Berif Communication

Interventional Closure of Patent Foramen Ovale (PFO) with Amplatzer PFO Occluder in Patients with Paradoxical Cerebral Embolism

Ali Mohammad Haji Zeinali, MD*, Hakimeh Sadeghian, MD

Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran.

Received 11 September 2006; Accepted 25 October 2006

Abstract

Background: *Percutaneous transcatheter closure has been proposed as an alternative to surgical closure or long-term anticoagulation in patients with presumed paradoxical embolism and patent foramen ovale (PFO).*

Methods: *There were two symptomatic patients (29 and 47 years old) who underwent percutaneous transcatheter closure of PFO after at least two events of cerebral ischemia; one embolic event had occurred under anti-platelet therapy. For both patients, Amplatzer PFO occluder measuring 25 mm in diameter were used. In both cases, complete occlusion by color Doppler and transesophageal contrast echocardiography investigation was achieved after the procedure and lasted at least up to 3 months after implantation as determined by our follow up. Mean fluoroscopy time was 16.7 minutes.*

Results: *Percutaneous transcatheter closure was technically successful in both patients (100%). No residual shunt was seen at the end of the procedure or in follow-ups. In-hospital follow-up was uneventful. At a mean follow-up of 3 months, no recurrent embolic neurological events were observed.*

Conclusion: *Transcatheter closure of PFO with Amplatzer PFO occluder devices is a safe and effective therapy for patients with previous paradoxical embolism PFO. Percutaneous closure is associated with a high success rate, low incidence of hospital complications, and freedom of cerebral ischemic events.*

The Journal of Tehran Heart Center 3 (2006) 167-170

Keywords: *Patent foramen ovale • Amplatzer PFO occluder • Cerebral emboli*

Introduction

Patency of the foramen ovale (PFO) has been identified as a potential risk factor for paradoxical embolism potentially followed by cerebral ischemic events.[1-5] Cryptogenic stroke (with no detectable source of embolism) accounts for about 40% of strokes in young adults.[6-7] Although the underlying mechanism by which PFO accounts for the phenomenon is not entirely elucidated yet, transseptal passage of emboli from the right- to the left-sided chambers of the heart appear to play an important role.[8] Moreover, patients with documented PFO and previous embolism are at increased risk of recurrent thromboembolic events in up to 4.2% even under therapeutic anticoagulation.3,[9-11] Thus, long-term management of

*Corresponding Author: ***Ali Mohammad Haji Zeinali,*** *Assistant professor of interventional cardiology, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran. 1411713138. Tel: +98 21 88029620. Fax: +98 21 88029637. E-mail: Ali_zeinali_cardio@ yahoo.com.*

PFO remains controversial. Oral anticoagulation9,[12-14] and surgical closure[15,16] are options to help prevent recurrent neurological events. However, both therapeutic strategies are associated with significant morbidity. As an alternative nonsurgical transcatheter closure using various devices has shown promising potential in small series.[17-19]

Methods

Patient population

From Aug. 2005 to Sep. 2005 two consecutive patients underwent transcatheter closure of a documented PFO; patients qualified after the occurrence of at least one transient ischemic attack (TIA) or stroke documented by PFO and detected by transoesophageal echocardiography (TOE). The diagnosis of ischemic stroke was based on symptoms and signs of a suddenly occurring neurologic deficit, and the corresponding findings on computer tomography or magnetic resonance imaging scans. TIA was defined as a focal neurologic deficit resolving completely within 24 hours. An ischemic event was considered to be resulting from paradoxical embolism when the following criteria were met: (1) presence of PFO with or without atrial septal aneurysm (ASA) and spontaneous or provocable right-to-left shunt on contrast TOE. (2) clinically and/or morphologically diagnosed TIA or stroke by a neurologist; and (3) exclusion of any other likely cause of systemic arterial embolism.

Morphology and Laboratory Examinations

A standardized neurological physical examination, cerebral computed tomography (CT) or magnetic resonance imaging (MRI) was performed before interventional device closure. A 12-lead electrocardiogram and contrast enhanced and color Doppler TOE with and without Valsalva maneuver were used to document right-to-left atrial shunt in all patients. Standard blood testing and screening for evidence of hypercoagulable states (proteins C and S, antithrombin III, lupus anticoagulant, anticardiolipin, factor V Leiden) completed the periinterventional laboratory panel in all patients.

Definitions

According to the present guidelines, a PFO was defined as a functional dehiscence between septum primum and septum secundum without evidence of an anatomic defect in the septa on TOE. An atrial septal aneurysm was defined as an abnormally redundant atrial septum with an excursion of ≥ 15 mm to either side of the septum.[20,21]

The degree of right-to-left shunt was quantified by the number of microbubbles in the left atrium on a still frame image during contrast TOE (saline solution); grade 0 = none; grade 1 = minimal (1-5 bubbles); grade 2 = moderate (6-25 bubbles); grade 3 = severe (>25 bubbles).[21]

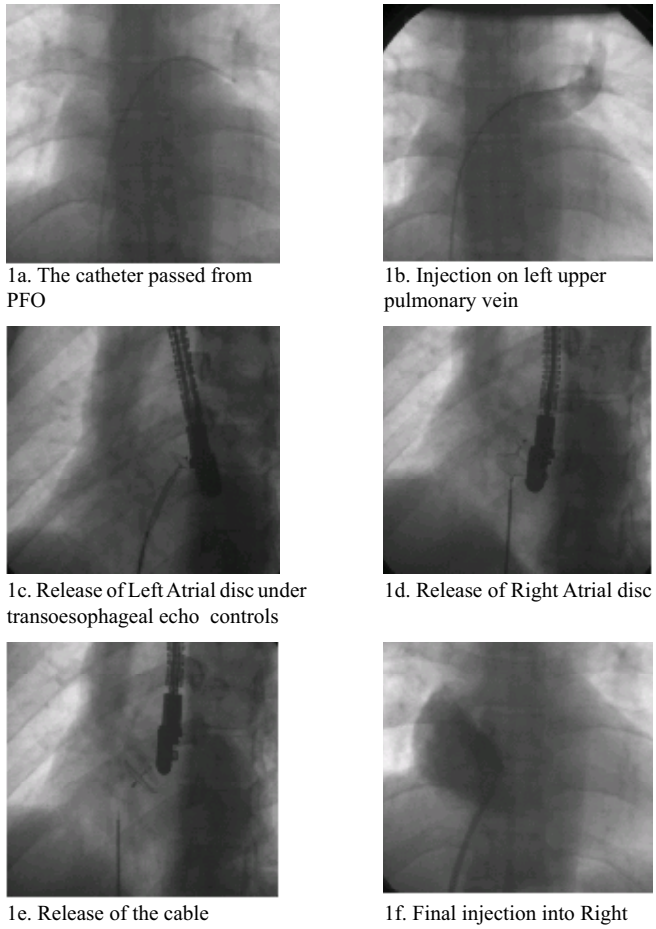
Implantation Procedures

PFO closure was performed with the Amplatzer PFO occluder (AGA Medical, Golden Valley, MN) (Figure 1). Design and technical details of the device and the technique of transcatheter implantation of the device across the intraatrial septum have been described previously.[21]

Periinterventionally, all patients received one IV doses of 1 gr cefazolin and 5,000 units of intravenous heparin during the intervention.

Postinterventional Care

Postinterventional care included 100 mg of oral aspirin per day for 6 months and 75 mg of oral Clopidogrel for 3 months. Standard prophylaxis for bacterial endocarditis was recommended for 6 months according to the guidelines of the American Heart Association.[22]



1a. The catheter passed from PFO

1b. Injection on left upper pulmonary vein

1c. Release of Left Atrial disc under transoesophageal echo controls

1d. Release of Right Atrial disc

1e. Release of the cable

1f. Final injection into Right Atrium which showed no shunt

Figure 1. Sequential stages of device implantation

Postprocedural Control and Follow-Up

Patients were monitored overnight and discharged the following day. A transthoracic contrast echocardiogram (TTE) examination was performed within 24 hours of percutaneous closure in all patients. There months after discharge patients were referred to the outpatient clinic for a physical follow-up exam and contrast echocardiography. Thereafter, patients were followed up by telephone interview and/or by contacting the referring physician.

Results

Patient Characteristics

Between Aug. 2005 and Sep. 2005, percutaneous transcatheter closure of a PFO was successfully performed in two consecutive patients with cryptogenic cerebral ischemia using an Amplatzer PFO occluder. Indications for transcatheter PFO closure included TIA in patients and multiple paradoxical embolisms had occurred in both patients. The first patient was 29 years old man with one syncope and TIA before anticoagulant therapy and one TIA under ASA therapy. The second patient was a 47 years old man with two TIA that one was under ASA therapy. None of patients had any incidence of hypercoagulable state.

Procedural Success and Complications

We used the Amplatzer PFO occluder of 25-mm diameter in both patients. None had echocardiographic evidence of atrial septal aneurysm. General anesthesia was not required in patients. Mean fluoroscopy time was 16.7 minutes and device implantation was successfully accomplished in all patients. Complete occlusion by virtue of totally abolished transseptal flow was present in all patients immediately after device deployment as assessed by angiography.

During the intervention, no deaths or systemic thromboembolic events were noted in our patients. No any persistent arrhythmia occurred during or after the procedure. There were no peri-interventional thromboembolic events in these patients and no evidence of thrombus formation on subsequent follow-up echocardiograms.

Follow-up

The mean follow-up period was 3 months. No patient suffered from any recurrent cerebral event after successful implantation of the Amplatzer PFO occluder. Thus, the rate of recurrent neurological events was zero during the follow-up.

References

1. Webster MW, Chancellor AM, Smith HJ, Swift DL, Sharpe DN, Bass NM, Glasgow GL. Patent foramen ovale in young stroke patients. Lancet 1988;2:11-12.

2. Lechat P, Mas JL, Lascault G, Loron P, Theard M, Klimczac M, Drobinski G, Thomas D, Grosgogeat Y. Prevalence of patent foramen ovale in patients with stroke. N Engl J Med 1988;318:1148-1152.

3. Bogousslavsky J, Garazi S, Jeanrenaud X, Aebischer N, Van Melle G. Stroke recurrence in patients with patent foramen ovale: the Lausanne Study. Neurology 1996;46:1301-1305.

4. Di Tullio M, Sacco RL, Gopal A, Mohr JP, Homma S. Patent foramen ovale as a risk factor for cryptogenic stroke. Ann Intern Med 1992;117:461-465.

5.Cabanes L, Mas JL, Cohen A, Amaenco P, Cabanes PA, Oubary P, Chedru F, Guerin F, Bousser MG, de Recondo J. Atrial septal aneurysm and patent foramen ovale as risk factor for cryptogenic stroke in patients less than 55 years of age: a study using transoesophageal echocardiography. Stroke 1993;24:1865-1873.

6. Steiner MM, Di Tullio MR, Rundek T, Gan R, Chen X, Liguori C, Brainin M, Homma S, Sacco RL. Patent foramen ovale size and embolic brain imaging findings among patients with ischemic stroke. Stroke 1998;29:944-948.

7. Hart RG, Miller VT. Cerebral infarction in young adults: a practical approach. Stroke 1983;14:110-114.

8. Kessel-Schaefer A, Lefkovits M, Zellweger MJ, Brett W, Ruter F, Pfisterer ME, Buser P. Migrating thrombus trapped in a patent foramen ovale. Circulation 2001;103:1928.

9. Hanna JP, Sun JP, Furlan AJ, Stewart WJ, Sila CA, Tan M. Patent foramen ovale and brain infarct: echocardiagraphic predictors, recurrence and prevention. Stroke 1994;25:782-786.

10. Mas JL, Zuber M. Recurrent cerebrovascular events in patients with patent foramen ovale, atrial septal aneurysm, or both and cryptogenic stroke or transient ischemic attack: French Study Group on Patent Foramen Ovale and Atrial Septal Aneurysm. Am Heart J 1995;130:1083-1088.

11. De Castro S, Cartoni D, Fiorelli M, Rasura M, Anzini A, Zanette E, Beccia M, Colonnese C, Fedele F, Fieschi C, Pandian NG. Morphological and functional characteristics of patent foramen ovale and their embolic implications. Stroke 2000;31:2407-2413.

12. Curec B, Mainra R, Johnson DH. Prevention of recurrent cerebral ischemic events in patients with patent foramen ovale and cryptogenic strokes or transient ischemic attacks. Can J Cardiol 1999;15:57-64.

13. Nendaz MR, Sarasin FP, Junod AF, Bogousslavsky J. Preventing stroke recurrence in patients with patent foramen ovale: Antithrombotic therapy, foramen closure, or therapeutic abstention? A decision analytic perspective. Am Heart J 1998;135:532-541.

14. Devuyst G, Bogousslavsky J, Ruchat P, Jeanrenaud X, Despland PA, Regli F, Aebischer N, Karpuz HM, Castillo V, Guffi M, Sadeghi H. Prognosis after stroke followed by surgical closure of patent foramen ovale: a prospective follow-up study with brain MRI and simultaneous transoesophageal and transcranial Doppler ultrasound. Neurology 1996;47:1162-1166.

15. Homma S, Dj Tullio MR, Sacco Rl, Sciacca PR, Smith C, Mohr JP. Surgical closure of patent foramen ovale in cryptogenic stroke patients. Stroke 1997;28:2376-2381.

16. Dearani JA, Ugurlu BS, Danielson GK, Daly RC, McGregor CG, Mullany CJ, Puga FJ, Orszulak TA, Anderson BJ, Brown RD Jr, Schaff HV. Surgical patent foramen ovale closure for prevention of paradoxical embolism-related cerebrovascular ischemic events. Circulation 1999;100:171-175.

17. Windecker S, Wahl A, Chatterjee T, Garachemani A, Eberli FR, Seiler C, Meier B. Percutaneous closure of patent foramen ovale in

patients with paradoxical embolism: long-term risk of recurrent thromboembolic events. Circulation 2000;101:893-898.
18. Hung J, Landzberg MJ, Jenkins KJ, King ME, Lock JE, Palacios IF, Lang P. Closure of patent foramen ovale for paradoxical emboli: intermediate-term risk of recurrent neurological events following transcatheter device placement. J Am Coll Cardiol 2000;35:1311-1316.
19. Du ZD, Cao QL, Loseph A, Koeing P, Heischmidt M, Waight DJ, Rhodes J, Brorson J, hijazi ZM. Transcatheter closure of patent foramen ovale in patients with paradoxical embolism: intermediate-term risk of recurrent neurological events. Cardiovasc Intervent 2002;55:189-194.
20. Chatterjee T, Aeschbacher BC, Meier B. Ischemic attacks and patent foramen ovale: transcatheter closure of patent foramen ovale in adults wing cryptogenic systemic embolism. J Interven Cardiol 1999;12:59-64.
21. Sharafuddin MJ, Gu X, Titus JL, Urness M, Cervera-Ceballos JJ, Amplattz K. Transvenous closure of secundum atrial septal defects: preliminary results with a new self-expanding Nitinol prosthesis in a swine model. Circulation 1997;95:2162-2168.
22. Dajani AS, Taubert KA, Wilson W, Bolger AF, Bayer A, Ferrier P, Gewitz MH, Shulman ST, Nouri S, Newburger JW, Hutto C, Pallasch Tj, Gage TW, Levison ME, Peter G, Zuccaro G Jr. Prevention of bacterial endocarditis: recommendations by the American Heart Association. Circulation 1997;96:358-366.