

ORIGINAL STUDIES

Interventional closure of patent foramen ovale with Nit-occlud® device in prevention of recurrent neurologic events—Long-term results

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Email: aaraszkiewicz@interia.pl**Abstract**

Background: Patent foramen ovale (PFO) was found to be associated with the increased risk of recurrent strokes or transient ischemic attacks (TIA) and there is a need of secondary prevention. Numerous devices have been developed and used for treatment.

Objectives: The aim of the study was to evaluate the safety and effectiveness of a new PFO occluder Nit-Occlud PFO Occlusion Device (PFM medical, Germany).

Methods: Between January 2012 and August 2016, 151 patients (mean age 41 ± 11 years) who had suffered from a cryptogenic thromboembolic event underwent transcatheter PFO closure with the PFM Nit-Occlud PFO device. The procedure was successful in 150 patients (99.3%). Mean clinical follow-up time was 24.4 ± 16.1 months. Echocardiographic follow-up was done at 6 weeks and 6 months post intervention by transesophageal contrast echocardiography in 90 (60%) of patients. Clinical end-point was death, non-fatal stroke, or TIA.

Results: No major periprocedural or in-hospital complications occurred. Stroke or TIA reoccurred generally in 5 (3.3%) patients (2 strokes and 3 TIA's). In one patient (0.7%) device, thrombosis was observed. Closure was sufficient with only minimal right-to-left residual shunt in seventeen cases of 90 examined patients (19%) after 6 weeks and in one patient (1.1%) 6 months post implantation.

Conclusions: The Nit-Occlud PFO device and its delivery system are safe and provides sufficient closure of PFO in patients who suffered from cryptogenic stroke, TIA or paradoxical peripheral embolism. It is associated with high procedural success and favorable rates of complete closure.

KEYWORDS

complications, prognosis, stroke, structural interventions

1 | INTRODUCTION

Patent foramen ovale (PFO) is a remnant of fetal circulation and it is present in 20–25% of the whole population, whereas prevalence of PFO reaches more than 40% in young patients with cryptogenic stroke [1,2]. The concept of paradoxical embolism as a result of persistent connection between left and right atrium as a cause of cryptogenic stroke, transient ischemic attacks (TIA) or myocardial infarction, has

been well established in the literature [3–7]. Especially patients with PFO and coexisting atrial septal aneurysm (ASA) and prior stroke are at substantial risk of recurrent ischemic events [8]. Catheter-based closure of PFO was introduced in 1992 by Bridges et al. [9]. Since that time, the number of different devices was introduced and tested. Observational long-term follow-up studies suggest that closure of PFO in patients with a history of ischemic stroke may reduce the risk of recurrent stroke as compared with medical therapy alone [10,11].

TABLE 1 Clinical characteristics of study group

Study group (n =; %)	151 (100)
Women (n =; %)	100 (66.2)
Men (n =; %)	51 (33.8)
Age (years; mean ± SD)	41 ± 11
Hypertension (n =; %)	22 (14.6)
Diabetes mellitus (n =; %)	4 (2.6)
Hypercholesterolemia (n =; %)	8 (5.3)
Thyroid diseases (n =; %)	11 (7.3)
Previous deep vein thrombosis (n =; %)	1 (0.7)
Inherited thrombophilia (n =; %)	1 (0.7)
Smoking (n =; %)	7 (4.6)
Epilepsy (n =; %)	1 (0.7)
Migraine (n =; %)	67 (44.4)
Systolic blood pressure (mm Hg) (mean ± SD)	117 ± 11
Diastolic blood pressure (mm Hg) (mean ± SD)	73 ± 10
Body mass index (kg/m ²) (mean ± SD)	28.6 ± 4
Serum creatinine (μmol/l) (mean ± SD)	83.4 ± 17.9
Glomerular filtration rate (ml/min/m ²) (mean ± SD)	84.7 ± 15.3

Recently some randomized controlled trials were also performed to prove the hypothesis that transcatheter closure of PFO is effective in prevention of recurrent ischemic events. Evaluation of the STARFlex Septal Closure System in Patients with a Stroke and/or TIA due to Presumed Paradoxical Embolism through a PFO (CLOSURE I), failed to show the superiority of closure over medical therapy alone [12]. Two other randomized controlled trials concerned the Amplatzer PFO Occluder device. These were the RESPECT (Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment) trial and the PC Trial (Percutaneous Closure of PFO Using the Amplatzer PFO Occluder With Medical Treatment in Patients With Cryptogenic Embolism) [13,14]. Both these trials trended toward a beneficial effect of device closure as compared to medical therapy, but the magnitude of effect estimate was low. It has been thought that the main limitation of these studies was modest statistical power. Per-protocol and as-treated analyses of the RESPECT Trial though indicated however, the superiority of PFO closure over medical therapy [14]. Subgroup post hoc analysis of the trial suggested that younger (<65 years) patients with substantial right-to-left interatrial shunt or ASA seem to benefit most from PFO closure. Although Amplatzer PFO Occluder (St. Jude, USA) seems to be the device most commonly used in clinical practice worldwide with the strongest scientific evidence, a few other devices are also available and tested in clinical studies [15–20].

The aim of our study was to evaluate the safety and efficacy of the novel, fine, low-profile Nit-Occlud PFO Occluder device (PFM, Germany) in patients with PFO and prior ischemic stroke in prevention of recurrent ischemic events.

2 | MATERIAL AND METHODS

Between September 2011 and June 2016 one hundred fifty one consecutive patients with PFO and cryptogenic ischemic events (ischemic stroke, TIA or both and/or peripheral embolism), who had underwent transcatheter PFO closure with PFM Nit-Occlud device were included in the study. The general characteristics of study population and indications for PFO closure and are listed in Tables 1 and 2, respectively.

A thromboembolic event was considered to be due to paradoxical embolism when the following criteria were met: the presence of PFO with spontaneous or provokable right-to-left shunt confirmed in contrast transoesophageal echocardiography (TOE), ischemic stroke and/or TIA verified clinically and neuroradiologically or peripheral thromboembolic event and exclusion of any identifiable cause for the cerebrovascular ischemic events other than the PFO.

Exclusion criteria included the presence of other potential risk factors of thromboembolic events (e.g., the source of thrombosis within the left heart), infectious endocarditis, heart valve prosthesis, internal carotid artery stenosis, atrial fibrillation, allergy to nickel or contrast, inability to take aspirin or clopidogrel for 6 months following the procedure and lack of patient's consent.

All the patients gave their written informed consent for the procedure and participation in observational study. Local Ethics Committee approved the protocol of the study.

The studied device is a self-expanding nitinol double disk umbrella. It is knitted from a single nitinol wire without any protruding fixation-clamps resulting in a very low profile (Figure 1A,B). The occluder consists of a double-layer right atrial disc and a single-layer left atrial disc. The left atrial disc is designed as a concave monolayer in order to minimize protrusion and potentially maximize endothelialization process. Both the left and right atrial discs are covered with polyethylene terephthalate (Dakron) to facilitate complete early closure. The system is originally attached to the delivery system, but it has to be loaded to delivery tube and flushed before use. The device is available in 3 sizes: 20, 26, and 30 mm. It is deliverable through 10F sheath via femoral vein approach.

Device implantation was guided by fluoroscopy and TEE (Figure 2). After identification and crossing, the PFO from right to left atrium with a 6F multipurpose catheter the stiff guidewire was placed in the upper left pulmonary vein. Then 10F vascular sheath was introduced. The size of the device was chosen depending on body size and weight, left atrial size, atrial septal anatomy, and the distance of PFO to superior

TABLE 2 Previous neurologic events in study group

Study group	n = 151 (100)
Previous stroke (%)	93 (61.6)
Previous TIA (%)	33 (21.9)
Previous stroke +TIA (%)	12 (7.9)
Migraine with co-existing MR brain lesions (%)	13 (8.6)

Abbreviations: TIA, transient ischaemic attack; MR, magnetic resonance.

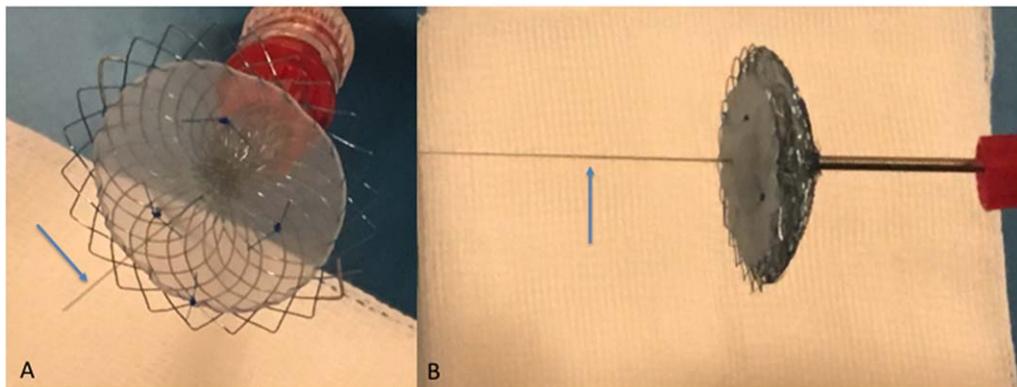


FIGURE 1 The Nit-Occlud PFO Occluder is a device premounted and knitted from a single nitinol wire. The occluder consists of a double-layer right atrial disc and a single-layer left atrial disc. The left atrial disc is designed as a concave monolayer. Both the left and right atrial discs are covered with polyethyleneterephthalat (Dakron[®]) (A). The system is originally attached to the delivery system but it has to be loaded to delivery tube. The wire filament (blue arrows) is the part of delivery system and it is removed during the release of the device [Color figure can be viewed at wileyonlinelibrary.com]

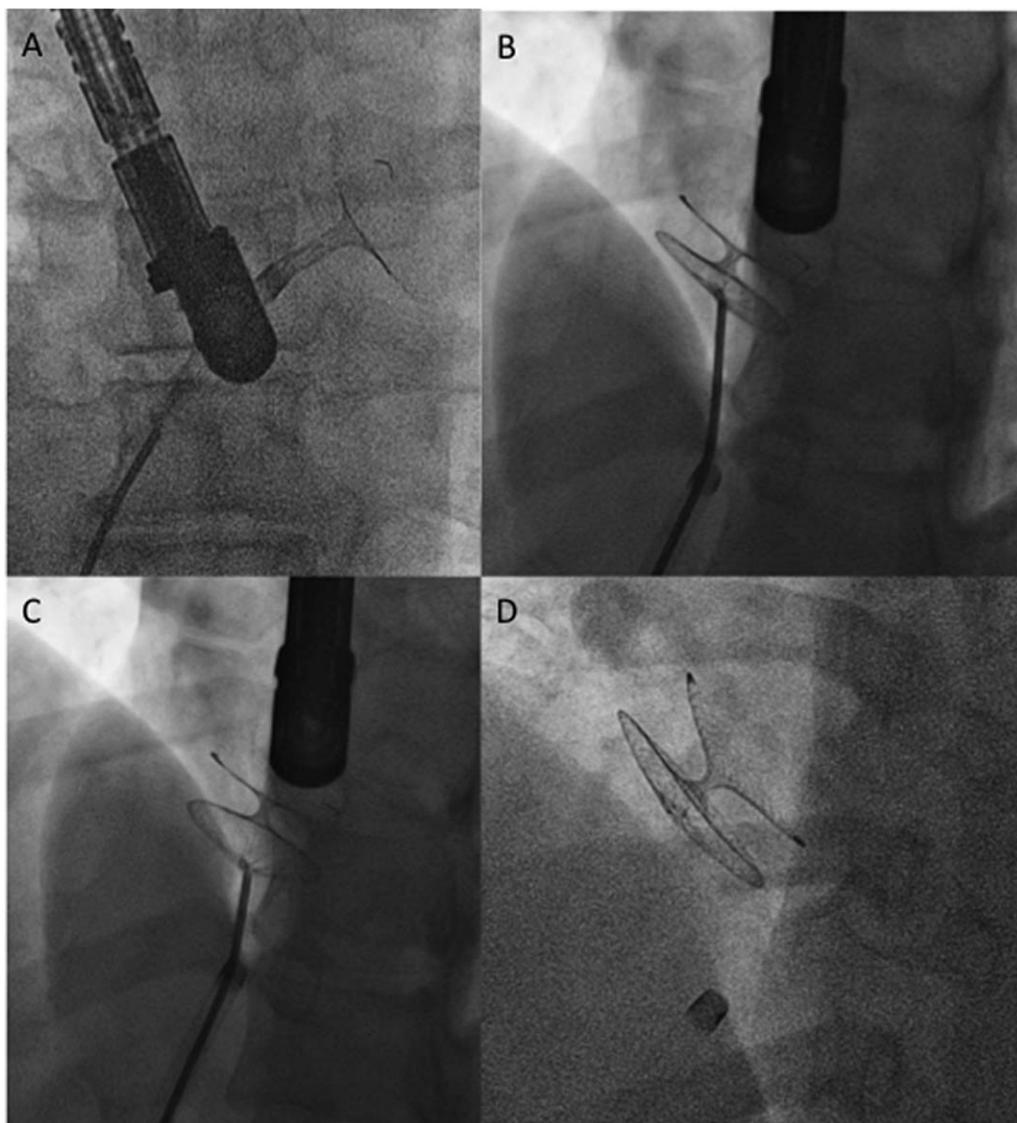


FIGURE 2 The Nit-Occlud PFO Occluder implantation. **A**, While maintaining the position of the device, the sheath was gently pulled back allowing deployment of the left atrial disk. **B**, Left atrial disk retracted together with the sheath to the atrial septum, and, following verification of septal support the sheath, pulled back allowing right atrial disk deployment. **C**, After confirmation of proper position of the device in TEE and fluoroscopy, tug-test was performed. **D**, The device in place after release

TABLE 3 Left-to-right shunt in transesophageal echocardiography in 6-week and 6-month follow-up in a group of 90 consecutive patients

Left-to-right shunt <i>n</i> = 90	Total	Mild	Moderate	Severe
At 6-weeks	17 (19%)	16 (17.7%)	1 (1.1%)	0 (0%)
At 6-months	1 (1.1%)	1 (1.1%)	0 (0%)	0 (0%)

vena cava, as it was described previously [20]. Once selected, the device was advanced through the sheath and, subsequently, the sheath and device pulled back from the left upper pulmonary vein into the left atrium. While maintaining the position of the device, the sheath was gently pulled back allowing deployment of the left atrial disc (Figure 2A). The expanded left atrial disc was then retracted together with the sheath to the atrial septum, and, following verification of septal support the sheath was pulled back further allowing right atrial disc deployment (Figure 2B). After confirmation of proper position of the device in TEE and fluoroscopy, tug-test was performed and subsequently the occluder was released (Figure 2C,D).

During device implantation 100 I.U./kg body mass of unfractionated heparin were administered. All patients received the loading dose of aspirin (300 mg per os) and clopidogrel (300 mg per os) and 1.0 g cephazolin intravenously before the procedure. After the procedure, all the patients were treated with aspirin 75 mg daily for 6 months and clopidogrel 75 mg daily for 3 months. Infective endocarditis prophylaxis was recommended for 6 months.

We monitored all the patients in periprocedural period in terms of arrhythmias, bleeding complications (including groin doppler ultrasonography), cardiac tamponade and other.

All the patients had transthoracic echocardiography performed the day after closure and 6 weeks after the procedure. After inclusion of the first 61 patients beginning from August 2013, we started to perform TOE with peri-device leak assessment systematically in all the next consecutive patients in addition to clinical observation. TOE was performed in the next 90 patients (60% of study group) 6 weeks and 6 months after the procedure. Residual shunting (right-to-left shunt) was assessed during Valsalva maneuver in TOE and based on color Doppler evaluation and agitated saline contrast passage to the left atrium. Passing contrast microbubbles were counted and categorized according to the following grades: grade 0: no microbubbles, grade 1: 1–9 microbubbles, grade 2: 10–20 microbubbles, grade 3: >20 microbubbles. Spontaneous appearance of contrast was considered to be grade 3.

2.1 | Follow-up evaluation

Patients were followed for a mean 24.4 ± 16.1 months (median 14.8 months, range; 6–62 months). The patients had follow-up visit after 6 weeks and after 6 months. Telephone follow-up was performed after 12 months and every next 12 months. None patient was lost to follow-up. A structured telephone interview in conjunction with neurological follow-up was performed to reveal recurrence of embolism such as TIA and stroke.

2.2 | Statistical methods

Continuous variables are expressed as mean or median and categorical data are reported as frequencies and percentages.

3 | RESULTS

The procedure was successful in 150 of 151 patients (99.3%). In one patient additional small ASD was revealed during the procedure and Figulla Flex II (Occlutech) device was implanted. Mean procedural duration time was 38.9 ± 19.2 min (from 15 to 120 min), mean fluoroscopy time 5.23 ± 4.49 min (1–21 min) and mean absorbed radiation dose was 77.7 ± 61.06 mGy (9–272). No major complications including death, cardiac tamponade, device embolism, serious bleeding were observed in periprocedural period. In one patient non-significant pericardial effusion was revealed (up to 4 mm) treated conservatively. Small access site hematoma (<5 cm of diameter) was observed in 34 (22.7%) patients and pseudoaneurysm (treated conservatively) in 3 (2%) patients. Prolonged bleeding from access site (>12 hr) was observed in 8 (5.3%) patients. All these minor complications were without any serious clinical sequelae (no blood transfusion or red blood count decrease). During the procedure, significant arrhythmias were observed in 8 (5.3%) patients, and in postprocedural period in the next 5 patients (3.3%) – atrial fibrillation in one patient and supraventricular tachycardia in 4 patients. All arrhythmias were treated successfully with antiarrhythmic drugs or finished spontaneously. In one patient, radiofrequency ablation of atrio-ventricular nodal reentrant tachycardia was performed 6 months after device implantation.

In the follow-up stroke or TIA reoccurred generally in 5 (3.3%) patients (2 strokes and 3 TIA's). In one patient with TIA device thrombosis on left atrial disc was observed (0.67%) six weeks after device implantation. No peripheral embolization was observed.

Echocardiographic follow-up data are showed in Table 3. Residual shunt at rest was revealed in 17 of 90 examined patients (19%) after 6 weeks and residual leak were observed in one patient (1.1%) in 6-month follow-up.

4 | DISCUSSION

Our prospective observational study showed novel PFM Nit-Occlud PFO Occlusion device to be safe and effective in prevention of recurrent cerebral ischemic events. As far as we know, our study is the largest one, evaluating this device. In the available literature, there is only one study on Nit-Occlud PFO device evaluating feasibility and safety of the device in the group of 63 patients with PFO after cerebrovascular events [20]. In this study of Steinberg et al. the device was successfully implanted in 98.4% patients with no relevant procedural complications. Residual shunt in TEE was noted in 12.7% after six weeks and in only 1 patient (2.4%) in six-month follow-up. At 18-months 5/63 (8%) neurologic events were reported [20]. We confirmed that implantation of Nit-Occlud PFO Occlusion device is technically feasible and safe. There were no major periprocedural or in-hospital complications. Only minor complications appeared, which



FIGURE 3 Transesophageal echocardiography in a patient with the left disk occluder thrombus (blue arrow) [Color figure can be viewed at wileyonlinelibrary.com]

were successfully treated without further clinical sequelae. Other formerly reported complications such as device embolization or intraprocedural TIA did not occur as well. The rate of residual right-to-left shunt 6 weeks (19%) and 6 months (1.1%) after device implantation is also comparable to that reported by Steinberg et al. Nit-Occlud compares well also with other types of the devices. In the study of Thaman et al., 166 patients with large PFO underwent closure with Amplatzer device ($n = 80$), GoreHelex (WL Gore, AZ; $n = 48$) or Premere (St. Jude Medical, MN; $n = 38$). On follow-up transthoracic echocardiogram, the rates of residual shunts were 32.5% with the Amplatzer, 58.3% with the Helex, and 39.5% with the Premere device, and over half of the shunts in each group were classified as severe [21]. In the Italian PFO Survey, 1,035 patients who underwent PFO closure with various devices were evaluated. Of these, 401 patients had 6-month follow up, and 78 (19.5%) had residual shunt [22]. Recently, Neuser et al. reported a group of 57 patients who underwent PFO closure with Figulla Flex II device (Occlutech, Germany) [23]. Of these, in 6-month follow-up, 5.6% had mild residual shunt.

Potential advantages of the Nit-Occlud PFO device include the concave shape of the monolayer left atrial disc [20]. This allows it to conform properly to the intraatrial septum and potentially might reduce the risk of thrombus formation. In our study however, one case of device thrombosis on left atrial disc has been revealed (0.7%), in a female patient with TIA, six weeks after device implantation (Figure 3). The patient was treated with enoxaparin one week and subsequently rivaroxaban was added to dual antiplatelet therapy for the next four weeks followed by rivaroxaban and clopidogrel for the next 5 months. No further complications were observed in this patient and no signs of thrombosis were revealed in control TOE in 6-month follow-up. Rigattelli et al. showed that device thrombosis appeared in 0.5% of 1,000 all-comer patients after PFO closure with different types of occluders [24]. In a meta-analysis of 28,142 patients after PFO or ASD closure from 203 studies, Abaci A. et al. showed that the risk of device thrombosis in long-term follow-up reached 1.2% (95% CI: 1.0–1.4%) [25]. Thus, in our opinion, the risk of device thrombosis was not related with the specific device type.

In our study, 5 neurologic events (2 strokes and 3 TIA's = 3%) in a follow-up period recurred. One stroke was observed in a patient with unrecognized previously paroxysmal atrial fibrillation. In one patient, TIA was probably associated with the left atrial disc thrombosis. In two other cases, TIA appeared in female patients with multiple risk factors (smoking, arterial hypertension). Direct association of the events to the occluder device is questionable. The event rate in our study is in a range of former studies with different devices. Using the Amplatzer device Carroll et al. in RESPECT trial reported 2% of recurrent neurologic events in as-treated-cohort of patients in PFO closure group [13]. In PC trial the reoccurrence of neurologic events were observed in 3% of patients from PFO closure group in 2.5 years follow-up period [14]. In observational trial with Amplatzer PFO device originated from our department and including the similar study population, as many as 7% of events in mean 2.6 years follow-up were reported [26]. In CLOSURE I trial neurologic events appeared in 6% of patients after PFO closure with STARFLEX device [12]. Aytemir et al. reported that in 17-month observation of patients after PFO closure with Occlutech Figulla® device neurologic events appeared in 1.2% of study population [27]. In our opinion, the results of the present study indicate that PFM Nit-Occlud PFO Occluder device is effective in preventing the recurrence of neurological events and comparable or might be even better to other types of occluders.

This study has important limitations. Firstly, the relatively small sample size in this single center study renders it difficult to generalize the findings to a larger population, although the study group is the largest population treated with the Nit-Occlud device. Secondly, in only 90 consecutive patients (60%) of whole study group TEE examination after 6 weeks and 6 months was performed.

5 | CONCLUSIONS

In conclusion, the PFM Nit-Occlud PFO Occluder seems to be safe and provides sufficient closure of intra-atrial communication in patients with PFO, who had suffered from cryptogenic stroke, TIA, or paradoxical peripheral embolism, comparable to former studies with the Amplatzer Occluder system. It is associated with high procedural success and favorable rates of complete closure.

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