Cardiovascular Revascularization Medicine xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Clinically apparent long-term electric disturbances in the acute and very long-term of patent foramen ovale device-based closure☆

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ARTICLE INFO

Article history:
Received 17 September 2016
Received in revised form 25 October 2016
Accepted 25 October 2016
Available online xxxx

Keywords:
Patent foramen ovale
Echocardiography
Stroke
Anatomy

ABSTRACT

Background/Purpose: Incidence of electrical disturbances in patients submitted to transcatheter patent foramen ovale (PFO) closure has not been fully clarified in a large population. The aim of the study is to assess the incidence of atrial fibrillation, supraventricular tachi-arrhythmias, and atrio-ventricular block in the acute and very long-term follow-up.

Methods/Materials: We reviewed the medical and instrumental data of 1000 consecutive patients (mean age 47.3 ± 17.1 years) prospectively enrolled in two centers over a 13-year period (February 1999 to February 2012) for right-to-left (R-to-L) shunt ICE-aided catheter-based closure using different devices.

Results: Successful transcatheter PFO closure was achieved in 99.8% of the patients. Implanted devices were: Amplatzer PFO Occluder in 463 patients (46.3%), Amplatzer ASD Cribriform Occluder in 420 patients (42.0%), Premere Occlusion System in 95 patients (9.5%), and Biostar Occluder in 22 patients (2.2%). Postprocedural electrical complications occurred in 5.9% of patients. The only independent predictors of electrophysiological complications were female gender (OR 2.3, 0.5–5.1 [95% CI], $p < 0.001$) and device disk >30 mm (OR 5.0, 1.2–7.2 [95% CI], $p < 0.001$). On a mean follow-up of 12 .3 ± 0.6 years (minimum 4- maximum 17 years), electrical complications occurred in 1.4% of patients including one only case of complete AVB and 5 cases of permanent AF. The only independent predictors were female gender (OR 2.3, 0.5–5.1 [95% CI], $p < 0.001$) and device disk >30 mm (OR 5.0, 1.2–7.2 [95% CI], $p < 0.001$).

Conclusion: Device-based closure of PFO using different devices, appeared very safe from an electrophysiological point of view with low incidence of electrical disturbances even in the very long-term follow-up.

1. Introduction

Transcatheter patent foramen ovale (PFO) closure is a quite safe intervention associated with low rate of both intra- and post-procedural complications [1–3]. Atrial arrhythmias after percutaneous PFO closure, have been reported in several series suggesting a causal link between mechanical closure of PFO and the new onset of post-procedural arrhythmias [4–7]. Nevertheless, data about the effect of interatrial septal device implantation on the occurrence of atrial arrhythmias and more in general of electric disturbances, especially in the long-term period, are scant. (See Fig. 1.)

Our study is aimed to evaluate the short- and very long-term outcomes of PFO device closure in terms of incidence of atrial fibrillation (AF), supraventricular tachi-arrhythmias, and atrio-ventricular blocks.

2. Material and methods

We prospectively collected the medical and instrumental data of 1000 consecutive patients (mean age 47.3 ± 17.1 years, Table 1) enrolled in a two secondary referral centers registry for R-to-L shunt catheter-based closure: the Department of Cardiovascular Disease, Cittadella General Hospital, Padua, Italy, and the Cardiovascular Diagnosis and Endoluminal Interventions Unit, Rovigo General Hospital, Rovigo, Italy, over a 13 years period (1° February 1999 to 1°February 2012). The same protocol of screening, which included in both centers brain magnetic resonance imaging (MRI), transesophageal echocardiography (TEE) and transcranial Doppler (TDC) studies before the procedure, implantation procedure, and follow-up were performed in both institutions.

☆ Disclosures: None of the authors has conflict of interest to disclose.

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http://dx.doi.org/10.1016/j.carrev.2016.10.008
1553-8389/

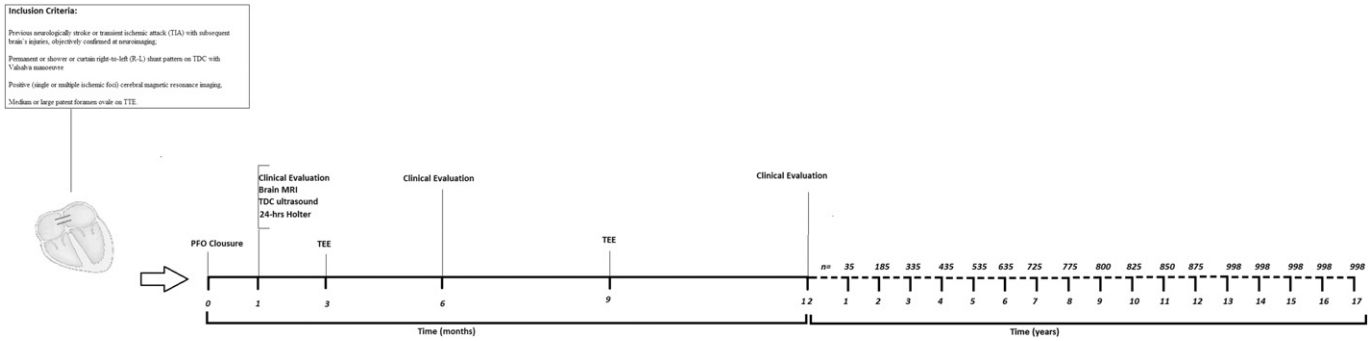

Fig. 1. Time-line of the follow up conducted in the study cohort.

Inclusion criteria for percutaneous closure of PFO included all the following [8,9]: 1) previous neurologically stroke or transient ischemic attack (TIA) with subsequent brain's injuries, objectively confirmed at neuroimaging; 2) permanent or shower or curtain right-to-left (R-L) shunt pattern on TDC with Valsalva maneuver, 3) positive (single or multiple ischemic foci) cerebral magnetic resonance imaging, 4) medium or large patent foramen ovale on TTE.

The local ethic committee approved the study and written informed consent was obtained from all patients enrolled.

The attempt of transcatheter closure was preceded by the mechanical 9F 9MHz 360° scan probe (UltraICE, EP Technologies, Boston Scientific Corporation, San Jose, CA, USA). The choice of this particular system was driven by economic issues and the need of a simple standardized protocol of study [10], which was not available for the electronical probe in 1999. The closure procedure was performed under ICE guidance following the exactly same device selection protocol in both institutions.

2.1. Echocardiography protocols

2.1.1. TEE protocol

TEE was conducted using a GE Vivid7 (General Electric Corp., Nowrfolk, and VI, USA) with contrast injection and Valsalva maneuver under local anesthesia: R-L shunt was defined as permanent, small, medium, and large following Homma et al. [11], whereas atrial septal aneurysms (ASA) were classified according to Olivares et al. [12]. PFO diameter was calculated measuring with electronic caliper the maximum opening of the PFO in the end-diastolic frames. Atrio-ventricular function was evaluated following the standard recommendations [13].

Table 1
Demographic and clinical data.

	Mean or no. (%)
Age (years)	47.3 ± 17.1
Female	560 (56%)
Smoking	253(25.3%)
High blood pressure	212(21.2%)
Hypercholesterolemia	278(27.8%)
Oral contraception	213(21.3%)
Deficiency of anti-thrombin III, C, S	29 (2.9%)
Factor V Leiden (eterozigozis)	14 (1.4%)
Mutation MTHFR (homozygosis)	244(24.4%)
Hyperhomocysteinemia	119(11.9%)
Antiphospholipid or anticardiolipin antibodies	18(1.8%)
Transient ischemic attacks	149 (14.9)
Stroke	851(85.1)
Platypneaorthodeoxya	7(0.7)
Contraindication to scheduled neurosurgery	5 (0.5)
TEE PFO mean diameter (mm)	8.9 ± 2.5
Permanent shunt TDC	512 (47.1)
Shower Shunt pattern TDC	440(44.0%)
Curtain Shunt pattern TDC	560(56.0%)
Medium Shunt TEE	301(30.1%)
Large Shunt TEE	699(69.9%)

PFO: patent foramen ovale; TCD: transcranial Doppler; TEE: transesophageal echocardiography.

2.1.2. Transcranial Doppler (TDC) protocol

TCD was performed using intravenous bubble study by a neurologist experienced in this examination, according to current standard [14] and using a TCD monitoring device (DWL MultidopX, ScanMed Medical, UK). Both MCAs were simultaneously monitored through the temporal window by the use of 2-MHz probes. The contrast was obtained by mixing 100 cm^3 of saline solution with 2–3 cm^3 of Emagel and loading a 10 cm^3 syringe with this mixture. The solution, agitated between two 10-mL syringes, connected by a 3-way stopcock, was immediately injected with a 20-gauge/32-mm catheter placed in the antecubital vein to obtain a bolus of air microbubbles. This procedure was performed 3 times during normal breathing and the same number of times during a Valsalva maneuver. The bolus of microbubbles was injected in 1 to 2 s when this 7-s period ended. We quantified the importance of R-L shunting by counting the number of signals in 1 MCA within 7 s of the injection, as previously reported: Mild (<10 bubbles within three cardiac cycles), moderate (> 10 bubbles within three cardiac cycles) with shower effect (many bubbles but still countable), severe (> 10 bubbles within three cardiac cycles) with curtain effect (many bubbles but not countable). A distinct pattern of shunt occurs when bubbles are identifiable before the Valsalva maneuver (basal or permanent shunt).

2.1.3. ICE study protocol

Patients who met the criteria for PFO closure were evaluated with an intracardiac echocardiography study using the mechanical 9F 9MHz UltraICE catheter (EP Technologies, Boston Scientific Corporation, San Jose, CA, USA) or the electronic 90° phased-array 8F intracardiac probe (ACUNAV, Biosense WebsterInc, Diamond Bar, CA, USA). The intracardiac echocardiography study was conducted as previously described [14,15], by performing a manual pull-back from the superior to the inferior vena cava through 5 sectional planes; measurement of diameters of the oval fossa, the entire atrial septum length and rims were obtained with electronic caliper edge-to-edge on the aortic valve plane and the 4-chamber plane. PFO tunnel length was also measured. Intracardiac echocardiographic monitoring of the implantation procedure was conducted on the 4-chamber plane. Normal diameter of fossa ovalis was defined as fossa ovalis < 15 mm in the four-chamber view.

Atrial septal aneurysms (ASA) were classified according to Olivares et al. [12]: ASA were classified in 1 to 5 depending on the excursion of the aneurysm (5 being the most severe aneurysm), and as R or L depending on the prevalence toward the right atrium or the left atrium of the excursion. RL identified ASA with a bidirectional excursion in which right atrium excursion was preponderant whereas LR means bidirectional excursion but preponderant toward the left atrium.

Hypertrophic rims were defined as having a thickness ≥ 8 mm, whereas lipomatosis was defined as thickness of ≥15 mm, on ICE study. Long tunnel-type PFO was defined as length ≥ 10 mm by intracardiac echocardiogram.

Please cite this article as: Rigatelli G, et al, Clinically apparent long-term electric disturbances in the acute and very long-term of patent foramen ovale device-based closure, Cardiovasc Revasc Med (2016), http://dx.doi.org/10.1016/j.carrev.2016.10.008