Cardiol Young 2002; 12: 224–228

ISSN 1047-9511

Original Article

Transcatheter closure of defects within the oval fossa using the Amplatzer® Septal Occluder

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Abstract This study reviewed the short-term outcome of transcatheter closure of the defects within the oval fossa using an Amplatzer® Septal Occluder. From January 1997 to December 2000, 210 patients with defects within the oval fossa underwent successful transcatheter closure. We reviewed a total of 190 patients with left-to-right shunts, assessing the patients for possible complications and the presence of residual shunts using transthoracic echocardiogram at 24 h, 1 month, 3 months and one year. Their median age was 10 years, with a range from 2 to 64 years, and their median weight was 23.9 kg, with a range from 8.9 to 79 kg. In 5 patients, a patent arterial duct was closed, and in 2 pulmonary balloon valvoplasty performed, at the same sitting. The median size of the Amplatzer® device used was 20 mm, with a range from 9 to 36 mm. The median times for the procedure and fluoroscopy were 95 min, with a range from 30 to 210 min, and 18.4 min, with a range from 5 to 144 min, respectively. Mean follow-up was 20.8 ± 12.4 months. Complete occlusion was obtained in 168 of 190 (88%) patients at 24 h, 128 of 133 (96.2%) at 3 months, and 103 of 104 (99%) at one year. Complications occurred in 4 (2.1%) patients. In one, the device became detached, in the second the device embolized into the right ventricular outflow tract, the lower end of the device straddled in the third, and the final patient had significant bleeding from the site of venupuncture. There were no major complications noted on follow-up. We conclude that transcatheter closure of defects within the oval fossa using the Amplatzer® Septal Occluder is safe and effective. Long-term follow-up is required, nonetheless, before it is recommended as a standard procedure.

Keywords: Defects within the oval fossa; transcatheter closure; Amplatzer® Septal Occluder

Since its introduction by King and Mills in 1976, transcatheter closure of defects within the oval fossa has been an attractive alternative to surgery. Various devices have been invented, and modified, to improve their weaknesses, increase the effectiveness, and to overcome the potential complications. The Amplatzer® Septal Occluder, has been shown to be superior to other currently available devices in terms of its safety and effectiveness, and it is technically easier to implant.[1–3] Some centers have recommended transcatheter closure using this device as a standard procedure for closure of defects within the oval fossa.[4,5] This technique, therefore, has been performed in our institution since January 1997. We report here our initial 4 years experience in 190 patients.

Methods

Patients

From January 1997 to December 2000, total of 210 patients successfully underwent transcatheter closure of defects within the oval fossa in National Heart Institute, Kuala Lumpur, Malaysia. The patients were preselected on the basis of an outpatient evaluation using transthoracic echocardiography, or transesophageal echocardiography in some adults. Transcatheter closure was attempted in those patients found to have hemodynamically significant defects within the oval fossa, of not more than two-thirds of

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Accepted for publication 21 January 2002

the interatrial length, and with good surrounding rims at least 6 mm from the atrioventricular valves, superior and inferior caval veins, pulmonary veins and coronary sinus. Those with very large defects, deemed too large for closure with the largest device available at the time, along with "ostium primum", sinus venosus, or multiple defects within the fossa deemed too far apart to permit safe closure, were referred for surgical closure. At present, the largest device available is 38 mm. Adults with defects measuring less than 28 mm, and children with defects measuring less than 18 mm on transthoracic or transesophageal echocardiography, were considered for the closure using the device. Written consent was obtained from every patient or guardian.

Procedure

All procedures were performed under general anaesthesia. Transesophageal echocardiography was routinely used to reassess the defect prior to the procedure, as well as being used to guide deployment of the device. Patients who were deemed suitable at this stage were subjected to routine cardiac catheterization, when balloons were used to size the defect prior to attempting transcatheter closure. Intravenous heparin at 50 μg/kg, and prophylactic antibiotics, were given on cannulation. A right pulmonary venous angiogram in a 4-chamber view, or left anterior oblique at 45 degrees angulation perpendicular to the atrial septum, was performed prior to the procedure to demonstrate the atrial defect. This set a "roadmap" for the arrangement of the atrial septum. Following the deployment of the device, a follow-through pulmonary arterial angiogram was performed in the same view to ensure that the device is in the correct position, in addition to transesophageal or transthoracic echocardiographic assessment.

Balloon sizing and implantation

At the initial stage, when the largest device available measured 20 mm, the stretched diameter of the defect was measured by a dynamic method using a Miller atrial septostomy catheter. When a larger device became available, we used the Sideris balloon catheter for sizing. Recently, the static technique using the AGA Medical balloon catheter was introduced, and presently is our preferred method for sizing. Sizing and implantation were performed as described in our previous publication.[6] All patients received prophylactic antibiotics for 24 h. Aspirin at 1–3 mg/kg, to a maximum of 150 mg daily, was started on the following day and continued for 6 months. Prophylaxis against endocarditis was recommended for 6 months whenever necessary.

Follow-up

A chest X-ray in anteroposterior and lateral views, an electrocardiogram, and transthoracic echocardiography were performed at 24 h, 1 month, 3 months, one year and yearly thereafter to look for residual shunts and possible complications, such as embolization and malposition of the device.

Statistical analysis

Data are expressed in median and range, or mean and standard deviation. Results of the procedure are presented as percentages. The difference between means was analyzed using Student's t-test. A linear regression analysis was performed to search for correlation between the size of defect as measured on transesophageal echocardiography and its stretched diameter determined by balloon sizing. A p value of less than 0.05 was taken as significant.

Results

From January 1997 to December 2000, a total of 210 patients successfully underwent transcatheter closure of defects within the oval fossa using an Amplatzer® Septal Occluder. This does not include those patients who were excluded because the defect was too large based on transesophageal echocardiographic findings before the procedure or after balloon sizing of the defect. Twenty patients who had a functional single ventricle heart with right to left shunts across the defect were excluded from this study.

We analysed the data from our 190 patients with left-to-right shunts, and have summarized the findings in Table 1. Of the patients, 49 (25.8%) were older than 18 years. Our youngest patient was a 2-year-old boy with Down's syndrome, who had an atrial septal defect of moderate size, measured at 11 mm on transthoracic echocardiography. The decision to close the defect at that age was mainly due to geographical reasons, since a second trip to our center was not practical. We found 13 with multiple

Table 1. Demographic and procedural data.

Sex	
Male	57 (30%)
Female	133 (70%)
Age (years)	4–64 (median 10)
Weight (kg)	8.9–79 (median 23.9)
Measured size of defect (mm)	
By transesophageal echocardiography	4–27 (median 14)
By balloon-sizing	9–36 (median 20)
Ratio of pulmonary to systemic flow	2.7 ± 1.4
Fluoroscopic time (min)	30–210 (median 94)
Procedural time (min)	4–144 (median 18.4)

https://doi.org/10.1017/S1047951102000501 Published online by Cambridge University Press

defects within the oval fossa in which the smaller defects were deemed close enough to the main hole to be closed using a single device. In 5 patients, we found an associated arterial duct, which was occluded using Gianturco coils in 4 and an Amplatzer® Ductal Occluder in the other. Significant valvar pulmonary stenosis in 2 further patients was treated by balloon dilation at the same sitting.

The majority of patients were asymptomatic. There were 11 patients who complained of shortness of breath on exertion, 8 had palpitations, and one had suffered a cerebrovascular accident. Associated arrhythmias were found in 7 patients, 2 with supraventricular tachycardia, 2 with atrial flutter, one with atrial tachycardia, one with atrial fibrillation, and the final one with sick sinus syndrome. All but the two patients with cerebrovascular accident and sick sinus syndrome, respectively, were adults. We performed concomitant radiofrequency ablation in the patient with supraventricular tachycardia, and coronary angioplasty in another patient with coronary arterial disease.

The size of the defect as measured on transesophageal echocardiography ranged from 4 to 27 mm, with a median of 14 mm. The median size of the device used was 20 mm, with a range from 9 to 36 mm. Using linear regression analysis, we found that the stretched diameter of the defect as determined by balloon sizing was 1.44 times the maximum diameter as measured on transesophageal echocardiography ($R^2 = 0.962$). The median time required for the procedure was 95 min, with a range from 30 to 210 min, and the median value for the period of fluoroscopy was 18.4 min, with a range from 5 to 144 min. The lengthy procedural time was mainly due to the time taken to size the stretched diameter. As we became more experienced, and familiar with the technique, the time needed became much less. The mean time for the procedure ($p = 0.01$), and the period of fluoroscopy ($p = 0.03$), was significantly shorter for the last 95 patients compared to the first 95. The times were 115 (±44.4) min, and 25.3 (±18.7) min, versus 88.4 (±34.3) min and 18.4 (±8.4) min, respectively. Mean follow-up was 20.8 ± 12.4 months, with a range from 6 months to 4 years.

We experienced no major complications or death (Table 2). In one patient, the device, sized 14 mm, detached inadvertently from the delivery cable. In this case, the right atrial discs failed to reform when fully deployed, instead taking on a mushroom configuration (Fig. 1). During subsequent manipulations, the device inadvertently detached from the cable and slipped into the right atrium. It was successfully snared with difficulty through an 11 French sheath. A different device of the same size was subsequently implanted uneventfully. This sequence accounted for our longest procedure and period of fluoroscopy. In another patient, the left atrial disc of the 26 mm device failed to open up properly. Again it appeared bulky, and took on a mushroom shape, despite it being retrieved and manually reshaped a few times. This was thought to be due to the excess size of the device. The procedure was abandoned due to unavailability of a smaller device, but successfully performed a year later using a 24 mm device without any complication. In another patient, an 18 mm device embolized into the right ventricular outflow tract on the next day, being discovered on routine investigation, and was successfully removed surgically, the septal defect also being closed by the surgeon. In retrospect, the device was undersized, as the defect was measured at 15 mm using transesophageal echocardiography. This correlates with an expected stretched diameter of 22 mm. Significant bleeding from the site of venepuncture site, requiring transfusion, occurred in another patient after the procedure. Transient and self-limiting arrhythmias occurred during the procedure in two adults. There was no incidence of thromboembolism or cardiac tamponade, as has been reported previously with other devices.

Table 2. Complications with transcatheter closure of defects within the oval fossa using the Amplatzer® Septal Occluder.

Inadvertent detachment	1
Embolization	1
Straddling of the lower end of device	1
Significant bleeding from site of venepuncture site	1
Total	4 (2.1%)

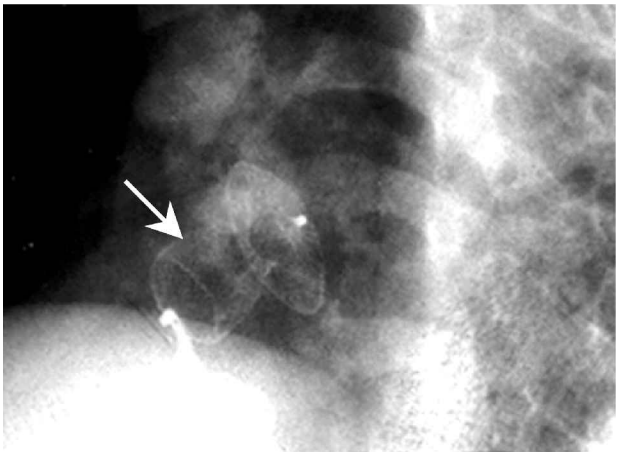

Figure 1.
The "mushroom shaped" Amplatzer® device. The right atrial disc failed to reform (arrow).

https://doi.org/10.1017/S1047951102000501 Published online by Cambridge University Press

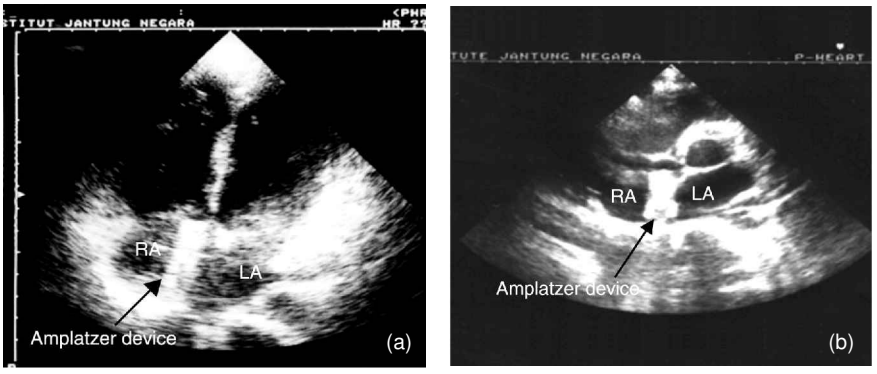

Figure 2.
Transthoracic echocardiography in the patient with straddling of the Amplatzer® device into the right atrium. The malposition is seen (a) in 4 chamber view and (b) in parasternal short axis view. RA: right atrium; LA: left atrium.

Almost two-thirds (64.9%) of our patients had trivial to small residual shunts following the procedure, mainly through the meshes of the device. Complete closure was obtained in 168 of 190 (88%) patients at 24 h, 128 of 133 (96.2%) at 3 months, and 103 of 104 (99%) at one year. In one patient, the lower end of the device was noted to be straddling, with both discs in the right atrium, at 3 months follow-up (Fig. 2). The upper end of the device, however, remained stable, and there was no obvious change in position on chest X-rays. This malpositioning might have occurred during the procedure itself. Apart from a small residual shunt at the inferior end, the device did not cause any obstruction to the atrioventricular valves, and remained at the same position at one-year follow-up. There was no incidence of fracture of the device, nor was there any incidence of obstruction to vital structures, endocarditis, or arrhythmia. All but one patient, who was symptomatic, experienced an improvement in symptoms. Atrial flutter recurred in one patient, but was controlled with anti arrhythmic therapy.

Discussion

Our results demonstrate an excellent performance of the Amplatzer® device in closing defects within the oval fossa, as has been reported by other investigators.[4,6–9] Its unique design is responsible for the higher rate of closure when compared to other devices.[1–3] The combination of the connecting waist that stents the defect, and polyester patches within the double-disc Nitinol wire mesh which promotes thrombosis, creates a good mechanism of closing the defect. Although a high percentage of patients have residual shunts through the wire mesh following the procedure, this disappears in most patients within 3 months. The device is technically easy to deploy, and it can be retrieved and repositioned without affecting its original shape. Its rounded edges prevent cardiac perforation and tamponade, which can occur with the buttoned device, and the Angel Wings device.[1–3] These safety mechanisms, together with its high effectiveness, have resulted in widespread adoption of the Amplatzer® occluder in many centers. In our center, use of the transcatheter technique has halved the surgical closure of defects in the oval fossa. The number of cases requiring surgical closure has reduced from 149 cases in 1995, before we started transcatheter closure, to 75 cases in the year 2000, when the full range of sizes of the device became available. On average, we perform 60 transcatheter closures per year.

Although it has been shown repeatedly that this technique is safe, it is still necessary to exercise great caution at every step of the procedure, from selecting the patients to implantation of the device. Detailed evaluation of the defect by a cardiologist who is familiar with the procedure, including the use of transesophageal echocardiography in adults, is important to avoid unnecessary cardiac catheterization and balloon sizing. The largest defect that we have closed so far, having a maximum diameter of 27 mm as measured on transesophageal echocardiography, was closed using a 36-mm device. In children, we use the value of 17 mm as measured on transthoracic or transesophageal echocardiography as the "cut-off" when deciding whether to close the defect surgically or attempt transcatheter closure, provided the rims of the oval fossa are considered suitable to accommodate the device. We usually defer the procedure until the children are bigger, certainly above 4 years of age, as we feel there is no necessity to perform it earlier when the majority are asymptomatic. The equation derived from this study is useful to predict the stretched diameter, especially when making decisions in the borderline cases. Use of an oversized device may result in deformity, with the device assuming a dumbbell or mushroom shape, while an undersized device may embolize. The solitary instance of embolization in our series could have been prevented if we had known the discrepancy between the

https://doi.org/10.1017/S1047951102000501 Published online by Cambridge University Press

stretched and predicted diameter. Deployment of the Amplatzer® device sometimes can be quite challenging, especially with devices larger than 28 mm, and when the defect is eccentric in location. With a large device, the left atrial disc is longer. Deployment of this disc is done simultaneously with pulling the delivery sheath into the right atrium, so that the entire left atrial disc is in the left atrium when it is fully deployed. This is to prevent deployment in the pulmonary vein or atrial appendage, situations that may cause twisting and lead to the "cobra head" malformation.[10,11] In cases where the defect is eccentric, we often need to rotate the delivery sheath anticlockwise while pulling the sheath towards the atrial septum, but without twisting the cable.

We feel that the use of fluoroscopy when deploying the device is complementary to transesophageal echocardiography in ensuring a proper placement of the device, although it is feasible to deploy under transesophageal echocardiography alone.[12] An unusual position of the device on fluoroscopy should alert the cardiologist to possible malposition of the device. With increased experience, and the use of the AGA balloon sizing catheter, the period of fluoroscopy has become shorter. Shim et al.[13] reported that the periods of fluoroscopy, and the measured surface entrance doses of ionizing radiation in patients undergoing occlusion with the Amplatzer® device, are similar to those undergoing routine diagnostic catheterization. In our opinion, the benefit from fluoroscopic guidance outweighs the risk of exposure to radiation.

In conclusion, the Amplatzer® Septal Occluder is a safe and effective alternative to surgery for closure of most defects within the oval fossa. The device fulfills almost all the criterions for an ideal device dreamt by an interventionist. It is easy to use, safe, and effective. It may appear bulky in a small patient, and this may affect the rate of endothelialisation, and therefore the potential risk of thromboembolism. Longer-term follow-up, therefore, is necessary before its insertion is recommended as a standard procedure.

Acknowledgment

We thank Mr Faizal for his assistance in the statistical analysis.

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