



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, Evangelismos General Hospital of Athens, Athens, Greece

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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.

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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 migraine³; 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).

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 Amplatzer 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 \pm 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) (range)	48.5 \pm 14.6 (22–78)	52.1 \pm 13.3 (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 (range)		15.5 \pm 4.8 mm (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.

Table 2
Procedural Features and Outcome of 110 Consecutive Patients Submitted to Device Closure.

Parameter	All Patients	PFO	ASD
Patients	110	75	35
Procedures	112	75	37
Easy wire passage	50	30	20
Balloon size of ASD (mm)	–	–	19.3 ± 5.8
Device (waist) size (mm)	–	–	22.9 ± 6.5
Device oversizing (mm)	–	–	3.7 ± 1.5
Device (right disk diameter)	–	25.8 ± 2.5	–
Device (left disk diameter)	–	21.7 ± 4.0	–
Fluoroscopy (min)	–	6.6 ± 7.1	7.4 ± 5.2
Procedure duration (min)	–	35.9 ± 21.5	49.0 ± 20.5
Successful initial closure	109 (99.1%)	74 (98.7%)	35 (100%)
Complications	2 (1.8%)	1 (1.3%)	1 (2.7%)
Sealed at 6 months	107 (98.2%)	74 (100%)	33 (94.3%)
Follow-up (months)	–	51.6 ± 37.8	30.0 ± 20.0
Stroke recurrence	–	0	–
Migraine improvement	45/54 (83.3%)	37/45 (82.2%)	8/9 (88.9%)

ASD = atrial septal defect; PFO = patent foramen ovale.

patients, the 25/25 mm device in 28 patients, the 35/25 mm device in 4 patients and the 30/30 mm device in 4 patients. In 3 patients with an IASA, the initially chosen 25/25 mm device could not be stabilized as it could be easily pulled through the PFO into the right atrium (n=2) or noted deformed (parachute shape) (n=1) and was exchanged for a larger 30/30 mm device which was then easily and successfully implanted. Finally, the mean sizes of the device disks were 25.8 ± 2.5 mm for the right disk and 21.7 ± 4.0 mm for the left disk.

Procedure duration averaged 35.9 ± 21.5 min and fluoroscopy time 6.6 ± 7.1 min. The only complication encountered was a pseudoaneurysm of the right femoral artery in one patient, apparently caused by inadvertent arterial puncture, managed with echo-guided local thrombin injection.

3.2. ASD group

The ASD group comprised 35 patients (Table 1). During the initial procedure for each patient, all ASDs were successfully closed (Table 2, Fig. 1). A typical ASD patient and the steps followed are presented in Fig. 3. During the procedure, in 3 patients there was need to upsize the initially selected device as it failed to get stabilized in place (n=2) or specific deformity of the disks was noted (n=1) before the device was detached from the attachment cable. One patient developed transient atrial fibrillation with no other periprocedural complications noted. At 2 weeks post-procedurally, the same patient developed a brief episode of paroxysmal nocturnal dyspnea managed with diuretic without further recurrences. At 6 months after the implantation, one patient with an ASD (size measured at 22.8 mm) with adequate rims, initially closed with a 24-mm device, had a moderate residual shunt and at attempting to place a new closure device, the device migrated into the pulmonary artery and was successfully recaptured with a percutaneous technique. The patient was subsequently scheduled and underwent successful surgery 6 months later. Small residual shunting was noted in another patient at the 6-month follow-up TEE, who was initially managed conservatively; a later attempt at 18 months to close the residual defect failed due to inability to cross it. All other patients reported no symptoms at a mean follow-up of 30 ± 20 months. Thus, complete and durable ASD closure was effected in 33 (94.3%) patients.

With regards to the measurements of the ASD size, a significant correlation was found between echocardiographic and fluoroscopic measurements ($r=0.78$, $p<0.0001$). However, most of the echocardiographic measurements underestimated ASD diameters compared with conventional balloon sizing (15.5 ± 4.8 mm vs 19.3 ± 5.8 mm, $t=6.6$, $p<0.001$) (Fig. 4). Moreover, the limits of agreement between the two methods calculated with the Bland-Altman analysis, were found between 2.7 and –10.9 mm, meaning that TEE measurement may be 2.7 mm above or 10.9 mm below the number obtained from balloon sizing. This is a fairly wide difference suggesting a lack of agreement between the 2 methods.

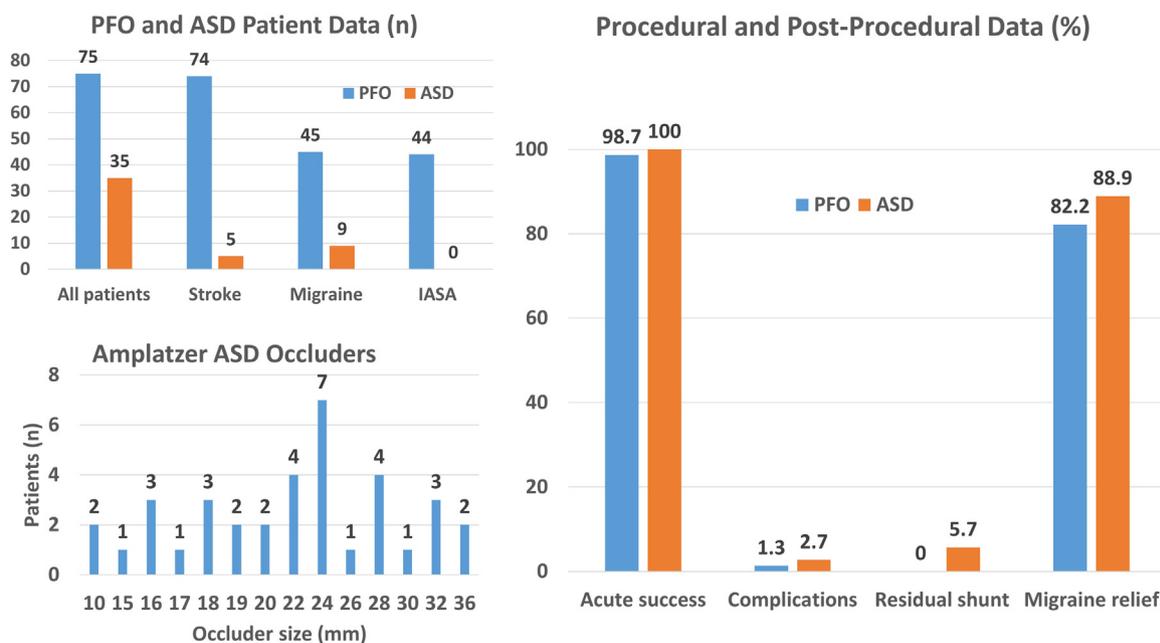


Fig. 1. PFO and ASD patient data are displayed in the left upper panel. Procedural and post-procedural data are presented in the right panel (numbers indicate percentages). A histogram of the sizes (mm) of the occluder device employed in each ASD patient is displayed in the left lower panel. ASD = atrial septal defect; IASA = interatrial septal aneurysm; PFO = patent foramen ovale.

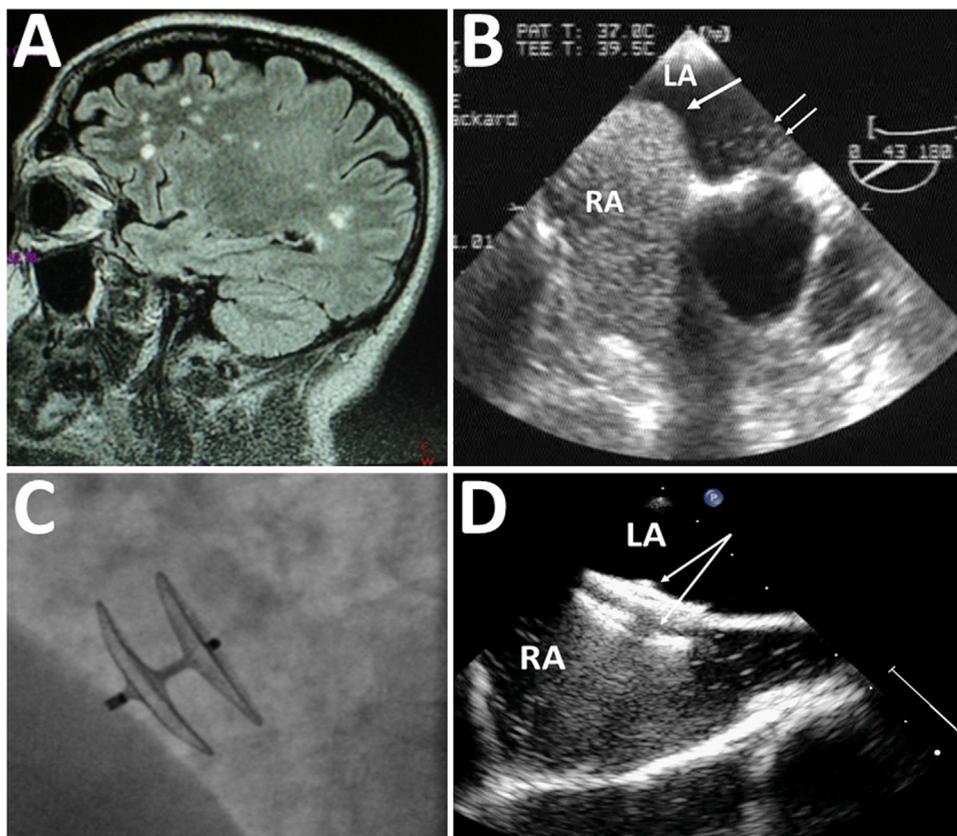


Fig. 2. A typical PFO patient having cryptogenic stroke(s) with brain MRI detecting multiple cerebral infarcts (white spots in **panel A**), TEE disclosing an aneurysmal interatrial septum (arrow in **panel B**) with positive bubble study (multiple bubbles passing through the PFO from the right atrium to the left atrium: double arrows in panel B), undergoing percutaneous PFO closure with the double disk device (**panel C**) guided by plain fluoroscopy, having a TEE the next day and 6 months later to confirm good device positioning and sealing of the PFO (no bubbles passing through to the left atrium, **panel D**; arrows indicate the left and the right disk of the device). LA = left atrium; RA = right atrium.

Finally, following an oversizing policy in our practice, the mean size of the devices employed was 22.9 ± 6.5 mm (range 10–36 mm); thus, there was a mean size difference from the measured defect size using the stretched balloon method and the selected device size (device waist) of 3.7 ± 1.5 mm. **Fig. 1** (left lower panel) displays the histogram of the size of the device employed in each patient.

3.3. Follow-up

At the 6-month post-procedural follow-up TEE examination, there was no residual communication detected during a bubble study in any PFO patient. Residual shunt was detected in two ASD patients as detailed above. During long-term follow-up of 51.6 ± 37.8 months for the PFO group and 30.0 ± 20.0 months for the ASD group, no further problems related to the procedure or the device were reported; no cases of recurrent stroke were encountered and no cases of device-related erosion were detected. With regards to the migraine symptoms among the 45 PFO patients and the 9 ASD patients, significant relief or resolution was reported by 37 (82.2%) and 8 (88.9%) patients respectively. During follow-up, there occurred 3 deaths due to unrelated causes.

4. Discussion

Use of current technique, a simplified and economical method for percutaneous closure of PFOs and ASDs which was performed under plain fluoroscopy and local anesthesia, achieved high procedural and long-term success in the present series of 110 patients. In most

centers, TEE or ICE has routinely been used to guide these procedures with their attendant cost, patient inconvenience and prolonged procedure duration.⁵ However, other investigators have suggested and used a fluoroscopy-guided approach with encouraging results.¹⁰ Although this may be considered feasible for the PFO cases, many still argue that the more challenging ASD closure procedure should best be guided by TEE or ICE.^{11–13} We also concur that ASD closure is a more demanding procedure, however, we were able to circumvent the lack of TEE guidance with use of the stretched balloon sizing technique followed by device oversizing. The latter was modified by further upsizing after the two cases that we encountered early during our experience with residual shunting, as well as a couple of cases with device slipping through the ASD during attempts of disk deployment and device positioning, despite documented adequate rims surrounding the defect. After adopting a >3 – 4 mm oversizing strategy, no further residual shunts were encountered at follow-up, nor was there any need for upsizing intraprocedurally. With regards to the large difference between the echo- and the balloon-measurements (**Fig. 4**) and the assertion by pediatric cardiologists that they usually rely on the echo measurement of the ASD to guide device selection,^{11,12} we believe this discrepancy is mostly due to the floppy texture of the adjacent ASD tissue in the adult population compared to the tissue sturdiness in the pediatric population. It should be noted that the ASD group referred to our center were much older patients (mean age 52 years).

The complication rate was very low in the current series. Among the 110 patients undergoing an initial procedure, only one (0.9%) vascular complication from inadvertent arterial injury (femoral artery pseudoaneurysm) occurred, which was managed

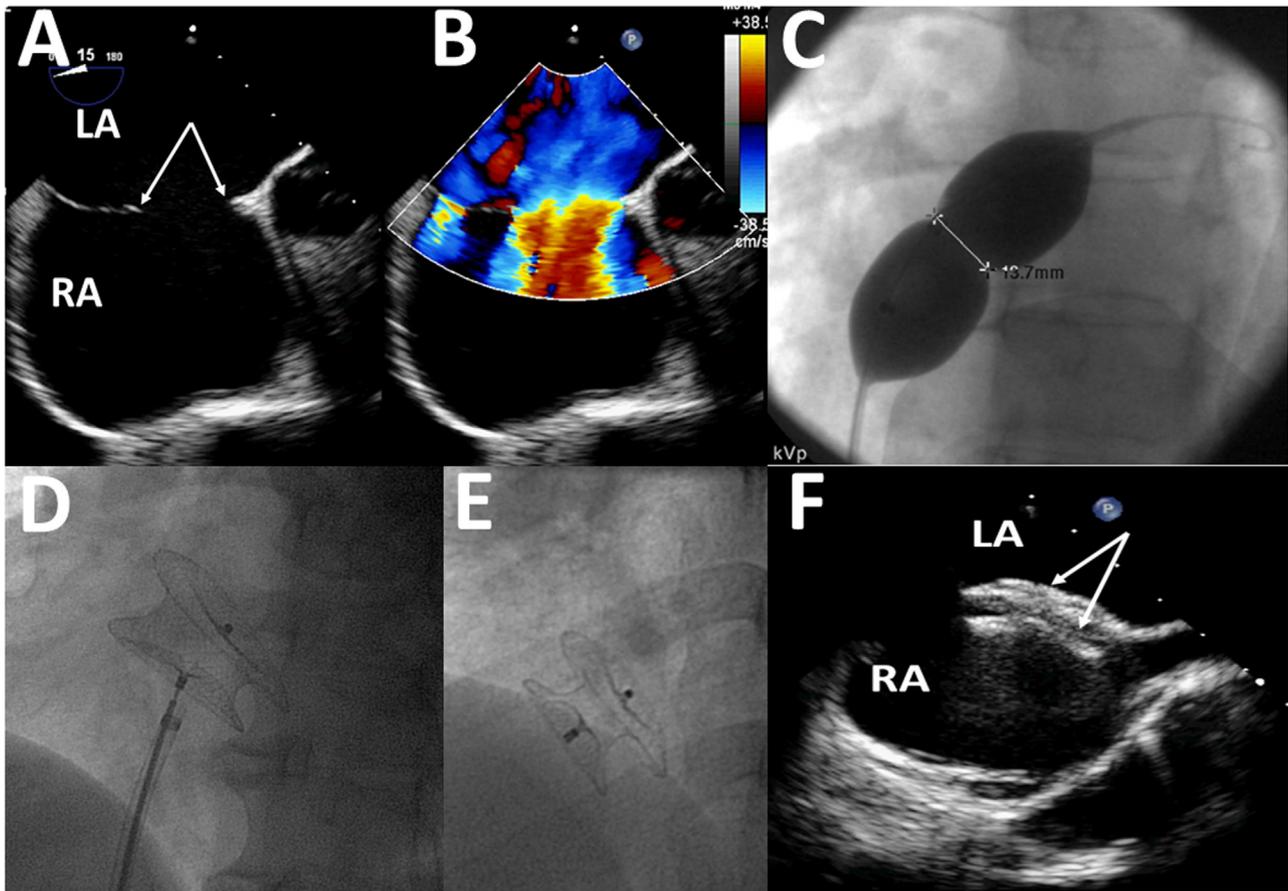


Fig. 3. A typical ASD patient having the ASD closed for right heart hemodynamic overload with pre-procedural TEE delineating the rims of the defect (arrows in **panel A**) and documenting significant left-to-right shunting (mosaic in **panel B**), intra-procedural measurement of the defect with the balloon-stretching method (**panel C**), followed by device positioning (**panel D**) and deployment (**panel E**), and finally next-day and 6-month TEE confirming good positioning (**panel E**) and lack of residual shunting.

with ultrasound-guided local thrombin injection. The rate of vascular complications in other series ranges from 0.5% to 3.2%.^{1,6,14} Subsequently, in one ASD patient undergoing attempted closure of a residual shunt 6 months later, the device got dislodged, but was successfully recaptured via a percutaneous technique. This is potentially a most risky complication which may necessitate urgent cardiac surgery to remove the device. It has been reported in 0.3–1.4%.^{15,16} Among other complications that have been

reported in other series, one may encounter increased incidence (5.7–8%)⁶ of atrial fibrillation temporally related to the procedure; we observed only one such patient in our series. The specific device employed in the current series has been reported to be the least thrombogenic among all other closure devices.¹⁷ Importantly, no cases of erosion or perforation occurred during long-term follow-up in our series, a complication that has been rare with an estimated incidence of 0.1–0.3%.¹⁸

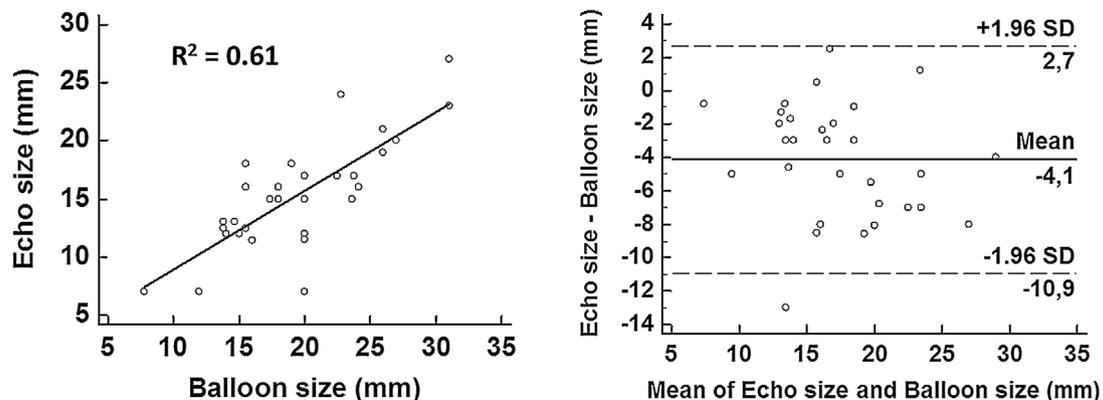


Fig. 4. Correlation between TEE and balloon measurements (**left panel**). Bland-Altman plot indicating the limits of agreement between TEE and balloon sizing (**right panel**). TEE = transesophageal echocardiography.

4.1. Cryptogenic strokes, PFO and PFO closure

Strokes are the third cause of death following cardiovascular disease and cancer.¹⁹ Approximately 10–40% are cryptogenic, i.e. of unknown cause, and in these patients the incidence of a PFO reaches 50% compared to the 25–30% incidence in the general population,²⁰ implying a relation between PFO and cryptogenic stroke, especially in people aged <55 years. This risk further rises up to 15-fold higher in the presence of an IASA.²⁰ The best imaging method to disclose these brain infarcts is MRI (Fig. 2). In some cases, the thrombus is caught by echocardiography straddling the PFO during its passage from the right to the left atrium, requiring surgical removal to avert a disastrous stroke.²¹

Diagnosis of a PFO requires a contrast or “bubble” study during TEE when rapid contrast or agitated saline solution is rapidly injected via the antecubital vein and a right-to-left passage of the bubbles is observed spontaneously or facilitated with a Valsalva maneuver (Fig. 2).

The management of PFO patients afflicted by cryptogenic stroke is based on antiplatelet or anticoagulant therapy, however relapses still occur at a percentage ranging from 4% to 25%, which has led to an alternate approach utilizing percutaneously implanted PFO occluders. The procedure is relatively simple and safe and appears to reduce stroke recurrence to 0–5%.²² However, initial studies comparing the two approaches were mostly retrospective²³ and only in the last few years, data from prospective randomized studies^{6,14,24} became available indicating a significant on-treatment effect, albeit not by intention-to-treat analysis, and thus the debate continued. Nevertheless, the number of procedures has been rapidly growing.²⁵

A recent pooled analysis of data from randomized PFO closure trials comprising 2303 patients concluded that among patients with PFO and cryptogenic stroke, closure significantly reduced recurrent stroke (hazard ratio: 0.58; $p=0.044$).⁴

Current American guidelines (2014, 2016) do not support PFO closure.^{26,27} However, recently (October 2016), based on the positive results of the extended (~6-year) follow-up of the RESPECT trial, showing significant stroke reduction with PFO closure (HR 0.55; $p=0.046$),²⁸ and on the aforementioned pooled analysis,⁴ the FDA approved the Amplatzer PFO Occluder device for prevention of recurrent strokes in patients with a cryptogenic stroke and a PFO.²⁹ Our approach to this issue has been consistent with the 2013 UK National Institute for Health and Care Excellence (NICE) guidance,³⁰ applied in a shared-decision making strategy that we routinely employ for every procedure recommended to our patients.

Among the risk factors predisposing to paradoxical emboli in patients with a PFO, an IASA and a eustachian valve, present in 44 (58%) and 12 (16%) patients respectively in our series, seem to have an important role.^{16,31–33} Device closure in these patients was highly successful as wire crossing of the PFO was easy and did not necessarily require larger devices, as one might have expected, with no residual shunting at the 6-month follow-up TEE examination. Long tortuous PFOs, encountered in 8% in our series, were the most difficult to cross.

Resorting to a transseptal puncture to close a PFO has recently been reported in a small series of patients with long PFOs.³⁴ It was employed in one and recommended in another patient in our series who had long and serpentine or sigmoid-shaped PFOs, while in another patient, just probing of the septum with the stiff transseptal system was adequate to straighten the PFO and allow wire passage without need for transseptal puncture.

In the current series, at the 6-month follow-up TEE examination, there was no residual communication detected during a bubble study in any PFO patient. During long-term follow-up of 51.6 ± 37.8 months, no further problems related to the procedure or

the device were reported. Importantly, no cases of recurrent stroke were encountered and no cases of device-related erosion were detected.

4.2. Percutaneous ASD closure

Surgical closure of an ASD has been performed for decades with relatively low morbidity and mortality rates. On the other hand, the percutaneous device closure technique has also been used as an alternative and preferable approach for several years, with excellent sealing rates of the defect (90–96%).¹⁵ Accurate sizing of the ASD is mandatory for subsequent optimal selection of the device and can be done either by TEE or ICE or with use of sizing balloons in the catheterization laboratory. The stretched or stop-flow balloon measurement of the ASD diameter is considered the gold standard among them.³⁵ Nevertheless, no general consensus exists on this issue.^{11,12} We have evaluated fluoroscopic balloon sizing of the ASD in comparison to TEE measurement in patients undergoing this procedure in our center, and found it to be more reliable at least for the adult patients in our initial,⁹ and current results. Pediatric cardiologists still rely on the echo measurement of the ASD.^{11,12} Our approach of selecting a device 3–4 mm larger than the stretched ASD diameter has led to no residual shunting, which was observed during the early stages of our experience when less oversizing was performed. Others have suggested use of three-dimensional TEE,³⁶ or ICE for ASD sizing and procedure guiding.¹³

Complications during balloon sizing are rare by avoiding oversizing of the balloon, repeated inflations or pulling-through the septum; some suggest that the stop-flow technique may confer fewer complications.³⁵

4.3. PFO/ASD and migraine

Beyond cryptogenic strokes, other reasons for PFO closure include diver's disease, platypnea-orthodeoxia syndrome, obstructive sleep apnea, etc.³⁷ There is also evidence of an association between PFO and increased incidence of migraine,^{3,38} which occurs in ~12% in the general population and in 27–50% among patients with cryptogenic strokes.³⁹ On the other hand, the ~25% PFO occurrence in the general population rises to 50% in the migraine population. Interestingly, migraine relief has been a fortuitous observation after PFO closure, however, current data do not support PFO closure for migraine as a sole indication.⁴⁰ Hypotheses for this favorable clinical outcome implicate vasoactive substances, like serotonin, produced in the liver and bypassing the lungs where they are usually deactivated and thus reaching the brain circulation via the PFO or the ASD,⁴¹ or paradoxical microemboli in the brain held responsible for the migraine.⁴² Importantly, several, mostly retrospective and observational, studies report high rates of migraine relief after device closure with rates reaching 50–80%.⁴³ In the present study, migraine relief was reported in 83.3% among the 54 patients (45 in the PFO and 9 in the ASD group) suffering from migraine prior to the closure procedure.³ However, a favorable effect could not be confirmed in randomized studies.^{40,44}

4.4. Study limitations

This study was not a randomized controlled trial. It was rather our experience in our intracardiac communication closure program based on a relatively small series of patients. However, the data were prospectively collected and the patients were followed-up in the long-term. On the other hand, over-stretching of the balloon and “over-sizing” of the defect might have not been avoided in some other patients. However, almost all patients

received a device of appropriate diameter since only one distal migration and no aortic erosions occurred; ensuring a surrounding rim of >5 mm in ASD patients has probably helped in this direction. The absence of intra-procedural TEE that might have helped us to reduce the complication rate (2 residual shunts) should also be noted; however, there was no residual shunt observed in the postprocedural TEE performed the next day. Importantly, our ASD group had mostly moderate-sized defects and these results may not allow extrapolation to larger ASDs or ASDs with deficient rims. Finally, this fluoroscopy-only guided approach to percutaneous closure of interatrial communications, although simplified, may not be the most appropriate for small volume operators or beginners.

5. Conclusions

PFOs and ASDs were treated safely and effectively with the percutaneous placement of an Amplatzer septal occluder device via a simple percutaneous technique with use of local anesthesia and fluoroscopy alone without a need for intra-procedural TEE or ICE and without general anesthesia. Closure procedures were initially successful in 99% of patients. By TEE follow-up study at 6 months, sealing of the defect was effected in 100% for the PFO and 94% for the ASD patients. No recurrent strokes were observed during mean long-term follow-up of >4 years for the PFO patients. Although the use of pre-procedural TEE has been a common practice for establishing the diagnosis and offering an initial assessment of the size of the ASD defect, it largely underestimates the size. Intraprocedural balloon sizing seems indispensable for choosing an occluding device of appropriate size, and when combined with an oversizing strategy of 3–4 mm it seems to eliminate residual shunting. Finally, closure of the communication offers migraine relief in >80% of patients.

Conflicts of interest

None to be declared.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.ihj.2017.07.020>.

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