Experience with Percutaneous Transcatheter Closure of Interatrial Communications at the Cardiovascular Center of Puerto Rico and the Caribbean

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Objective: The annual rate of percutaneous transcatheter closure of atrial septal defects (ASDs) and patent foramen ovales (PFO) has markedly increased in the United States over the past decade. This technique has been used at the Cardiovascular Center for Puerto Rico and the Caribbean since 2005. We report on the clinical characteristics and the immediate and short-term follow-up of adult patients who underwent this procedure at this center from 2008 to 2012.

Methods: One hundred and two consecutive medical records of adult Hispanic patients who underwent this procedure at our center from 2008 to 2012 were identified. A retrospective analysis of the clinical characteristics and the immediate and short-term clinical and echocardiographic follow-up of those patients was performed.

Results: The study population comprised 70 women and 32 men, with a mean age of 51 years (age range: 19 to 80 years). Of those, 43 (42%) underwent ASD closure and 60 (59%), closure of a PFO. A 99% procedural success rate was achieved. There were only 3 procedural complications, including the failure of the initial implantation of 1 device, which required the endovascular removal of that device and the implantation of another, a hematoma at the vascular access site, and 1 brief episode of atrial fibrillation.

Conclusion: Based on our review of the available records, we were able to determine that the percutaneous transcatheter closure of interatrial communications proved to be, at our institution, a safe procedure with a high success rate and a low incidence of in-hospital complications. To our knowledge, this is the first report on the utilization of this interventional procedure in Puerto Rico. [*P R Health Sci J 2015;34:159-163*]

Key words: PFO, ASD, Puerto Rico, Hispanics, Amplatzer, CardioSEAL

Interatrial septal communications such as atrial septal defects (ASDs) can lead to pulmonary hypertension, right-sided heart failure, or atrial arrhythmias; patent foramen ovale (PFO), in particular, has been implicated as a source of paradoxical embolism and cryptogenic strokes in young adults (1). The percutaneous closure of these communications has opened new areas of research and treatment. An improvement in device design together with better interventional techniques and low complication rate have made this procedure an attractive therapeutic option for patients with these disorders and has, at many institutions, replaced surgical closure in those with a suitable anatomy (2). This has led to a marked increase in the annual performance rate of this intervention in the United States over the past decade (3, 4). This procedure has been in use at the Cardiovascular Center for Puerto Rico and the Caribbean (CVCPRC) since 2005. We report on a retrospective review of the clinical characteristics and the immediate and short-term clinical and echocardiographic follow-up of adult Hispanic patients who underwent this procedure at this institution from 2008 to 2012.

Atrial septal defects are the most common congenital cardiac lesions after bicuspid aortic valve in adults; 75% of these are of the ostium secundum variety (5). Ostium primum, coronary sinus, and sinus venosus variants are much less common. The consequences of large, prolonged left-to-right shunting through an ASD include right ventricular volume overload and increased pulmonary flow, which may lead to pulmonary hypertension, Eisenmenger's syndrome, right heart failure, atrial arrhythmias or paradoxical embolism (6). Long-term complications have been described to occur in up to 10% of patients with ASDs, with age being the single most important predictor of long-term outcome (7).

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Percutaneous device closure is an effective, safe, and commonly employed alternative to surgical closure in patients with ostium secundum ASDs. Clinical studies have described positive outcomes in the great majority of ASD patients treated with percutaneous closure, which has been associated with a reduction in left atrial volume and improvements in right and left ventricular function (8). Improvement in functional capacity has also been reported in a study of 32 asymptomatic adult patients who underwent atrial septal defect closure at a mean age of 43 years and whose mean baseline pulmonary-to-systemic blood flow was around 2.0 mL/kg per minute. At 6 months, the peak oxygen intake of patients undergoing cardiopulmonary-exercise testing significantly improved compared to that before closure. A significant correlation was found between the magnitude of the functional improvement and baseline pulmonary-to-systemic blood flow, even in patients with values over 2.0 mL/kg per min. (9).

The joint American College of Cardiology (ACC)/American Heart Association (AHA) 2008 Guidelines for the Management of Adults with Congenital Heart Disease recommend either surgical or percutaneous ASD closure in patients with right atrial and ventricular enlargement, regardless of symptoms (10). Other indications for closure in those guidelines include the presence of a significant left-to-right shunt, defined as a pulmonary-to-systemic flow (Qp/Qs) ratio greater than 1.5, the occurrence of paradoxical embolism and documented platypnea-orthodeoxia.

Percutaneous closure of these defects has grown in acceptance because it has proven to be safe and less painful; in addition, it can be performed as an ambulatory procedure. Thus, it has become a valuable alternative to surgery because of its similar success rate, lower complication rate and shorter length of hospital stay (11). Despite this, operator and center experience remain important decisional considerations. The rate of short term complications seem to correlate with the number of procedures performed annually at each center (12).

A patent foramen ovale (PFO) is a common embryonic defect in the interatrial septum and is found in 15% to 25% of the adult population; it has been related to serious clinical syndromes such as recurrent stroke, myocardial infarction and systemic embolism (13). Optimal therapy for prevention of recurrent stroke and transient ischemic attack in PFO patients has yet to be clearly defined. Among the management strategies most often used are drug therapy with vitamin K antagonists or antiplatelet agents, surgical repair and percutaneous closure. Suture closures of incidental patent foramen ovales are routinely performed during surgeries being undertaken for other reasons, but the primary surgical repair of this condition is infrequently advocated. Whether the treatment of a PFO is best accomplished pharmacologically or via percutaneous device closure remains the subject of intense debate and one that requires greater study. An objective comparison of the relative safety and efficacy of each approach can be accomplished through the analysis of additional data, which could be gathered via further randomized, prospective clinical trials (14). As the clinical trial data have so far been insufficient, the current AHA and American Stroke Association Guidelines for the Prevention of Stroke in Patients with Stroke or Transient Ischemic Attacks assign a class IIb, level of evidence C indication to percutaneous device closure (15).

Materials and Methods

A retrospective review of the medical records of consecutive adult Hispanic patients who were selected for percutaneous transcatheter closure of ASD and PFO at our center from 2008 to 2012 was performed. All patient information regarding clinical and procedural data was collected on a set data sheet and entered into a common database for review and analysis. The study was approved by the Institutional Review Board (IRB) of the Medical Sciences Campus of the University of Puerto Rico. Only data related to adult patients above 18 years of age who underwent these procedures were included in the review. One hundred and ten medical records were initially identified, of which only 102 patients were entered into the study, as they met the aforementioned inclusion criteria. All the operators performing the procedures had formal training in interventional cardiology and more than 3 years of experience inserting the pertinent devices.

Procedure

The closures of ASDs and PFOs were performed using either the CardioSEAL or the Amplatzer septal occluder. All procedures were performed in the catheterization laboratory, with fluoroscopic and TEE guidance, while patients were under conscious sedation. All the patients received intravenous antibiotics at the time of the procedure, followed by dual antiplatelet or anticoagulation therapy. At the start of the procedure, the groin area received 10 ml of 2% subcutaneous lidocaine. Before device implantation, the patients underwent percutaneous diagnostic cardiac catheterization from the right femoral artery and right femoral vein. Hemodynamic and oxygen saturation measurements were performed. During the intervention, either a direct thrombin inhibitor or heparin was administered intravenously for anticoagulation. Subsequently, a 6F introducer was placed in the right femoral vein using the modified Seldinger technique, and a 6F multipurpose catheter was advanced, with the help of a 0.035 mm Terumo wire, across the interatrial septum until it reached the left upper pulmonary vein. A left atriogram was done in the AP projection to confirm the catheter position. The multipurpose catheter was then replaced over the wire by an 11F Mullins catheter. A balloon catheter was advanced over the guide wire and stretched; the sizing of the defect was accomplished using angiography and TEE. Device selection was performed depending on the size and characteristics of the septum. For ASD closure, a device with a size 2mm greater than the top flow diameter was usually suitable. For PFO closure, the size of the right disc of the device

was chosen to be twice the size of the right opening of the tunnel. Once the device was chosen, it was cautiously advanced over the stiff exchange wire and deployed at the interatrial septum. The adequacy of the device's position was assessed by both TEE and fluoroscopy. Residual shunts were assessed and the optimal placement of the device was verified by TEE with color flow Doppler.

Chest x-rays, two-dimensional echocardiography and ECGs were performed before discharge. Patients were discharged on dual antiplatelet and/or anticoagulation therapy (which was maintained for 3 to 6 months). Endocarditis prophylaxis was prescribed, following the 2007 American Heart Association Prevention of Infective Endocarditis guidelines (16).

Results

The patient population included 102 consecutive adult patients who underwent transcatheter closure of an ASD or a PFO at our center from 2008 to 2012. The clinical characteristics of these patients are shown in Table 1. There were 70 (69%) women and 32 (31%) men, with a mean age of 51 (range: 19 to 80) years.

Most interventions involved PFO closure; that group consisted of 60 (59%) patients with a mean age of 49 years. ASD occlusion was performed in 43 (42%), which patients had a mean age of 53 years. One patient had both defects. All PFO interventions were done on patients who had been referred to our center because of their history of multiple neurological events (despite appropriate medical therapy); of these, 17 (17%) had associated atrial septal aneurysms.

Thirty-six patients with ASDs had right ventricular enlargement (documented by echocardiography), 1 had platypnea-orthodeoxia and 6 had a history of neurological events, both of which are indications for ASD closure, according to current AHA/ACC Guidelines for the Management of Adults with Congenital Heart Disease.

The procedural data, described in Table 2, shows a 99% success rate, with small or no residual shunts after device deployment in all patients. The average size of the device used was 24 mm. Only 1 patient required the implantation of a second device. The device most frequently employed was the Amplatzer septal occluder. As shown in Table 3, there were no deaths in the studied population. One access-site hematoma occurred during one of the interventions, as well as a brief episode of atrial fibrillation. There was failure in the initial implantation of 1 device, requiring its endovascular removal and the implantation of a new one. No major complications requiring emergency cardiac surgery occurred in any patient within 30 days of his or her procedure.

Discussion

The main indication for ASD closure is the presence of a significant shunt, as evidenced by right heart volume overload with or without symptoms, such as exercise intolerance, fatigue, dyspnea, heart failure, paradoxical emboli, or atrial arrhythmias. Percutaneous device closure is an alternative to surgical closure only in patients with ostium secundum ASDs with the appropriate anatomic characteristics. The ideal defect should be less than 30 mm in diameter, with a rim of tissue around the defect of at least 5 mm, to prevent obstruction of the coronary sinus, right pulmonary veins, venae cavae or atrioventricular valves (17).

Table 1. Patient population

No. of patients	102
Age, yrs.	51 ± 14
Females	70 (69)
Males	32 (31)
ASD	43 (42)
Females	32 (74)
Males	11 (26)
Mean age (yrs.)	53
PFO	60 (59)
Females	39 (65)
Males	21 (35)
Mean age	49
Clinical history and characteristics	
Hypertension	63 (62)
Hypercholesterolemia	31 (30)
Diabetes mellitus	12 (12)
Coronary artery disease	11 (11)
Current smoker	5 (5)
Hypothyroidism	11 (11)
Epilepsy	5 (5)
Multiple neurologic events	66 (65)
Migraine	2 (2)
COPD	2 (2)
OSA	2 (2)
ASD post-surgical repair	1 (1)
Tetralogy of Fallot	2 (2)
TGA s/p Mustard	1 (1)
Platypnea-orthodeoxia	1 (1)
Thromboembolic risk factors	
Paroxysmal atrial fibrillation	1 (1)
DVT at time of index event	0 (0)
Prior history of DVT	0 (0)
OCP use, fertile female	0 (0)
History of pulmonary embolism	0 (0)
Echocardiographic risk factors	
Atrial septal aneurysm	17 (17)
Bicuspid aortic valve	2 (2)
Mitral valve prolapse	4 (4)
Pulmonary regurgitation	1 (1)
Pulmonary stenosis	1 (1)
Right ventricular enlargement	36 (36)
Spontaneous right-to-left shunting	1 (1)
Possible right atrial thrombus	0 (0)

Values are n (%) or mean ± SD. Legend: TGA s/p Mustard = Transposition of great vessels post-Mustard procedure; COPD = chronic obstructive pulmonary disease; OSA = obstructive sleep apnea; DVT = deep venous thrombosis; OCP = oral contraceptive pills

All patients with ASDs in this report had right ventricular enlargement and met the criteria for the procedure in question according to the current AHA/ACC Guidelines for the

Management of Adults with Congenital Heart Disease. The devices were successfully deployed in 99% of the patients; the complication rate was low, and no urgent surgical intervention was required as of 30 days post-implantation. The observed results favorably compare with those reported in the medical literature (18, 19, 20, 21).

Table 2. Procedural data

Amplatzer	64 (63)
CardioSEAL	38 (37)
Procedural success (%)	101 (99)
Mean device size, mm	24 ± 6
Need for second device	1(0)
Estimated blood loss, mL	7 ±7.3
Immediate residual shunt	
No residual shunt	77 (75)
Small shunt	25 (25)
Moderate shunt	0 (0)
Large shunt	0 (0)
Contrast used, mL	37 ± 38
Fluoroscopy time, min	15 ± 7.3

Values are n (%) or mean ± SD

Although data from nonrandomized observational studies have shown benefits from PFO closure in patients with recurrent cryptogenic strokes, the most effective therapeutic strategy for the prevention of strokes in these patients remains unsettled (22, 23, 24). As already mentioned, randomized data and large clinical trials are lacking; more of both are required if this issue is to be sufficiently clarified. In recently reported randomized controlled trials, such as CLOSURE I, percutaneous PFO closure with the STARFlex device was not associated with a benefit greater (in terms of the prevention of recurrent embolic events) than that associated with medical therapy alone (25). Likewise, in the primary intention-to-treat analysis, members of the RESPECT trial did not find there to be any significant benefit associated with PFO closure when performed on adults who had had a cryptogenic ischemic stroke. However, closure was found superior to medical therapy alone in the prespecified per-protocol and as-treated analyses because of the former's low rate of associated risks (26). Larger randomized trials are required before definitive recommendations can be made regarding the optimal management of patients with this clinical disorder.

Although the review of the available data shows this procedure to have a high success rate and adequate safety profile, we acknowledge the limitations in the present review, as it is a small retrospective evaluation of medical records and the studied population was a select group of patients referred to our center because of recurrent neurologic events. This cohort might be different from study populations described in other series in the literature. Additionally, the intermediate and long-term follow-up of most patients in this review were performed by the referring primary care physicians, and thus the intermediate and long-term end points were not available for analysis. A prospective evaluation of a larger sample of patients with PFO and recurrent embolic events (and with a longer follow-up period) is needed if we are to adequately assess the clinical benefits and complications of this procedure in the prevention of recurrent neurologic events in our population at large.

Table 3. In-Hospital and adverse events at 30 days

Death	0 (0)
Respiratory failure requiring intubation	1 (0)
Access-site hematoma	1 (0)
Stroke	0 (0)
Device migration	0 (0)
Emergency surgery	0 (0)
Endovascular removal	1 (0)
Pericardial tamponade	0 (0)
Atrial fibrillation	1 (0)
Supraventricular tachycardia	0 (0)
Pericardial effusion	0 (0)

Values are n (%)

In conclusion, the percutaneous transcatheter closure of ASD and PFO was shown in this study to be an effective and safe therapeutic intervention for patients with ostium secundum ASD or PFO and recurrent embolic events (with appropriate indications and favorable anatomic characteristics). The procedure was associated with a high success rate and a low incidence of in-hospital complications when performed by an experienced team of skilled operators. To our knowledge this is the first report on the utilization of this interventional procedure in Puerto Rico.

Resumen

Objetivo: La tasa anual de cierres percutáneos de defectos del septo interatrial y del foramen oval permeable ha incrementado marcadamente en los Estados Unidos en la última década. Este procedimiento ha sido utilizado en el Centro Cardiovascular de Puerto Rico y del Caribe desde el 2005. En esta publicación se describen las características clínicas y el seguimiento intrahospitalario de pacientes Hispanos adultos sometidos a estos procedimientos en este centro del 2008 al 2012. Métodos: Se identificaron 102 expedientes de pacientes adultos consecutivamente sometidos a estos procedimientos en esta institución del 2008 al 2012. Se efectuó un análisis retrospectivo del perfil clínico y del seguimiento hospitalario y ecocardiográfico inmediato y a corto plazo de estos pacientes. Resultados: La población incluyó 70 mujeres (69%) y 32 hombres (31%), con edad promedio de 51 años. Cuarenta y tres (42%) pacientes tenían un defecto del septo interatrial; 60 (59%) tenían un foramen oval permeable. La tasa de éxito fue de 99%. Sólo hubo 3 complicaciones: falla en la implantación inicial de un dispositivo (lo cual requirió su extracción por vía endovascular y la inserción de otro dispositivo), un hematoma pequeño en el acceso vascular y un episodio breve de fibrilación

atrial. Conclusión: El cierre percutáneo de los defectos demostró ser seguro y efectivo, y tuvo una baja incidencia de complicaciones en el período estudiado. A nuestro entender este es el primer informe en la literatura médica sobre la utilización de este procedimiento en Puerto Rico.

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