





Transcatheter closure of patent foramen ovale in patients with cryptogenic stroke: impact on arrhythmia in 3 months follow-up

Wpływ przezcewnikowego zamknięcia przetrwałego otworu owalnego u pacjentów z udarem kryptogennym na zaburzenia rytmu serca – obserwacja 3-miesięczna

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Abstract

Introduction. Patent foramen ovale (PFO) is a common abnormality, occurring in about 25% of the population. Percutaneous PFO closure is recommended for selected patients in the prevention of recurrent thromboembolic events. Although transcatheter closure of PFO is recognized as a safe procedure, potential complications, such as atrial fibrillation, may occur. The purpose of this study was to assess the prevalence of arrhythmia in patients before and after PFO closure.

Material and methods. The authors retrospectively reviewed the medical records of 45 patients [median age 45 (interquartile range 35–61) years; 80% female] who underwent percutaneous PFO closure. 24-hour Holter electrocardiograms (ECG) were done both before and 3 months after the procedure in 21 patients [median age 49 (38–65) years; 81% female], however, data of predominant underlying rhythm was available for all 45 patients.

Results. There were no statistically significant differences in maximal and minimal heart rate, number of supraventricular and ventricular extrasystolic beats, pauses, episodes of supraventricular and ventricular tachycardia in patients before and after the PFO closure procedure. Median average heart rate was significantly higher before the procedure [70 (67–78) bpm vs. 69 (62–77) bpm; $p = 0.03$]. Among the 45 patients, one had a history of paroxysmal atrial fibrillation (AF) before the procedure. During the follow-up, no AF was found.

Conclusions. Transcatheter closure of PFO did not affect arrhythmias observed in 24-hour Holter ECG monitoring of the patients. The procedure has a low risk of complications if performed in selected patients by an adequately trained operator in an experienced centre.

Key words: patent foramen ovale, percutaneous closure, cryptogenic stroke, arrhythmia, atrial fibrillation

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Introduction

The foramen ovale is an anatomical structure, which connects the right and left atrium in the fetal circulation. After birth, it physiologically closes by age two, however, it remains patent in about 25% of the population [1]. Due to patent foramen ovale (PFO) commonness, its presence in itself is not considered a pathology [2]. Nevertheless, an association between PFO and cryptogenic stroke has been found and proved [3, 4].

Ischemic strokes account for over 80% of all strokes and are a result of obstruction of arteries supplying the brain [5]. In as many as 25% of ischemic stroke cases, the cause of ischemia is unknown; in such cases, the term cryptogenic stroke is used. Most of the cryptogenic strokes are considered embolic [6]. In 2014 the term of embolic stroke of undetermined source (ESUS) was formed to describe patients with a non-lacunar ischemic stroke and no specific cause of stroke. The set criteria to define ESUS enabled the conduction of randomized controlled trials in this population [7].

PFO is one of the main pathologies etiologically associated with ESUS. The presumed mechanism of ischemic stroke in patients with PFO is a paradoxical embolization. The embolism is caused by the infiltration of the venous thrombus from the right to the left atrium under hemodynamic conditions where the PFO is opened [8]. The transcatheter PFO closure is a percutaneous procedure performed for the prevention of recurrent strokes in patients with a history of cryptogenic stroke and PFO. It was first introduced in 1992; since then the efficacy and safety of closing PFO have been examined in several studies. Despite the initially disappointing results of randomized trials (such as CLOSURE 1 or PC Trial), subsequent studies (e.g. DEFENSE-PFO) confirmed the effectiveness of interventional therapy in high-risk PFO patients [2]. In 2019 a joint task force of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and 8 other European societies published a position paper on the management of patients with PFO. The authors stated that the transcatheter PFO closure should be performed 'in carefully selected patients aged from 18 to 65 years with a confirmed cryptogenic stroke, transient ischemic attack (TIA), or systemic embolism and an estimated high probability of a causal role of the PFO as assessed by clinical, anatomical and imaging features' [9].

The transcatheter PFO closure is considered as an effective and safe procedure. According to the European position paper, the primary technical success of PFO closure approaches 100% with complete closure seen in 93–96% at one year [9]. The perioperative complications could be divided into major ones (such as device embolization or device thrombosis) with an incidence of 1.5% and minor

ones (such as residual leakage and atrial arrhythmias) with an incidence of 7.9% [2]. Implantation of a PFO occluder significantly increases the likelihood of atrial fibrillation. In a meta-analysis of randomized control trials, a 4.6% incidence was reported after 3.8 years of follow-up [9]. Furthermore, arrhythmia after the PFO closure procedure can be manifested by atrial additional beats or, less often, by transient atrioventricular conduction disturbances [2].

Despite the increasing popularity of the procedure, there have been only several studies on complications of the PFO closure procedure thus far and only a few on arrhythmic ones. The purpose of this study was to assess the prevalence of arrhythmia in patients before and after the PFO closure.

Material and methods

Study population

We retrospectively analyzed the data of 45 patients who underwent percutaneous PFO closure in the Department of Cardiology and Congenital Diseases of Adults, Polish Mother's Memorial Hospital Research Institute in Lodz between June 8, 2017, and February 19, 2020. All patients who were qualified for the procedure had confirmed brain ischemic lesions in neuroradiological imaging and high-risk PFO detected in transesophageal echocardiography (TEE). Almost all procedures were performed with the use of Occlutech Figulla Flex II PFO Occluder (Occlutech GmbH, Jena, Germany), in two cases Occlutech Figulla Flex II ASD Occluder was used due to PFO anatomy. All patients had a follow-up hospitalization about 3 months after their procedure.

The study was performed in accordance with the guidelines and regulations approved by the Bioethics Commission of the Polish Mother's Memorial Hospital Research Institute in Lodz and approval from this commission was obtained.

Data collection

All data were collected from the medical records of the Department of Cardiology and Congenital Diseases of Adults. A variety of demographic data was collected including age, sex, body weight, height, body mass index (BMI), body surface area (BSA), systolic (SBP) and diastolic blood pressure (DBP) at admission and heart rate (HR) at admission. The authors searched for a history of heart failure, coronary artery disease, hypertension, paroxysmal and permanent atrial fibrillation, diabetes mellitus, hypercholesterolemia, deep vein thrombosis, obesity, migraine along with a history of smoking and excessive alcohol consumption.

We studied the results of examinations performed during patients' hospitalizations. All patients underwent contrast TEE before the procedure. From TEE reports parameters associated with PFO were obtained. These included

the presence of right-to-left shunt during the Valsalva manoeuvre, dimensions of the PFO canal and distances of the edge of the canal from the aorta, mitral ring and superior vena cava. It was checked whether atrial septal aneurysm (ASA), Chiari network or Eustachian valve were identified. During follow-up hospitalization, all patients had transthoracic echocardiography (TTE), in which the placement of a device and closure effect was assessed.

24-hour Holter electrocardiograms (ECGs) were done both before and 3 months after the procedure in 21 of 45 patients. Reports from follow-up 12-lead ECGs were available in all cases, therefore data of predominant underlying rhythm was available for all 45 patients.

Statistical analysis

The STATISTICA 13.1 software package (StatSoft, Poland) was used for analysis. A p-value of < 0.05 was considered significant. The Shapiro-Wilk test was used to assess the normality of distribution. Nominal variables were presented as numbers and percentages. Continuous variables were expressed as mean and standard deviation (variables

with normal distribution) or median with the first and third quartiles (variables with nonnormal distribution). Student's t-test was used to compare continuous variables with normal distribution and with homogeneity of variance. For nonnormally distributed variables, the Mann-Whitney U test was used. The dichotomous data were analyzed by the chi-squared test, chi-squared test with Yates correction or Fisher exact test. Wilcoxon signed-rank test was used to assess the differences of continuous Holter ECG parameters from tests done before and 3 months after the PFO closure procedure. Collected data were analyzed for all 45 patients and the 21-patients subgroup, for whom findings of Holter ECG done both before and 3 months after the procedure were available.

Results

Both in the group of 45 patients as well as in the 21-patients subgroup, females made up about 80% of patients, with a median age of 45 (35–61) years in the first group and 49 (38–65) years in the second (Table 1).

Table 1. Basic characteristics of patients

Parameter	PFO closure (N = 45)	PFO closure: Holter ECG done both before and 3 months after the procedure (N = 21)	p
Gender (female) [N, %]	36 (80%)	17 (81%)	0.81
Age [years]	45 (35–61)	49 (38–65)	0.28
Body mass [kg]	66 (58–79)	66 (58–79)	0.94
Height [m]	1.67 ± 0.093	1.66 ± 0.091	0.69
BMI [kg/m ²]	24.57 ± 3.69	24.83 ± 3.78	0.8
BSA [m ²]	1.72 (1.59–1.95)	1.72 (1.62–1.95)	0.96
SBP at admission [mm Hg]	124.87 ± 15.19	125.19 ± 17.52	0.94
DBP at admission [mm Hg]	76.62 ± 11.27	74.1 ± 11.18	0.4
HR at admission [/min]	70 (64–78)	70 (60–70)	0.35
Hypertension [N, %]	13 (29%)	7 (33.33%)	0.94
Heart failure [N, %]	2 (4.4%)	1 (4.76%)	0.56
Coronary artery disease [N, %]	2 (4.4%)	2 (9.52%)	0.8
Diabetes mellitus [N, %]	0	0	-
Hypercholesterolemia [N, %]	27 (60%)	14 (66.7%)	0.8
Deep vein thrombosis [N, %]	2 (4.4%)	1 (4.76%)	0.56
Smoking [N, %]	10 (22.22%)	7 (33.33%)	0.51
Excessive alcohol use [N, %]	1 (2.22%)	1 (4.76%)	0.83
Obesity [N, %]	2 (4.4%)	1 (4.76%)	0.56
Migraine [N, %]	9 (20%)	5 (23.81%)	0.98
Paroxysmal AF [N, %]	1 (2.22%)	1 (4.76%)	0.83
Permanent AF [N, %]	0	0	-

Nominal variables were presented as numbers and percentages. For continuous variables with non-normal distribution median values with the first and third quartiles are given. For parameters with normal distribution mean values ± standard deviation (SD) are given; PFO – patent foramen ovale; ECG – electrocardiogram; BMI – body mass index; BSA – body surface area; SBP – systolic blood pressure; DBP – diastolic blood pressure; HR – heart rate; AF – atrial fibrillation

Table 2. Findings in transesophageal echocardiography

Parameter	PFO closure (N = 45)	PFO closure: Holter ECG done both before and 3 months after the procedure (N = 21)	p
Right-to-left shunt during the Valsalva manoeuvre [%]	100	100	-
Length of PFO canal [mm]	7 (5-11)	8 (5-11)	0.93
Diameter of PFO canal [mm]	4 (3-5)	4 (3-4)	0.6
Distance of the edge of the canal from aorta [mm]	7 (5-8)	6.5 (5-8)	0.44
Distance of the edge of the canal from mitral ring [mm]	13 (12-15)	13.5 (12-15.5)	0.57
Distance of the edge of the canal from superior vena cava [mm]	13 (12-17)	13 (11.5-16.5)	0.66
Chiari network [N, %]	0	0	-
Eustachian valve [N, %]	3 (6.67%)	0	0.55
Atrial septal aneurysm [N, %]	12 (26.67%)	8 (38.1%)	0.51

Nominal variables were presented as numbers and percentages. Continuous variables were expressed as median values with the first and third quartiles; PFO – patent foramen ovale; ECG – electrocardiogram

About 30% of patients had a history of hypertension and about 60% of hypercholesterolemia. In the group of all 45 patients, 22% admitted to smoking. Interestingly, as many as 20% of patients in both groups had a history of migraines. Only one patient had a history of paroxysmal atrial fibrillation before the procedure and none of the patients had a diagnosis of permanent atrial fibrillation (AF). In the statistical analysis, there were no significant differences in the basic characteristics' parameters between the two groups.

Table 2 shows the findings from transesophageal echocardiography. Right-to-left shunt during the Valsalva maneuver was identified in all patients. In the group of 45 patients, the median length of the PFO canal was 7 (5-11) mm and the median diameter was 4 (3-5) mm [in the 21-patient subgroup the values were 8 (5-11) mm and 4 (3-4) mm, respectively]. In the first group, the median distance of the edge of the PFO canal from the aorta was 7 (5-8) mm; from the mitral ring – 13 (12-15) mm; from the superior vena cava – 13 (12-17) mm. None of the patients had a Chiari network, but in 3 cases an Eustachian valve was discovered. 12 patients (26.67%) had an ASA. In the statistical analysis, there were no significant differences in transesophageal echocardiography parameters between the two groups.

Table 3 shows the findings in 24-hour Holter ECG done before and 3 months after the procedure (N = 21 patients). Before the procedure, one patient had atrial fibrillation; the other 20 patients (95%) had sinus rhythm. After the procedure, all patients had sinus rhythm. There were no statistically significant differences in minimal and maximal heart rate, the number of supraventricular

and ventricular extrasystolic beats, the number of pauses over 2 seconds, the number of episodes of supraventricular and ventricular tachycardia in patients before and after the PFO closure procedure. Only the median average heart rate was significantly higher before the procedure [70 (67-78) bpm vs. 69 (62-77) bpm; $p = 0.03$]. There were no traces of atrioventricular conduction disturbances in the Holter ECG reports.

12-lead ECG reports of the other 24 patients (patients who did not have Holter ECG done before and after the procedure) showed that all had sinus rhythm and no abnormalities in ECG were identified.

Transthoracic echocardiography done in all patients during a follow-up hospitalization showed that the patent foramen ovale was successfully closed in all cases.

Discussion

The results of this study revealed that transcatheter closure of PFO did not affect arrhythmias observed in 24-hour Holter ECG monitoring of the patients 3 months after the procedure. During the follow-up, no atrial fibrillation was found and Holter ECG arrhythmia parameters (such as the number of supraventricular and ventricular extrasystolic beats) from before and after the procedure were not significantly different.

The mere presence of patent foramen ovale does not appear to be significantly associated with cardiac arrhythmias [10]. Atrial arrhythmias, however, are known complications of percutaneous PFO closure [2, 9]. In a heart with PFO, the fast pathway of atrial conduction from the sinoatrial (SA) node to the compact atrioventricular (AV)

Table 3. Findings in 24-hour Holter electrocardiogram done before and 3 months after the procedure (N = 21)

Parameter	Before procedure	After procedure	p
Sinus rhythm [N, %]	20 (95%)	21 (100%)	> 0.99
HR min [/min]	51 (45-57)	50 (45-55)	0.54
HR max [/min]	115 (102-127)	109 (100-128)	0.4
Average HR [/min]	70 (67-78)	69 (62-77)	0.03
Pauses > 2 s [N]	0	0	-
ExSV [N]	16 (4-86)	18 (5-51)	0.94
Episodes of SVT [N]	0	0	-
ExV [N]	3 (0-134)	8 (0-141)	0.79
Episodes of VT [N]	0	0	-

Nominal variables were presented as numbers and percentages. Continuous variables were expressed as median values with the first and third quartiles; HR – heart rate; ExSV – number of supraventricular extrasystolic beats; SVT – supraventricular tachycardia; ExV – number of ventricular extrasystolic beats; VT – ventricular tachycardia

node typically courses along the anterior margins of a patent foramen ovale. Furthermore, the superior margins of a patent foramen ovale include Bachmann's bundle, which is considered the main pathway of interatrial conduction. Therefore, it is intuitive to assume that some direct mechanical irritation or injury to these structures may occur after percutaneous PFO closure [11–13]. Several pathophysiological mechanisms of procedure-induced arrhythmias are suggested in the literature. These include mechanical irritation of atrial structures, postprocedural inflammatory reaction and a direct impact of PFO occluder on atrial electrophysiology (inflammation and scarring around the closure device can lead to anisotropic conduction and macro-reentry around the occluder) [9, 10, 14].

AF is one of the most frequent undesirable events following transcatheter percutaneous closure of PFO [9]. In a meta-analysis by Turc et al., the authors analyzed data from all available randomized controlled trials (RCTs), which compared PFO closure, anticoagulation, and antiplatelet therapy for the prevention of stroke recurrence in patients with PFO-associated cryptogenic stroke. The study, which included 3560 patients enrolled in 6 RCTs, revealed that PFO closure is superior to antithrombotic therapy, but is associated with an increased risk of atrial fibrillation. The pooled incidence of new-onset AF per 100 patients treated was 4.56 [95% confidence interval (CI) 3.58–5.63]. The authors concluded that future studies will have to assess the clinical relevance of atrial fibrillation induced by PFO closure [15].

The type of PFO closure device may play a role in the risk of postprocedural AF. For example, in the Closure trial, the use of the Starflex (NMT Medical, USA) device was associated with a significant increase in

postprocedural AF [16]. In a study by Gevorgyan Fleming et al., the authors compared a residual shunt rate and complications associated with six different devices used for PFO closure: Amplatzer Cribriform, Amplatzer ASO (AGA Medical Corp., USA), Amplatzer PFO (Abbott Vascular, USA), Gore Cardioform, Gore Helex (Gore Medical, USA), CardioSEAL (NMTMedical, USA). A total of 467 patients were retrospectively enrolled in the study and 320 of them received a quantitative assessment of right-to-left shunting both before and after the PFO closure. The highest closure rate was achieved with the Gore Cardioform device (100%, N = 104), the lowest – Amplatzer PFO (85%, N = 33). Atrial fibrillation was the most common significant adverse event. The highest AF incidence of 13% was identified in patients with Gore Cardioform device, while in patients with Gore Helex and Amplatzer PFO it was only 4% [17]. In the study centre, Occlutech (Jena, Germany) devices are used. The company launched their first occluder in 2003 and their current third-generation device, available since October 2011, is called Figulla Flex II [18]. Several studies have been conducted to evaluate the efficacy and safety of this device. Neuser et al. [18] retrospectively studied the medical records of 57 patients who underwent the PFO closure with the Figulla Flex II PFO device. The closure was sufficient with no residual right-to-left shunt in 94.4% of all patients at 6 months post-implantation. One patient was diagnosed with paroxysmal atrial fibrillation [18]. A study by Hildick-Smith et al. prospectively enrolled 100 patients who underwent the PFO closure with the same device. During a six-month follow-up, one case of new-onset atrial fibrillation was detected [19]. Trabattoni et al. [20] compared the acute and 12-month results of percutaneous closure of PFO with Figulla Flex II and Amplatzer PFO. The study

showed that both primary technical success and results at a 12-month follow-up were comparable between the two groups. AF was detected in 4 patients from the Amplatzer PFO group and in 1 from the Figulla group [20]. In the presented study, 43 procedures were performed with the use of Figulla Flex II PFO Occluder and 2 with the use of Figulla Flex II ASD Occluder, due to PFO anatomy. One patient had a history of paroxysmal atrial fibrillation before the procedure, but during the follow-up, no episode of AF was found.

Arrhythmias after PFO closure may also be manifested by atrial additional beats or atrioventricular conduction disturbances [2]. Nevertheless, the incidence of symptomatic postprocedural arrhythmias other than atrial fibrillation seems to be low. In the last four randomized clinical trials regarding PFO closure, a total of 1210 patients underwent the procedure (RESPECT – 499 patients; CLOSE – 238 patients; REDUCE – 413 patients; DEFENSE-PRO – 60 patients). Arrhythmic complications of the PFO closure in these studies were as follows: in RESPECT – 2 cases of AF, 1 case of atrial flutter (AFL) and 1 case of nonsustained ventricular tachycardia; in CLOSE – 10 cases of AF, 1 case of AFL, 1 case of atrioventricular block and 5 cases of (unspecified) tachyarrhythmia; in REDUCE – 28 cases of AF and 1 case of AFL; in DEFENSE-PRO – 2 cases of AF. These numbers show that postprocedural arrhythmias other than AF/AFL in these patients were rare [21–24].

We found one study, which compared findings in Holter ECG monitoring from before and after the PFO closure. Ateş et al. evaluated the effect of PFO closure in 47 patients, using 24-hour Holter ECG monitoring and magnetic resonance imaging (MRI). Amplatzer PFO occluder and Occlutech Figulla PFO occluder were used in 34 and 13 patients, respectively. 4 patients (8.5%) had occasional supraventricular extrasystolic beats (ExSV) and 3 patients (6.3%) had occasional ventricular extrasystolic beats (ExV) before the procedure. After the PFO

closure, occasional ExSVs were detected in 2 patients (4.2%), frequent ExSVs (defined as > 2000 beats/day) also in 2 patients, occasional ExVs in 1 patient (2.1%), frequent ExVs (defined as > 30 beats/h) also in 1 patient and type 1 atrioventricular block in 1 patient (2.1%). No atrial fibrillation, atrial flutter or atrial tachycardia were detected. Overall, the incidence of arrhythmia did not statistically increase after the procedure ($p = 0.917$) [25]. The presented study similarly showed that Holter ECG arrhythmia parameters from before and after the procedure were not significantly different.

Limitations of the study

There are several limitations to this study. These include its retrospective nature and the fact that data was collected only in one centre and was not compared to a control group. Furthermore, only follow-up from 3 months after the procedure was available. Finally, only 21 patients had Holter ECG done both before and after the procedure.

Conclusions

This study revealed that in the study patients the percutaneous PFO closure was safe and effective. The procedure did not affect arrhythmias observed in Holter ECG monitoring of the study patients, neither atrial fibrillation nor atrioventricular conduction disturbances were found. All PFOs were successfully closed, as seen during follow-up TTEs. The results of this study provide additional evidence that the current scientific consensus on PFO closure is valid. The procedure has a low risk of complications if performed in carefully selected patients by an adequately trained operator in an experienced centre.

Conflict of interest

The authors declare that they have no conflict of interest.

Streszczenie

Wstęp. Przetrzywały otwór owalny (PFO) to częsta anomalia, występująca u około 25% populacji. Zabieg przezskórny zamykania PFO zaleca się u wybranych pacjentów w celu zapobiegania nawrotom incydentów zakrzepowo-zatorowych. Mimo że przezcewnikowe zamykanie PFO jest uznawane za zabieg bezpieczny, może być przyczyną potencjalnych powikłań, takich jak migotanie przedsionków (AF). Celem pracy była ocena występowania arytmii u pacjentów przed zabiegiem zamknięcia PFO i po nim.

Materiał i metody. Retrospektywnie przeanalizowano dokumentację medyczną 45 pacjentów (mediana wieku 45 [zakres międzykwartyłowy 35–61] lat; 80% kobiet), którzy przebyli zabieg przezskórny zamknięcia PFO. Dwudziestoczterogodzinne monitorowanie elektrokardiograficzne (EKG) metodą Holtera wykonano przed zabiegiem oraz 3 miesiące po zabiegu u 21 pacjentów (mediana wieku 49 [38–65] lat; 81% kobiet), jednak dane o rytmie prowadzącym były dostępne w odniesieniu do wszystkich 45 pacjentów.

Wyniki. Nie wykazano istotnych statystycznie różnic w zakresie maksymalnej i minimalnej częstości pracy serca, liczby nadkomorowych i komorowych pobudeń dodatkowych, liczby pauz, liczby epizodów częstoskurczów nadkomorowych lub komorowych u pacjentów przed zabiegiem zamknięcia PFO i po tym zabiegu. Mediana średnich częstości pracy serca była istotnie wyższa przed zabiegiem (70 [67–78]/min vs. 69 [62–77]/min; $p = 0,03$). U jednej osoby spośród 45 pacjentów stwierdzano napadowe AF przed zabiegiem. Podczas 3-miesięcznej obserwacji nie wykryto żadnego epizodu AF.

Wnioski. Zabieg przezcewnikowego zamknięcia PFO nie wpłynął na arytmie obserwowane w 24-godzinnym monitorowaniu EKG metodą Holtera w badanej grupie. Zabieg cechuje się niskim ryzykiem powikłań, o ile jest wykonywany u właściwie zakwalifikowanych pacjentów, przez odpowiednio wyszkolonego operatora i w ośrodku z doświadczonym personelem.

Słowa kluczowe: przetrzywały otwór owalny, przezskórne zamknięcie, udar kryptogeny, arytmia, migotanie przedsionków

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