

Implantation of an Occlutech Figulla® PFO occluder in a patient with patent foramen ovale and history of embolic stroke

Radosław Kręcki, Jan Zbigniew Peruga, Michał Plewka,
Maria Krzemińska-Pakuła and Jarosław Damian Kasprzak

2nd Chair of Cardiology, Medical University of Łódź, Bieganski Hospital, Łódź, Poland

Abstract

The most common interventions in structural heart diseases for various age groups are percutaneous occlusions of septal defects. We present the case of a woman with patent foramen ovale (PFO) periodically causing a right-to-left shunt, after an incident of stroke, with migraine attacks, treated by percutaneous closure of PFO with use of a novel occluder device — an Occlutech Figulla®. The procedure was performed under X-ray and transesophageal echocardiographic monitoring. The novel Occlutech device described above features easy manipulation, good safety and some constructional innovations that enable the time of antiplatelet prophylaxis to be shortened, thus potentially minimizing procedure related risk. (Cardiol J 2008; 15: 380–383)

Key words: patent foramen ovale, percutaneous devices

Introduction

The most common interventions in structural heart diseases in various age groups are percutaneous occlusions of septum defects [1]. We present the case of woman with patent foramen ovale (PFO) periodically causing a right-to-left shunt, after an incident of stroke, with migraine attacks, treated by percutaneous closure of PFO with use of a novel occluder device — an Occlutech Figulla® (Fig. 1). To the best of the authors' knowledge, there are no previous publications in MEDLINE reporting the use of this device for PFO occlusion.

Case report

The patient was a professionally active 41-year-old woman, 1 year after a minor stroke with clinical presentation of right hemiparesis, suffering from

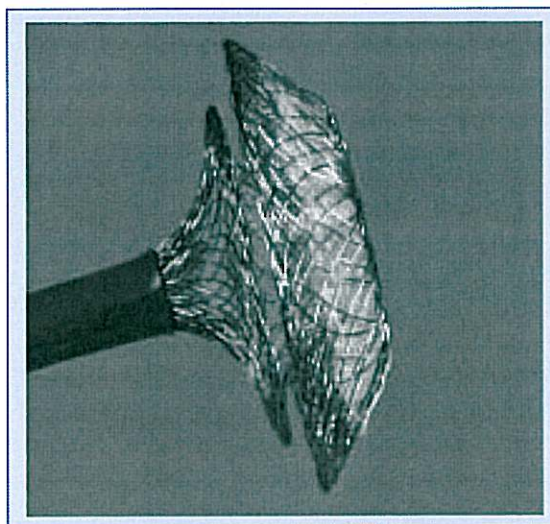


Figure 1. Occlutech Figulla® PFO Occluder.

Address for correspondence: Radosław Kręcki, MD, 2nd Chair of Cardiology, Medical University of Łódź, Bieganski Hospital, Kniaziewiczza 1/5, 91–347 Łódź, Poland, tel./fax: +48 42 25 16 015, e-mail: rkrecki@gazeta.pl

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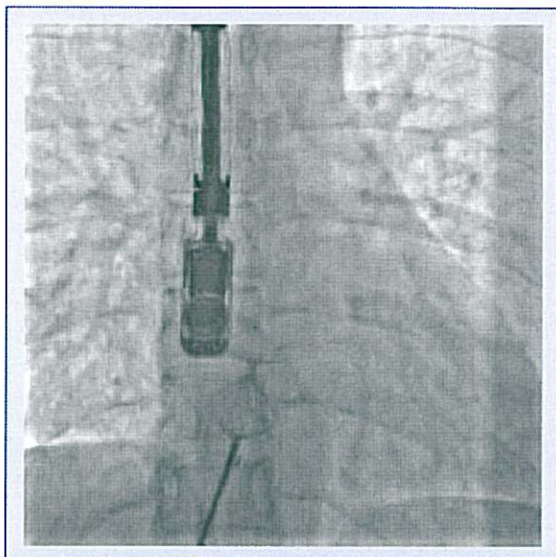


Figure 2. Freeing of right disk PFO Occluder device with transesophageal echocardiography and radiological monitoring (projection AP).

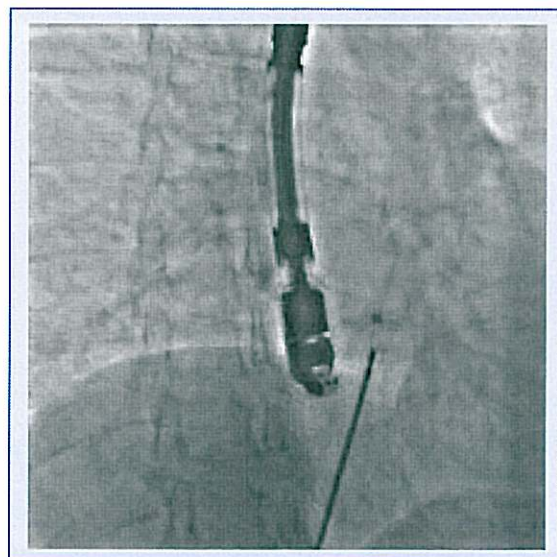


Figure 3. Fixation of Figulla® PFO Occluder with transesophageal echocardiography and radiological monitoring (projection RAO 10).

typical migraine attacks with aura. She was admitted to our Department, in stable condition, to optimize her treatment. Echocardiography demonstrated a patent foramen ovale with right-to-left shunt during a Valsalva test, without signs of right atrial overload (right atrial diameter in diastole in four chamber view: 35 mm). In order to precisely visualize PFO morphology and to exclude atrial thrombus and other contraindications to percutaneous closure of PFO, we performed transesophageal echocardiography showing a 4 mm maximal diameter of PFO tunnel. A novel device, an Occlutech Figulla® PFO Occluder, was chosen.

The procedure was performed under X-ray and transesophageal echocardiographic monitoring with premedication of midazolam *iv.* (up to 8 mg total). One day before the procedure the patient received 325 mg acetylsalicylic acid and 75 mg clopidogrel, in a catheterization laboratory, just before procedure 5000 U unfractionated heparin (activated coagulation time — ACT 220 s). After placement of the right femoral vein sheath, a guidewire was advanced into the left atrium through the open foramen ovale and positioned in the upper left pulmonary vein, followed by insertion of a Mullins 12 French catheter under transesophageal echocardiographic monitoring. The device was introduced through the catheter and the left atrial disc was released by pushing it out on the left atrial side. Withdrawal of the Mullins sheath allowed the release

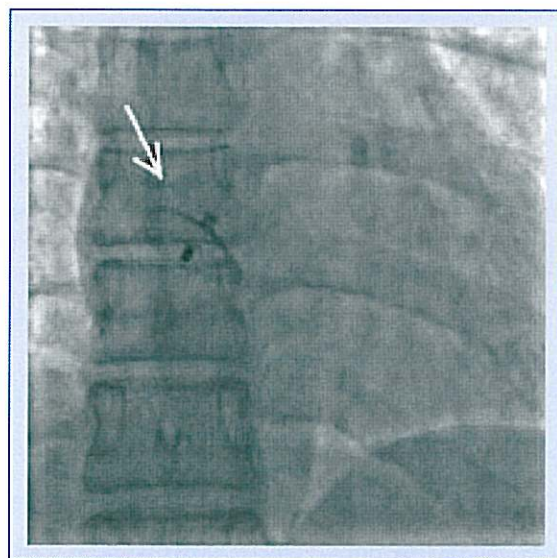


Figure 4. Figulla® PFO Occluder after implantation procedure (projection LAO 30 — arrow).

of the right atrial disc (analogous to the technique use for Amplatzer occluder implantation) (Fig. 2–4). The correct position and complete PFO closure was seen in transesophageal echocardiography. On the next day the correct position of the occluder without residual flow was confirmed in control transthoracic echocardiography (Fig. 5, 6). The patient was

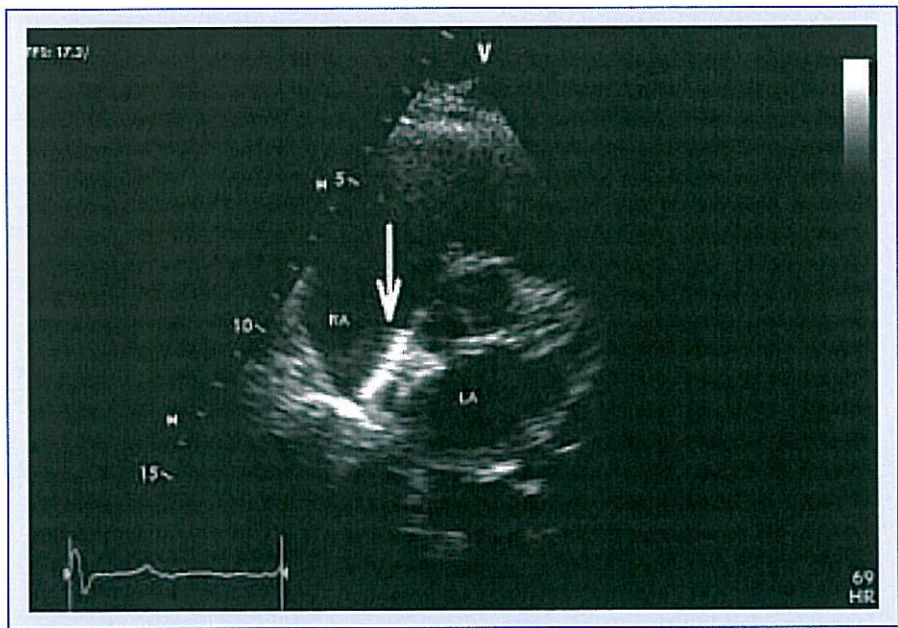


Figure 5. Transthoracic echocardiography. Modified parasternal short axis view. Figulla® PFO Occluder after implantation procedure (arrow); LA — left atrium, RA — right atrium.

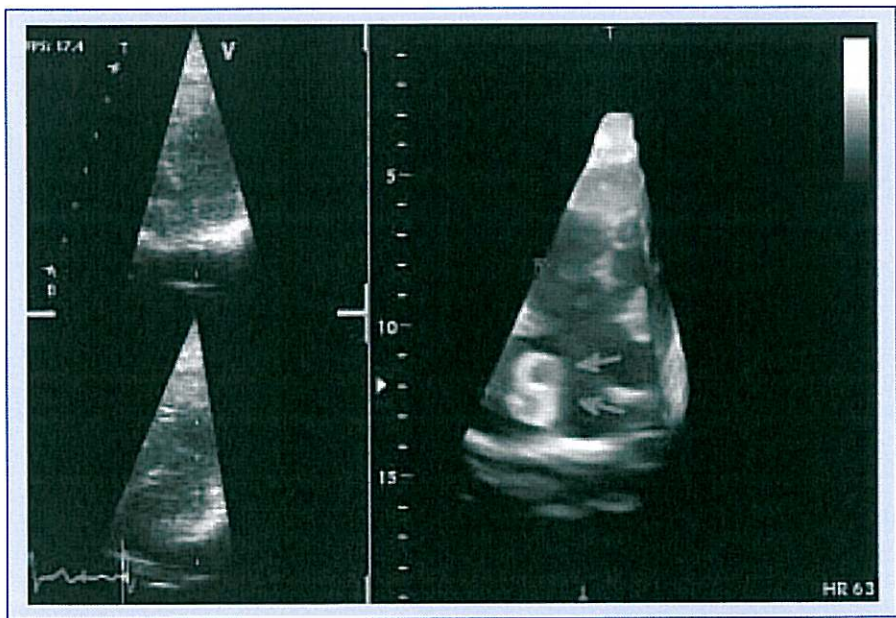


Figure 6. Transthoracic echocardiography 3D in real time. Right atrial view showing a right disk of the implant with characteristic protuberance of the delivery channel.

discharged with the following medical recommendations: 75 mg clopidogrel for 3 months, 100 mg acetylsalicylic acid for 6 months and 12 months stan-

dard antibiotic prophylaxis for endocarditis (before possible dental, gastroenterological and gynecological procedures).

Discussion

Patent foramen ovale, the remnant of fetal circulation, is a common finding present in 25% of the population [2]. A relationship between PFO and several clinical conditions, such as stroke, migraine, platypnea-orthodeoxia syndrome, neurological decompression illness in divers, high altitude pulmonary oedema and economy class syndrome, have been documented [3, 4]. The morphology of PFO is various and dependent on the age of the patient. PFO images, obtained from the echocardiography, enable a PFO classification to be made based on the diameter, length of tunnel and concomitant pathologies of the interatrial septum [5]. Given the large number of asymptomatic subjects, no standard preventive therapy is currently recommended. The best treatment modality to prevent recurrent stroke in patients with PFO has not been defined [6]. Interventional closure of the PFO has become a promising alternative for lifelong antiplatelet or anticoagulant therapies. Observational non-randomized studies have shown percutaneous PFO closure to be more effective than medical treatment for stroke prevention, in particular in patients with complete closure, as well as in patients with cerebrovascular events at baseline [7].

The Figulla® PFO Occluder is a recently registered implant type, made up of two nitinol disks, intended for the closure of a persisting foramen ovale. Construction and implantation procedure are analogous to an Amplatz® Occluder. However, there are some important structural innovations, encouraging the use of the novel device for PFO closure. An atraumatic tip, increased flexibility and minimizing the amount of material implanted (25% less material in the left atrium, 50% less with the single disc PFO device) make the Figulla® PFO Occluder safer and more comfortable during implantation than other devices. Additionally, the Figulla® PFO Occluder inflicts less risk of “ballooning”, and the increased flexibility of discs offers optimized adherence to the septum and left atrial wall.

Faster endothelialization reduces the time of antiplatelet prophylaxis with clopidogrel to 3 months.

Conclusions

Contemporary techniques of percutaneous closure of interatrial septum defects allow the individualization of device choice. The novel Occlutech device described above features easy manipulation, good safety and some constructional innovations that enable the time of antiplatelet prophylaxis to be shortened thus potentially minimizing procedure related risks.

Acknowledgements

The authors do not report any conflict of interest regarding this work.

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