventricle after puncturing of the femoral vein percutaneously under local anesthesia, and right ventriculography was performed. Subsequently, a 7F balloon-tipped end-hole catheter was manipulated through the ASD into the left upper pulmonary vein. A 260 cm guide-wire, 0.9 mm in diameter, was applied through the catheter. An occlusion balloon catheter was then introduced into the left atrium. The balloon was positioned across the ASD, inflated with diluted contrast medium then gently pulled back against the septum until slight resistance was met. The diameter of the waist of the balloon—the "stretched diameter"—was measured fluoroscopically. In addition, the stretch diameter was reconfirmed visually by reinflation with the same amount of contrast medium after withdrawing the catheter from the patient. For ASD $\geq$ 34 mm, the stretch diameter is the greatest diameter as measured from multiple views by TTE. The occluding device was selected to be the same size or 1–2 mm smaller than the stretched diameter. The device size refers to the diameter of the connecting waist.

The device was inserted over the exchange guide wire into the left atrium after the introduction of an F12 sheath. The correct position of the delivery sheath was verified through a test injection of contrast medium. The left atrial disk was deployed and pulled back gently against the atrial septum under fluoroscopic and ultrasonic guidance. With gentle tension on the delivery cable, the sheath was pulled back and the right atrial disk was deployed while the waist of the occluding device opened. To ascertain that the occluding device was securely in place across the ASD, the delivery cable was tugged gently several times while observing it ultrasonically. The cable was detached from the device once the device was confirmed as secured. A TTE examination was then performed to verify the position of the occluding device and to detect any residual shunt.

Following the procedure, the patient was anticoagulated with heparin and aspirin for 48 h, then clopidogrel 75 mg daily, and aspirin 300 mg daily for 6 months. Follow-up was mainly performed by physical examination and TTE to assess the device position, residual shunt or thrombus formation.

Results

The diameter ranges of the ASDs were 30–35 mm (mean 32.00 ± 1.89 mm) measured with a balloon catheter in 14 of 18 patients. In 4 patients, the largest diameters of the ASD were 36, 38.5, 38.7 and 40 mm. The chosen occluded devices with diameters from 30 to 38 mm were used for closure of the ASD based on the dimensions evaluated by TTE. In 1 patient with an ASD diameter of 34 mm, an initial 34 mm occluding device failed to retain but subsequent deployment of 36 mm device was successful (Table 1). Almost all immediate postprocedure ultrasonic examinations showed small left-to-right residual shunt, which disappeared after 1 week. One patient with an ASD diameter of 34 mm developed a postprocedure third-degree atrioventricular block (AVB), which resolved to sinus rhythm in 3 weeks without intervention. Follow-up from 1 to 29 months after the procedure showed no significant complications. A TTE showed that the occluding devices were maintained in proper position and closely adhered to the atrial septum (see Fig. 1). The size of the right atria progressively became smaller in comparison to the preclosure states. Cardiac function was also restored to patients with cardiac dysfunction secondary to the ASD.

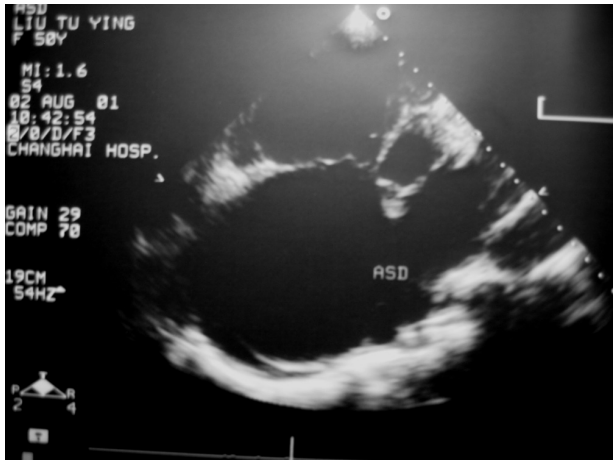
TABLE 1 Patients' basic information, Atrial Septal Defects diameter measured with echocardiography and balloon catheter, and occluder diameter chosen

Sex	Age	Echo-D (mm)	Balloon-D (mm)	Occluder-D (mm)
F	53	28	30	30
M	31	32	34	34
F	25	31	34	34
M	46	29	33	34
F	36	33	35	34
F	21	28	30	30
F	42	38.7	—	38
M	18	26.3	32	32
F	47	40	—	38
F	18	38.5	—	36
F	12	30	34	36
F	19	36	—	36
F	24	26	34	34
F	34	29	30	30
F	36	28.4	30	30
F	16	30	32	32
F	46	21.8	30	30
M	45	28	30	30
Mean		30.76	32.00	33.22
S.E.M.		4.86	1.89	2.84

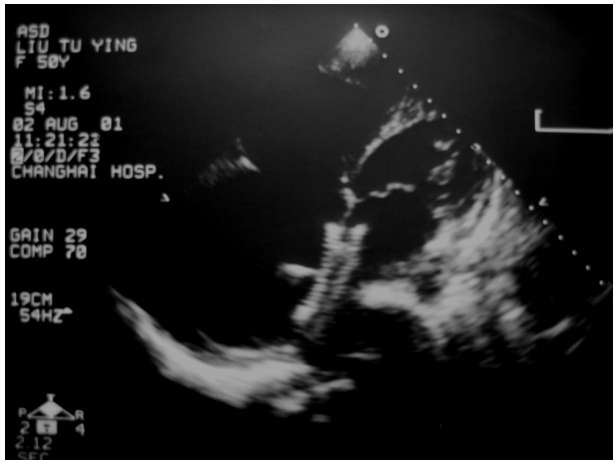
Abbreviations: Echo-D = diameter measured with transthoracic echocardiography; Balloon-D = diameter measured with balloon catheter under fluoroscopy; Occluder-D = diameter of chosen occuluder.

Discussion

Secundum ASD is a common congenital heart disease. In the past, surgery was the only option for a large ASD. However, in recent years, many types of occluding devices have been developed and used to repair the



(A)



(B)

FIG. 1 Transthoracic echocardiography preclosure and immediate postclosure. (A) Preclosure, (B) postclosure.

ASD, such as Cardio-seal,[7] Sideris,[8] Angel Wings[2,3] and Amplazter.[1–5] Clinical studies demonstrated that the first three types of occluding devices were used only for patients with ASDs with a diameter less than 30 mm.[2,3,7,8] We observed that most large ASDs have sufficient residual septal tissue that can facilitate the closure of the ASD by the transcatheter approach. The following three aspects must be considered before a transcatheter procedure: (i) accurate measurement of the ASD size and shape; (ii) choice of the occluding device with proper diameter and (iii) accurate measurement of the residual septum surrounding the ASD.

For ASDs with a diameter ≥ 30 mm, the occlusion balloon can easily pass through the septal defect from the left to the right atrium. It is difficult to maintain the balloon in place across the ASD to obtain the accurate stretched diameter. Zhu et al.[6] reported that the size and the shape of the ASD can be obtained with reasonable confidence using 3D-TTE. They observed that the echocardiographic results were consistent with those from the catheter-balloon method. From our clinical observations, the diameter of the ASD (< 30 mm) measured with TTE was consistent with the stretched diameter measured with the occlusion balloon catheter. In this study, the ASD diameters obtained from TTE in 13 patients were almost the same as the stretched diameters measured with a balloon catheter. In our opinion, TTE is a reliable method in quantitating ASD diameters. The presence of sufficient amount of residual tissue around the ASD is another important criterion for successful deployment of an occluding device. Otherwise, the occluding device will be easily dislodged back into the right atrium and cause an untoward clinical sequelae. The residual septum around the ASD can be accurately measured ultrasonically and the distance from the edge of the ASD to superior and inferior caval veins, right pulmonary vein, aortic root, atrioventricular valves and coronary sinus can be reasonably obtained.[8] The diameter of the occluding device was selected to be the same size or 1–2 mm smaller than the stretched diameter, or the diameter measured with TTE. In this study, the occluding device diameter was chosen based on the balloon-stretched diameter in 15 of the patients. For the other 3 patients who had an ASD size ≥ 34 mm, the device diameter was chosen based on the results obtained from the ultrasound, and was successfully deployed. Another dilemma for a large ASD is choosing the location for the placement of the occluding device, especially for patients with an uneven septum, because the occluding device can be easily jammed into the thin portion of the septum. If this occurs, it is advisable to retract the occluding device into its sheath and then resend the catheter to the left atrium, and then reopen the left disk. With the retentive propensity of the nickel-titanium frame, the occluding device is not malleable at body temperature, thus making it difficult to withdraw into the sheath. Hence, an F12 delivery sheath was chosen for an occluding device diameter greater than 30 mm.

Residual shunting was common immediately after the device was deployed and would typically disappear in about 1 wk. This early shunting was associated with the loose and thin nylon membrane of the occluding device. Several weeks later, endothelialization will cover the surface of the device, and neointima will form and would fully close any residual shunting (unpublished data).

The following complications were reported after catheter closure of an ASD such as displacement of occluding device, cardiac tamponade induced by cardiac rupture,[3] AVB,[5] thromboembolism[1] and pulmonary artery occlusion by the device.[2] Displacement of an implanted occluding device correlates with its construction and the operator's experience. If the device was properly positioned across the ASD, the location of the occluding device would not be changed when gently tugged. Furthermore, before releasing the device from the cable, fluoroscopy at LAO 45° with cranial 25° should be chosen to confirm whether the left and right disks were successfully opened. If two disks are still

closely attached, it is suggestive that they are not abutting the apposing wall of the defective septum. In this case, the device should be redeployed or risk displacement after being released from the cable.

Immediate postprocedure third-degree AVB was observed in 1 patient with an ASD diameter of 34 mm. Because heart rates were ranging about 50–60 bpm, no intervention was needed except closed observation. The AVB resolved spontaneously after 3 wks. Third-degree AVB may be associated with reversible tissue damage at the atrioventricular junction where it was pressed by the occluding device. The same phenomenon was reported by Chan in 1999.[5] In our opinion, if the pacing site is from the atrioventricular junction and heart rate above 50 bpm without symptoms, no intervention is necessary. Further measures should be taken if the AVB continued for more than 3 wks.

There was no significant complication observed in our patients. Some of the reasons might be due to the use of nitinol occluding devices and anticoagulation. The nickel-titanium occluding device has a good histocompatibility. To date, this device has been used in thousands of patients and only a small percentage developed thrombus.[1] In the previous study, we implanted an occluding device into the canine heart without heparin and an antiplatelet agent. Three months later, histological analysis showed that there was no thrombus formation on the surface of the occluding device or in the heart, and endothelialization was observed on the surface of the device (unpublished data). Heparin use during and after the procedure, with aspirin, is useful for prevention of thrombus or thrombus embolism.

In conclusion, a large ASD with diameter of 30–40 mm was successfully closed with an Amplazter device utilizing the transcatheter approach. The ASD diameter obtained ultrasonically was sufficiently accurate to aid in choosing the proper size of the occluding device.

Study Limitations

For catheter closure of a large ASD, the distances from the ASD edge to the pulmonary vein, caval veins, the coronary sinus and atrioventricular valves are the important factors to be considered. The device and delivery system underwent small modifications during the study period to overcome procedural difficulties. The patient population reported on was small.

The Ampatzer occluding device was extremely effective in this study population. There was complete occlusion in all patients by 1-wk to 29-month follow-ups. There were no significant complications. The cardiac function was markedly improved after closure. The device was safe, effective, and reliable when the protocol was carefully followed. Extensive clinical studies are required to evaluate catheter-based closure of large ASDs.

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