Original Article

Percutaneous Device Closure for Secundum-type Atrial Septal Defect: Short and Intermediate-term Results

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Abstract

Background: Device closure of an isolated secundum type atrial septal defect (ASD) has been used as an alternative method for open surgical closure with comparable success and lower morbidity. In this study we evaluated the procedural success and mid-term follow-up results of percutaneous closure of secundum ASD with an Amplatzer™Septal Occluder(ASO) device or a Figula ASD occluder device.

Method: From June 2001 to January 2009, 74 consecutive patients were scheduled for percutaneous device closure in two centers in Tehran, Iran. All patients had a stretched defect diameter of 30mm or less. After using a sizing balloon to measure the stop-flow diameter, device implantation was performed under the guidance of a trans-esophageal echocardiography (TEE).The size was generally 1 – 2 mm larger than the stretched diameter. Patients were followed for an average of 11±4 months.

Results: The median stretched diameter of the defect was 20.7±4.8 mm (range: 8 – 30 mm).A total of 73 devices were used in this study. Device closure was successful in 72 (97.2%) out of 74 patients. Repositioning of the device was required in one patient. Major complications(including significant residual shunt and device embolization) occurred in 3 (4%) patients.There was no procedure-related mortality in our patients. Mild-to-moderate residual shunt was detectable in 10 (13.7%) patients immediately following the procedure and in 5 (6.7%) patients 24 hours after the procedure. None had residual flow across the device at the end of the follow-up period.

Conclusion: Device closure of ASD has a safety profile comparable to open surgical repair and can effectively close the defect with excellent procedural and mid-term results.

Keywords: Amplatzer™ ASD closure device, figula ASD closure device, percutaneous ASD closure,secundum atrial septal defect.

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Introduction

Percutaneous device closure of an atrial septal defect (ASD) was introduced in the 1970s and has been proven to be a safe, effective method in the treatment of this anomaly.[1,2] Since then, a number of devices have been used for this purpose with comparable results,[3–6] but most experiences have been with the Amplatzer™ Septal Occluder (ASO) device (AGA Medical Corp., GoldenValley, MN, USA). Most studies have shown high procedural success rates with good long term results following device closure of ASD.[4,5]

Thus far, no large study about the efficacy and safety of this procedure in the Iranian adult population has been undertaken. Therefore, in this study we attempt to assess the procedural success, complication rates and mid-term results of percutaneous device closure in Iranian patients with isolated secundum ASD.

Patients and Methods

We included all patients with isolated secundum type ASD and hemodynamically significant left to right shunt. These patients underwent device closure of the defect with either an ASO device (AGA Medical Corp., Golden Valley, MN) or a Figula ASD occluder device (Occlutech, Helsingborg, Sweden). The procedures were performed by experienced attending physicians at Rajaie Cardiovascular center and Day General Hospital (Tehran, Iran). The study continued from June 2001 to January 2009. A written consent was taken from all patients and their relatives after informing them of the available treatment options. The study protocol was based on standard interventional methods of percutaneous ASD closure and was approved by both centers'Medical Ethics Committees. Trans-esophageal echocardiography (TEE) was performed before the procedure to measure the size of the defectand the surrounding rims. Also, during the procedure, TEE was performed in all patients to assess the proper position of the device and to rule out the presence of a large residual shunt or compression of the mitral or tricuspid valve apparatus. One day after the procedure, trans-thoracic echocardiography was performed to confirm the proper position of the device and cessation of the left to right shunt. During the follow-up period, trans-thoracic echocardiography was performed after one month and every six months thereafter. Patients were followed for 11 ±4 months.

Patients were excluded if there was an insignificant left to right shunt [defined as pulmonary to systemic blood flow ratio (Qp/Qs) of less than 1.5] and device closure in these patients was not attempted. Those with an insufficient defect rim (< 5mm except for the antero-superior rim) were considered unsuitable for device closure[7] and were also excluded from the study. We did not include patients with other types of ASD such as ostium primum or

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sinus venosus type ASD or those with associated anomalies such as partial anomalous venous connection.

Before device implantation a thorough angiographic and hemodynamic study was performed that included pulmonary artery pressure measurement and shunt calculations.Then, patients underwent general anesthesia and the defect was sized with a sizing balloon under the guidance of a multi-plane TEE. The stop-flow diameter rather than the waist diameter was regarded as the real defect size. The technique of device deployment was as previously described in the literature.[3,5] All patients were fully heparinized and received intravenous cefazolin (1 – 2 g) before the procedure and for the first 48 hours after the procedure. Electrocardiography, chest X-ray and echocardiography were performed to rule outany complications and to confirm the proper position of the device. Patients were generally discharged 24 to 48 hours after the procedure. All patients received aspirin (100 – 300 mg/qd) and clopidogrel (75 mg/qd) for six to twelve months.

The information regarding device size or echocardiographic variables are expressed as mean ± SD or median and range. Categorical variables such as complication rate are shown as percentages. SPSS version 15.0 software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

Results

We included 74 consecutive patients (23 men, 51 women), with a median age of 31 years (range: 8 – 77 years).Pulmonary artery systolic pressure before the procedure was in the range of 14 – 65 mmHg(median: 33 mmHg). There were 7 (9.4%) patients who had moderate pulmonary hypertension (defined as systolic pulmonary pressure: 50 – 70mmHg).No patient had severe pulmonary hypertension. The median stretched diameter of the ASD was 20.7 mm (range: 8 – 30 mm). There were 2 patients that had two defects and both had total cessation of shunt flow with implantation of a single device. Overall, 73 devices were implanted; 66 were the ASO device and 7 were the Figula occluder device. There was no preference for choosing Amplatzer or Figula occluder devices. Selection was based on availability of the device in the hospital. Device size ranged from 8 to 30 mm (median: 22 mm).

In 72 (97%) patients the procedure was successful. The procedure failed in 2 patients. One had a stretched diameter of 25mm with an insufficient anterior and antero-superior rim. In this patient device closure with a 26 mm ASO device was attempted but the device could not be stabilized with certainty. Therefore the device was retrieved and the procedure terminated. The other patient had a stretched diameter of 30mm with sufficient rims. Due to the lack of devices larger than 30mm in our catheterization laboratory at that time, a number 30 ASO device was selected but could not fit the defect properly and was, therefore, retrieved.

Intra-procedural TEE showed that a residual shunt was present in 10 patients at the end of the procedure. Out of these patients, 9 had a mild residual shunt defined as a jet width < 2 mm byTEE.[7]One patient had a moderate left to right shunt (jet width: 2 – 4 mm by TEE) immediately after device implantation. One day after the procedure, all patients underwent trans-thoracic or TEE to rule out the possibility of delayed device displacement and to re-evaluate the degree of residual shunt. Out of the 10 patients with post-procedural residual shunts, 5 showed no shunt flow 24 hours after the procedure. At the end of the follow-up period no patient had a detectable residual shunt by trans-thoracic echocardiography.

There was no death during the hospital course in our group of patients. No major complications occurred during a mean follow-up of 11 months. No endocarditis or thrombo-embolic events were reported during this follow-up period. Also, we did not have a patient with new-onset migraine headache or significant aggravation of migraines among our patients in the follow-up.

Discussion

Major complications occurred in 3 (4%) out of 74 patients. In one of our patients, device mal-positioning occurred after an apparently successful procedure.This patient had a stretched defect diameter of 23mm and received an ASO size 24mm with successful immediate results. However, follow-up echocardiography performed the following morning showed a significant left to right shunt and inappropriate position of the device across the defect. The patient was returned to the catheterization laboratory for successful repositioning of the device. Cessation of the shunt flow was confirmed by intra-procedural TEE. The patient had no residual shunt in the follow-up period.

Another complication occurred in a patient with a defect stretched diameter of 26mm who underwent device closure with a 26mm ASO. After implantation she became hypotensive and echocardiography showed pericardial effusion and early diastolic right ventricular collapse suggestive for tamponade. After pericardial drainage she was sent for surgical exploration and open closure of the defect. Close inspection by the surgeon revealed that the device had caused erosion of the superior aspect of the right atrium near the interatrial septum. The device was removed and the patient underwent an open ASD closure and right atrial repair with successful results.

In the third patient with a major complication, a 28 mm ASO device embolized to the left pulmonary artery after being released from the cable. Attempts to snare the device were unsuccessful. The patient was transferred to the operating room and surgical removal of the device as well as open repair of the ASD were successfully performed.

Surgical correction of secundum-type ASD has been associated with high success rate and low risk of mortality.[4] However, morbidities related to median sternotomy, possible blood transfusion and length of hospital stay are considered as drawbacks, particularly in the presence of a less invasive percutaneous approach. Since its introduction in 1974 by King et al.[1,2] percutaneous ASD closure has proven to be as efficacious as surgery and associated with less morbidity. Studies with different types of occluder devices have shown similar rates of procedural success.[3–6]

In Iran, although there are several studies regarding ASD device closure in the Iranian patient population,[8,9] they are either underpowered due to low numbers of patients or have primarily focused on the pediatric population. Our study is the largest experience with this procedure thus far in Iran and its acceptable results could be regarded as a proof of efficacy and safety of this procedure in both the Iranian and Middle Eastern population.

In this study we mainly used an ASO, therefore the results can be mostly attributed to this device. As we mentioned earlier, the maximum stretched diameter of the defect among our patients was 30 mm, which was due to previous reports of higher complication rates when selecting larger than 30 mm defects for percutaneous device closure.[4]

Balloon sizing seems to be quite reliable in device size selection as in our study the selected device size virtually stopped flow and had a proper position in all but one patient. Mild or moderate degrees of residual shunt flow (with a jet width of less than 4mm across the defect) were present in 10 (13.5%) patients immediately after the procedure. By the following morning, this number decreased to 5 (6.7%) patients. The main reason for this could be invisible thrombus formation on the surface of the polyester fabric meshed within the nitinol structure of the device. With passage of time, the possibility of residual flow presence is reduced because the device surface is endothelialized and becomes a structure "within" the inter-atrial septum. In our study, none of the patients had residual shunt an average of 11 months after the procedure.

The clinical success rate in our study was 93.2%, which was in concordance with previous studies that have invariably reported procedural success rates of more than 90%.[4,5]

Percutaneous ASD closure could be considered at least as safe as surgical closure. Although a study-defined major complication occurred in about 4% of patients, these complications generally do not lead to fatal events and could be corrected by percutaneous re-intervention or surgical procedures. However, we did not include patients that had a stop-flow diameter of more than 30mm. Therefore we must limit our judgment about the efficacy and safety of our experience only to ASD secundum defects with diameters of no greater than 30mm.Longer follow-up is obviously needed to confirm the favorable results of our study.

Conflicts of interest: *No conflicts of interest have been claimed by the authors*

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