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Transcatheter patent foramen ovale closure is effective in reducing migraine independently from specific interatrial septum anatomy and closure devices design☆

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Abstract

Background: Relationships between migraine improvement after transcatheter patent foramen ovale (PFO) closure and both specific interatrial septum anatomy and different devices design have not been investigated yet. We sought to assess effectiveness of transcatheter PFO closure in reducing or curing migraine with aura in patients with previous paradoxical embolism in relation with specific interatrial septum anatomy and different closure devices.

Methods and Results: We prospectively enrolled 34 patients (22 female and 12 male, mean age 40±3.7 years) who were referred to our centre over a 12-month period for PFO transcatheter closure and migraine with aura and previous paradoxical embolism. All procedures were performed using mechanical intracardiac echocardiographic guidance. Patients were assigned to Amplatzer PFO or ASD Multifenestrated Occluder and Premere Occlusion System implantation dependently from intracardiac echocardiography anatomical findings, which included short-channel with moderate atrial septal aneurysm (ASA) in 6 patients (17.6 %), long-channel with moderate ASA in 3 patients (8.8%), short-channel with huge ASA in 5 patients (14.7%), multifenestrated ASA in 4 patients (11.7%), long-channel PFO without ASA in 10 patients (29.4%), and long-channel PFO with mild ASA in 6 patients (17.6%). Accordingly, 18 patients received an Amplatzer Occluder (9 PFO Occluder and 7 ASD Multifenestrated Occluder), and 16 received a Premere Occlusion System. After a mean follow-up of 9.0±2.8 months, all patients improved their migraine symptoms (mean Migraine Disability Assessment Score 30±1.5 at baseline versus 6.0±2.9 in the follow up, $P<.03$) independently from specific interatrial septum anatomy and different closure devices.

Conclusion: Although our study had several limitations, it suggests that independently from interatrial septum anatomy and device type, PFO closure in patients with migraine with aura resulted in a high rate of migraine improvement.

Keywords: Stroke; Patent foramen ovale; Transcatheter closure; Migraine

1. Introduction

Migraine headaches have a high prevalence in the general population and account for significant morbidity, lost productivity, health care visits and money spent. Some studies and ongoing trials suggested that closure of the patent

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foramen ovale (PFO) may reduce or resolve migrainous headaches [1–3] and, especially, migraine with aura, but relationships between migraine improvement extent and both specific interatrial septum anatomy and different occluder devices design have not been yet investigated. We sought to assess effectiveness of transcatheter PFO closure in reducing or curing migraine with aura in patients with previous paradoxical embolism and the relationships between results and interatrial septum anatomy and different closure devices.

2. Methods

We prospectively enrolled 34 patients (22 female and 12 male, mean age 40±3.7 years) who were referred to our centre over a 12-month period for PFO transcatheter closure and migraine with aura despite antiheadache therapy (Table 1).

Indications for PFO percutaneous closure included all the following [4]: the concurrence shower or curtain pattern of shunt on transcranial Doppler [5] with Valsalva manoeuvre, positive (single or multiple ischemic foci) cerebral magnetic resonance imaging, previous stroke or transient ischemic attack and medium or large PFO on transesophageal echocardiography [6]. Written informed consent was obtained from all patients enrolled in the study.

Migraine with aura was diagnosed according to the International Headache Society criteria [7]: Migraine Disability Assessment Score (MIDAS) [8] was used to assess migraine headache incidence and severity.

2.1. Intracardiac echocardiography protocol

A 9F 9-MHz UltraICE catheter (EP Technologies, Boston Scientific, San Jose, CA, USA) was used to perform a complete intracardiac study as previously described [9,10].

Table 1
Patients characteristics in the 12-month database

	Mean or no. (%)
Age	40±3.7
Male/female	12/22
Previous stroke	15/34 (44.1)
Silent cerebral ischemia (magnetic resonance imaging)	19/34 (55.8)
Migraine with aura :	34/34 (100)
Blurred vision, haemianopsia, cortical blindness	20/34 (58.8)
Hemilateral loss of force and paresthesies	14/34 (41.1)
MIDAS	30±1.5
TC Doppler shower pattern	21/34 (61.7)
TC Doppler curtain pattern	13/34 (38.2)
Atrial septal aneurysm (TEE)	20/34 (58.2)
Medium Shunt on TEE	23/34 (67.6)
Large Shunt on TEE	11/34 (33.4)
Abnormalities of the coagulative cascade proteins:	
deficiency of anti-thrombin III, factor V Leiden	6/34 (17.6)
Autoantibodies:	
Antiphospholipid or anticardiolipin	2/34 (5.8)
Platypnea orthodeoxya	2/34 (5.8)

TC, transcranial; TEE, transesophageal echocardiography.

The intracardiac echocardiography protocol (ICE) study was conducted by performing a manual pullback from the superior vena cava to the inferior vena cava through five sectional planes and measurement of diameters of the fossa ovalis; the entire atrial septum length and rims were obtained with electronic caliper edge-to-edge on the aortic valve plane and the four-chamber plane. PFO tunnel length was carefully measured. Atrial septal aneurysm has been classified by intracardiac echocardiography following the classification of Olivares et al. [11]. PFO channel was distinguished in short (<9 mm) and long (>10 mm) channel. Intracardiac echocardiographic monitoring of the implantation procedure was conducted on the four-chamber plane. However, decision about device to be used was made after intracardiac study.

2.2. Closure protocol

On the basis of ICE findings the operators selected the Amplatzer Occluder family (PFO Occluder, Cribriform Occluder, AGA Medical, Golden Valley, MN, USA) or the Premere Closure System (St. Jude Medical GLMT). The Amplatzer PFO occluder has been selected when ASA was bidirectional but moderate (3RL or 3LR ASA), whereas the Premere occlusion system has been chosen when ASA was absent or in case of motionless or unidirectional ASA (1R, 2L ASA), and when PFO tunnel length was >10 mm. The Amplatzer Cribriform Occluder has been selected in case of multiperforated ASD, keeping attention to cross with the guidewire the most central hole in the fossa ovalis under ICE guidance as previously described [12]. This kind of device was selected also when ASA was huge and bidirectional (5RL ASA) in order to obtain a complete coverage of the fossa ovalis at both sides of the atrial septum.

2.3. Follow-up protocol

In patients who underwent closure, transesophageal echocardiography was scheduled at one month and repeated at 6 months after closure if there was no more than a trivial shunt. Patients underwent transcranial Doppler echocardiography and magnetic resonance imaging of the brain 1 month after the procedure. Transthoracic echocardiography was scheduled at 6 months and 1 year after the transcatheter closure. Any residual shunt was graded as trivial, small, moderate and severe, as previously described [13]. Clinical cardiological and neurological visits were scheduled at 1, 6, and 12 months.

2.4. End points definition

Procedural success was defined as ability to release the device in a stable position on fluoroscopy and ICE guidance with no more than a trivial shunt. Complications included groin haematomas of any grade, atrial wall perforation, pericardial effusion, entrapment of device or sheath or ICE equipment through venous valves or embryonic remnants,