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Abstract: Introduction. Atrial septal defect (ASD) transcatheter occlusion techniques have become alternatives to surgical procedures. We evaluated the efficiency and safety of the Occlutech Figulla-N device in percutaneous closure of secundum ASDs in symptomatic children younger than 2 years of age. **Methods.** The study included 17 patients (9 girls, 8 boys; mean age, 10.3 ± 2.1 months). Mean weight was 7.4 ± 1.3 kg, with secundum ASDs measuring more than 8 mm with a hemodynamically significant shunt, resulting in failure to thrive, right ventricular dilatation, and pulmonary hypertension. Two girls had fenestrated ASD secundum. Defect size and total interatrial septal length were estimated by transthoracic (TTE) and transesophageal (TEE) echocardiography in 3 views. Procedures were performed under fluoroscopic and TEE guidance. Patients were followed-up at 1, 3, 6, and 12 months with TTE. **Results.** The mean defect size was 15.4 ± 2.7 mm on TTE and 17.1 ± 1.9 mm on TEE. The mean device size was 17.8 ± 3.6 mm (range, 10 to 24 mm). The mean pulmonary artery pressure was 54 ± 18 mm Hg. The device was placed successfully in all patients including fenestrated ASDs that were closed with a single device placement. No residual flow was seen after device placement in patients. Complications were seen in 2/17patients (11.8%) in the form of sinus tachycardia in 1 patient and femoral vein hematoma in 1 patient.

At 6 and 12 months, all the patients were asymptomatic. No cardiac perforation, device erosion, embolization, thrombus formation, or malposition of the device was observed. Three patients developed mild insignificant mitral regurgitation. **Conclusions.** ASD closure in severely symptomatic children younger than 2 years of age using the Occlutech Figulla-N occluder is safe and efficient. Meticulous care to patient selection, adequate defect sizing, and device size selection are keys to lower incidence of complications.

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Key words: Occlutech Figulla-N device, atrial septal defect

An atrial septal defect (ASD) is, due to its frequency, the fourth most common congenital heart disease, appearing in 3.78 of every 10,000 live newborns.[1] The diagnosis of an ASD, with signs of right ventricular volume overload, is an indication for its closure. Although surgical repair of atrial septal defects is a safe and widely accepted procedure with negligible mortality, it is associated with morbidity, discomfort, and a thoracotomy scar as well as the possibility of bleeding, arrhythmia, postpericardiotomy syndrome, and residual left to right shunts across the surgical patch.[2,3]

Conventional treatment with surgery through a median sternotomy using cardiopulmonary bypass has been considered the gold standard for ASD closure for more than 45 years.[4] Since the first transvenous ASD closure was performed by King and Mills in 1976,[5] a number of transcatheter closure devices have been designed and tested in clinical studies.[6-9] Today, with advances in percutaneous device technology, percutaneous closure has proved to be a safe technique to close ASDs.[2,10-12] Although transcatheter closure of ASDs is well established in children, there are scarce data available on the transcatheter closure of large ASDs in symptomatic children younger than 2 years of age. In this study, we aim to evaluate the safety and efficiency of the Occlutech Figulla device in this subset of patients.

Methods

Patients. The present work was designed as a prospective cohort study that included 17 children less than 2 years of age presenting to our center with ASD secundum between February 2010 and February 2011 who fulfilled the inclusion criteria. All parents gave informed consent for the procedure.

All patients were evaluated with transthoracic two-dimensional and color Doppler echocardiography with multiple subxyphoid and precordial windows. Each of the following criteria had to be fulfilled prior to inclusion: (1) the presence of an ostium secundum ASD with left to right shunt; (2) a distance of >5 mm from margins of the defect to the mitral and tricuspid valves, superior vena cava, right upper pulmonary vein, and coronary sinus; (3) dilation of right atrium and right ventricle indicating right ventricular overload; (4) ASD size >8 mm; and (5) adequate interatrial septal length, measured by multiplane transesophageal echocardiography (TEE) which was performed just before the transcatheter intervention and all through the procedure.

Routine examination before catheterization included a standard 12-lead electrocardiography (ECG), a chest x-ray, and a transthoracic echocardiography (TTE). Complete blood counts, prothrombin time (PT), prothrombin concentration (PC), partial thromboplastin time (PTT), and international normalized ratio (INR) were performed to exclude bleeding disorders. After ASD

closure, the patients remained in the hospital for 1 night, and received aspirin 5 mg/kg/day for 6 months. Before discharge, an ECG, biplane chest x-ray, and TTE examination were performed. Follow-up examinations including ECG and TTE were scheduled at 1, 3, 6, and 12 months after the procedure to evaluate residual shunt, the position and stability of the device, and its relationship with adjacent anatomic structures. Thirteen patients were followed for 1 year, 3 patients were followed for 6 months, and only 1 patient was followed for 3 months.

Device description. The Occlutech Figulla-N occluder (Occlutech GmbH) is made up of 0.082-0.186 mm nitinol wires that are tightly woven into two flat discs with a 4 mm connecting waist. The device diameter (the diameter of the waist) is available in varying sizes ranging from 6 to 40 mm, with 1.5 mm increments up to 12 mm, 3 mm increments up to 36 mm, and a 4 mm increment thereafter. The left and right atrial discs are 12 to 16 mm and 8 to 10 mm larger than the diameter of the connecting waist, respectively. The great advantage of this device is the absence of the left atrial disc micro screw, which decreases the chance for clot formation on the left atrial disc and increases flexibility due to movement ability of the device. It contains only one stainless-steel hub at the right atrial disc for wire connection. The size of the delivery sheath varies from 9 to 12 Fr for device diameters 6 to 27 mm.

Technique. Percutaneous transcatheter closure was performed under TEE guidance and premedication with heparin with a dose of 50 U per kilogram. After placement of the right femoral vein sheath, a guidewire was positioned into the upper left pulmonary vein through the ASD. Under continuous fluoroscopic and TEE monitoring, the left atrial disc was deployed. The system was then pulled back to straddle the ASD, and the long sheath withdrawn to deploy the waist and right disc of the Amplatzer septal occluder device. Once a satisfactory position was confirmed on TEE, the position and stability of the device were verified by a gentle tug on the device. The device was then released and the sheath and connecting wire removed from the groin.

Device size selection. The device size 1-2 mm larger than the ASD diameter was selected with particular emphasis on the size of the left atrial disc and the IAS length, especially in those small children.

All patients were discharged on treatment with aspirin for 6 months. Prophylaxis for infective endocarditis was recommended during the first 6 months.

Statistical analysis. Data were analyzed using the statistical package for social sciences version 15 (SPSS Inc). Numerical data were expressed as mean and standard deviation or median and range as appropriate. A *P*-value <.05 was considered significant.

Results

Demographics and clinical data. This study included 17 patients younger than 2 years of age. Patients included 9 girls and 8 boys with a mean age of 10.3 ± 2.1 months range, 9-18 months) and a mean weight of 7.4 ± 1.3 kg (range, 5.9-9.1 kg). On physical examination, the patients had a median heart rate of 127 ± 12 bpm. Four patients (23.5%) had audible systolic murmurs of relative pulmonary stenosis due to increased pulmonary flow and 3/17 patients (17.6%) had mild hepatomegaly. Plain chest x-ray revealed cardiomegaly in 16/17 patients (94.1%), mainly right atrial (RA) and right ventricular (RV) dilatation.

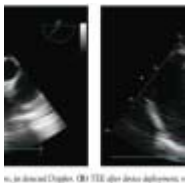
Thirteen out of 17 patients (76.5%) were treated with captopril at a mean dose of 1.9 ± 1.1 mg/kg/day in 3 divided doses and frusemide at a mean dose of 2.7 ± 0.8 mg/kg/day. Eight out of 17 patients (47%) had a history of at least one acute lower respiratory tract infection requiring parenteral antibiotics.

Preprocedural transthoracic echocardiography. TTE verified an isolated ASD secundum with RA dilatation with a mean of 15.4 ± 4.7 mm and RV dilatation with a mean of 21.3 ± 6.4 mm. Tricuspid valve regurgitation grades II-III was observed in all 17 patients. No associated cardiac anomalies were detected. The mean ASD size was 15.4 ± 2.7 mm on TTE. RA and RV measurements were taken by 2-dimensional examination using apical 4-chamber view. Right ventricular end diastolic diameter (RVEDD) z-score was 1.6 ± 1.3 and the RA z-score was 1.4 ± 1.1.

[4]All patients had sufficient rims (>5 mm). Two cases out of 17 (11.7%) had a fenestrated ASD (two separate ASDs with interatrial septal [IAS] tissue in between); the first case had 4.5 mm and 6 mm ASDs with 4 mm of IAS tissue, while the second had 5.5 mm and 7.4 mm ASDs separated by 3.5 mm of IAS tissue. IAS aneurysm was detected in 1 case (5.9%) (Table 1).

Transesophageal echocardiography. TEE confirmed the diagnosis of isolated ASD and revealed a mean ASD size of 17.1 ± 1.9 mm on TEE. Mean IAS length was 23.8 ± 5.8 mm (range, 21 to 35 mm). Sufficient ASD rims were observed in all cases (Table 1).

Procedure. The mean time between diagnosis and device closure was 2.2 ± 3.6 months. All cases were performed under general anesthesia and intra-operative TEE guidance. RT femoral vein access was achieved in 15/17 cases, and LT access in 2/17 cases. All cases received parenteral heparin at a dose of 50 IU/kg during the procedure together with cefotaxime 100 mg/kg. Mean device size used was 17.8 ± 3.6 mm (range, 10 to 24 mm). Long and short sheaths used were 11 and 12 Fr (as per the manufacturer's recommendations for each selected device). Device placement was successful in all patients including the 2 girls with fenestrated ASDs, which were closed with a single device (21 mm and 24 mm, respectively). The mean procedure time was 54.7 ± 16.3 minutes. No case of embolization was recorded.



[5]No residual flow was detected by intra-operative TEE and color flow Doppler after device deployment (Figure 1).

Complications were seen in 2/17 patients (11.8%) but none affected the procedural success. One patient (4 months old, 6.8 kg, ASD size 14 mm by TEE) developed transient sinus tachycardia during the procedure, but it recovered to normal rate spontaneously. The second patient (20 months old, 8.5 kg, ASD size 19 mm by TEE) developed groin hematoma and femoral vein thrombosis 3 hours after the procedure. He received urokinase injection and was maintained on low molecular weight heparin for 2 days. The thrombus resolved on the 4th postoperative day as verified by Doppler examination.

At 6-month follow-up, patients were asymptomatic. No cardiac perforation, pericardial effusion, infective endocarditis, device erosion, embolization, thrombus formation, or malposition of the device was observed. No device damage, such as broken nitinol wires or detachment of the central posts, could be detected. Three out of 17 patients (17.6%) developed mild insignificant mitral regurgitation, detected by TTE 1 month after closure that resolved spontaneously at 6-month follow-up.

Discussion

Interventional ASD closure is now widely practiced and has replaced surgical ASD closure in many centers.[7] Improvements in design have made the devices retrievable, and reduction in the size of the introduction systems allows interventional treatment even in young patients. We specifically used the Occlutech-N device. Other devices have been introduced by the

same manufacturer, namely, the new Occlutech Flex design, which has many advantages, such as no hub, a reduced amount of material used in braiding, more flexibility, and a hinge at the center providing better adaptability to the IAS. It also allows for the use of smaller delivery sheaths from 7-14 Fr. These advantages are even more pronounced in the Flex II version, with additional newer braiding technique and more flexible, smaller delivery sheaths (7-12 Fr). These devices should be the focus of future studies.

However there are still few data available on the transcatheter closure of ASDs in infants and children younger than 2 years of age. In a 2007 study by Diab et al,[10] the safety and efficacy of secundum ASD closure with the Amplatzer septal occluder (ASO; AGA Medical Corporation) were evaluated in 15 patients less than 1 year of age. They concluded that device closure of ASDs is an effective and fairly safe alternative to surgery in infants.[10-12] The Occlutech Figulla occluder is a safe and efficient device to close secundum ASDs. Immediate, short-, and mid-term clinical results and success rates are comparable with those obtained by the ASO device reported in previous studies.[7,8]

In the present study, procedural success was attained in all cases. This was achieved by strict adherence to the previous recommendations regarding all rims of the ASDs being >5 mm. Proper sizing by TTE and TEE was also very effective in size selection of the devices implanted.

Halabi and Hijazi[13] used 12 and 15 mm devices to close multiple ASDs in a child and concluded that this device could be used to close multiple defects with good results. Adopting this experience, two of the cases with fenestrated ASD were closed successfully using a single occluder; the bigger defect was stented with the device, while the LT atrial disc covered the other with no residual flow.

The previously reported rate of residual shunt was 9.1% for ASD cases at 60-day follow-up which diasappeared after 180 days.[12] Çeliker et al[14] reported the immediate residual shunt rate as 43.8% in a group of 80 children undergoing percutaneous closure of ASDs, probably caused by additional tissue captured by the retention disc, or additional defects that were not stented but only covered by the discs, which prevents complete defect occlusion and promotes residual leakage. In the present study, no residual shunt was documented at the end of the procedure or through the follow-up period.

Procedure-related complications including transient atrioventricular block, atrial arrhythmias, thrombosis, cardiac perforation, pericardial effusion, and pulmonary thromboembolism are usually associated with transcatheter closure of large defects and the use of large devices.[15,16] Kaya et al[17] reported no thrombus formation or serious complications in 12 patients undergoing percutaneous transcatheter septal closure of ASDs using the ASO device during a follow-up period of 11.6 ± 2.3 months. In the present study, the complication rate was 11.8% (2/17).

The possibility of the retention discs impinging on sensitive structures is particularly pertinent when dealing with small children. An additional consideration is the length of the IAS, which should be sufficient to accommodate the device.

In a study by Cardenas and co-workers in 2007,[18] a group of 52 children underwent percutaneous ASD closure at a weight ≤15 kg, in four Belgian tertiary referral pediatric cardiology centers. No major complications occurred. Clinical improvement was noted in 91.7% of the symptomatic patients. Minor complications were more frequent in the presence of large ASDs (>15 mm), but not in smaller babies (<10 kg).

In this series of 17 children less than 2 years old, a total of 3 out of 17 patients (17.6%) developed mild insignificant mitral regurgitation that resolved spontaneously at 6-month follow-up. Preoperative TTE reported no cleft mitral valve or mitral valve prolapse in these patients. Postoperative TTE revealed no impingement on the mitral valve and no device oversizing.

Conclusion

ASD closure in severely symptomatic children younger than 2 years of age using the Occlutech Figulla-N occluder is safe and efficient. Meticulous care toward patient selection, adequate defect sizing, and device size selection are keys to lower incidence of complications.

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