Indian Heart Journal xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj

Original Article

Simplified percutaneous closure of patent foramen ovale and atrial septal defect with use of plain fluoroscopy: Single operator experience in 110 consecutive patients

Antonis S. Manolis[a,*], Spyridon Koulouris[b], Efthymia Rouska[b], John Pyrros[b]

[a] Third Department of Cardiology, Athens University School of Medicine, Athens, Greece
[b] Department of Cardiology, Evagelismos General Hospital of Athens, Athens, Greece

ARTICLE INFO

Article history:
Received 9 March 2017
Accepted 29 July 2017
Available online xxx

Keywords:
Patent foramen ovale
Atrial septal defect
Percutaneous closure
Amplatzer occluder
Cryptogenic stroke
Paradoxic embolism
Migraine

ABSTRACT

Objective: Percutaneous closure of patent foramen ovale (PFO) and atrial septal defect (ASD) is routinely performed under general anesthesia or deep sedation and use of transesophageal (TEE) or intracardiac echocardiography, incurring longer duration and higher cost. We have used a simplified, economical, fluoroscopy-only guided approach with local anesthesia, and herein report our data.
Methods: The study includes 112 procedures in 110 patients with PFO (n = 75) or ASD (n = 35), with use of an Amplatzer occluder, heparin and prophylactic antibiotics. Balloon sizing guided ASD-device selection. All patients received aspirin and clopidogrel for 6 months, when they all underwent TEE.
Results: All PFOs but one (98.7%) and all (100%) ASDs were successfully closed with only one complication (local pseudoaneurysm). At the 6-month TEE, there was no residual shunt in PFO patients, but 2 ASD patients had residual shunts. During long-term (4.3-year) follow-up, no stroke recurrence in PFO patients, and no other problems were encountered. Among 54 patients suffering from migraine, symptom relief or resolution was reported by 45 (83.3%) patients.
Conclusion: Percutaneous placement of an Amplatzer occluder was safe and effective with use of local anesthesia and fluoroscopy alone. There were no recurrent strokes over >4 years. Migraine relief was reported by >80% of patients.

1. Introduction

Over the past several years there have been significant advances in percutaneous management of intracardiac communications, thus obviating open heart surgery.[1] Among them, a growing number of atrial septal defect (ASD) and patent foramen ovale (PFO) device closure procedures have been performed.[2] The indications for ASD closure include evidence of right ventricular volume overload with a pulmonary to systemic blood flow ratio (Qp/Qs) > 1.5/1 before the development of significant pulmonary hypertension; the defect must have adequate rims to support the device and a maximal stretched diameter of ~35 mm.[2] PFO has been implicated in the pathogenesis of cryptogenic stroke, arterial desaturation, decompression illness, and migraine[3]; however, great controversy has clouded the indications for percutaneous PFO closure, which is currently considered an option for patients with a cryptogenic stroke, in whom paradoxical embolism through the PFO is considered to be the cause.[2,4]

In most centers, these percutaneous procedures are performed under general anesthesia or deep sedation and intra-procedural use of transesophageal echocardiography (TEE) or use of intracardiac echocardiography (ICE) and intravenous sedation, all incurring longer procedure duration and much higher cost.[5,6] Since the beginning of our program of percutaneous closure of intracardiac communications, we have used a simplified and economical fluoroscopy-only guided approach with use of local anesthesia,[7–9] have found it safe and effective and herein report our prospectively collected data and results.

2. Patients and methods

2.1. Study population

Over 10 years, 112 procedures were performed in 110 patients who were referred for percutaneous closure of a PFO after having

Abbreviations: ASD, atrial septal defect; IASA, interatrial septal aneurysm; MRI, magnetic resonance imaging; PFO, patent foramen ovale; TEE, transesophageal echocardiography.

* Corresponding author at: Third Department of Cardiology, Athens University School of Medicine, Athens, Greece.
E-mail address: asm@otenet.gr (A.S. Manolis).

http://dx.doi.org/10.1016/j.ihj.2017.07.020

suffered cryptogenic strokes, and 35 patients with secundum-type ASD with right ventricular volume overload and a Qp/Qs ratio of ≥1.5, who constitute the present study group. For every procedure, an informed written consent was obtained from each patient.

2.2. Transesophageal echocardiography

All patients had a diagnostic TEE study performed before the procedure, either by their referring cardiologist or by our team; all outpatient TEE exams were reviewed by our team. Special attention was paid for accurate assessment of ASD morphology including measurements of maximal diameter aiding in device selection and surrounding rim dimensions requiring >5 mm superoanterior (aortic) and inferior vena cava rims for optimal device placement and avoidance of belated cardiac erosion problems. All PFO patients had an agitated saline (bubble) study during TEE with performance of a Valsalva maneuver. There was no intra-procedural TEE or other echo guidance in any patient. As detailed below, most patients were submitted to TEE the day after the procedure and all patients had a TEE at 6 months later to confirm device position and adequate sealing.

2.3. Percutaneous device closure technique

All patients received aspirin and clopidogrel for 1 week before the procedure, and prophylactic antibiotic was administered intravenously one hour before the procedure, with two additional doses administered afterwards. Intravenous heparin (5000–7000 u) was used during the procedure.

In all subjects, the procedure was exclusively performed under local anesthesia with use of plain fluoroscopy guidance alone without intra-procedural transthoracic echocardiography, TEE or ICE. All procedures were performed with use of an Amplatzer® Septal Occluder (St. Jude Medical, Inc., St. Paul, Minn, USA), delivered via a long 8–12 Fr sheath. The device implantation technique is described in more detail in Supplement A. Briefly, via a right femoral venous approach, the patients were catheterized and an initial attempt was made to cross the communication with use of a standard 0.35" J-tipped guidewire. If this was not successful, crossing was assisted with use of a multipurpose or an Amplatz catheter, occasionally with contrast injection against the interatrial septum, or use of a hydrophilic wire, and in more difficult cases wire passage was guided with use of a steerable electrophysiology catheter probing and crossing the communication. After crossing the PFO, the preselected Amplatzer occluder was introduced. For the ASD patients, measurement of the ASD diameter was first performed with use of a sizing balloon, on which device selection was based but oversized by 3–4 mm and deployed via the special delivery system. After the device was secured in place, the delivery system was removed and pressure applied at the groin for hemostasis.

The day following the procedure, TEE was repeated or a transthoracic echo performed to check for device position and any residual shunt or other peri-procedural complications. In the early part of our series, every patient had a TEE the next day; however, in the latest part, we have modified our approach and currently forego TEE and perform instead a transthoracic echo in the majority of PFO patients but have continued performing TEE in the ASD patients. All patients were discharged home at 24–48 h with aspirin and clopidogrel for 6 months. At 6 months, all patients underwent a repeat TEE. Further annual clinical follow-up was scheduled in all patients. A simple, not standardized, clinical questionnaire was used for evaluating migraine symptomatology, comparing the pre- with the post-procedural clinical status of each patient.

2.4. Statistical analyses

Data are expressed as mean ± standard deviation and/or percentages. Additionally, data are depicted in chart and/or histogram formats. Data were analyzed with SPSS 23 for Windows (SPSS Inc., Chicago, IL). Agreement between methods was evaluated using paired *t*-test and Pearson correlation, but also a Bland-Altman analysis to calculate the limits of agreement with the use of the statistical package MedCalc v. 16.8.4 (MedCalc Software, Ostend, Belgium).

3. Results

Patients' characteristics, data and procedural results are presented in Tables 1 and 2, and Figs. 1–4. Overall the initial procedure was successful in 109 (99.1%) patients, 74 (98.7%) PFO and 35 (100%) ASD patients (Table 1, Fig. 1). There was only 1 (0.9%) major vascular complication in a PFO patient.

3.1. PFO group

The clinical and echocardiographic characteristics of the 75 PFO patients are presented in Table 1 and Fig. 1. A total of 45 (60%) PFO patients also suffered from migraine. Recurrent strokes and multiple brain infarcts on MRI had been documented prior to the procedure in 22 (29.3%) patients (Fig. 2).

All PFOs but one (98.7%) were successfully closed with use of an Amplatzer occluder (Table 2, Fig. 1). In one patient with a serpentine-shaped PFO, the guidewire could not pass through, and due to long procedure duration, the procedure was aborted and a repeat procedure via a transseptal puncture approach was recommended. Easy wire passage via the PFO was performed in 30 (40%) patients; in 43 patients wire crossing was assisted with use of supportive catheters (multipurpose, Amplatz), while in 9 patients wire passage was guided with use of a steerable electrophysiology catheter. In two patients, there was need for use of a transseptal puncture system; probing sufficed to enable PFO crossing in one, while transseptal puncture was performed in the other patient. Serpentine or sigmoid-shaped PFOs were visualized with contrast injection in four cases with difficult crossing. A typical PFO patient and the steps in which the patient was approached are displayed in Fig. 2. The selection of the specific Amplatzer occluder is detailed in Supplement A. Briefly, the 25/18 mm Amplatzer occluder device was implanted in 38

Table 1
Clinical and echocardiographic characteristics of the study population.

Parameter	PFO	ASD
No of patients	75	35
Men/Women	33/42	14/21
Age (years)	48.5 ± 14.6	52.1 ± 13.3
(range)	(22–78)	(17–75)
Cryptogenic Stroke	74 (98.7%)	5
Multiple strokes	22 (29.3%)	
Diver's disease/CVA	1	
Platypnea-orthodeoxia	3	
Migraine	45 (60%)	9 (25.7%)
IASA	44 (58.7%)	
Eustachian valve	14 (18.7%)	
DOE/Fatigue		31
RVE		30
Qp/s > 1.5:1		23
PHTN		8
Echo size of ASD		15.5 ± 4.8 mm
(range)		(7–27 mm)

ASD = atrial septal defect; F: female, M: male, CVA = cerebrovascular accident; DOE: dyspnea on exertion; IASA = interatrial septal aneurysm; PFO = patent foramen ovale; RVE; right ventricular enlargement, PHTN = pulmonary hypertension.

Please cite this article in press as: A.S. Manolis, et al., Simplified percutaneous closure of patent foramen ovale and atrial septal defect with use of plain fluoroscopy: Single operator experience in 110 consecutive patients, Indian Heart J (2017), http://dx.doi.org/10.1016/j.ihj.2017.07.020