# Late-onset acute limb ischemia after transcatheter patent foramen ovale closure with Occlutech Figulla Flex II PFO Occluder

**Juraj Dúbrava[a], Maria Hajzoková[b], Erika Drangová[c], Ivo Gašparovič[d]**

[a] *Department of Cardiology, University Hospital, Bratislava, Slovakia*
[b] *Department of Cardiology, National Institute of Cardiovascular Diseases, Bratislava, Slovakia*
[c] *Department of Diagnostic and Interventional Radiology, National Institute of Cardiovascular Diseases, Bratislava, Slovakia*
[d] *Department of Cardiosurgery, National Institute of Cardiovascular Diseases, Bratislava, Slovakia*

ARTICLE INFO

*Article history:*
Submitted: 2. 3. 2025
Accepted: 6. 7. 2025
Available online: 30. 7. 2025

*Kľúčové slová:*
Akútna končatinová ischémia
Foramen ovale patens
Occlutech Figulla Flex II PFO occluder
Perkutánny uzáver
Trombus

SÚHRN

**Kontext***:* Trombogenéza je veľmi zriedkavá komplikácia po katétrovej oklúzii foramen ovale patens (PFO). Kazuistika neskorej symptomatickej trombózy oklúzora Occlutech Figulla Flex II PFO nebola podľa vedomostí autorov dosiaľ publikovaná.
**Kazuistika:** Ide o prípad 45-ročného muža s anamnézou periférnej artériovej embolizácie s následným uzáverom PFO oklúzorom Occlutech Figulla Flex II PFO. Pacient absolvoval 6-mesačnú duálnu protidoštičkovú liečbu klopidogrelom (75 mg denne) a kyselinou acetylsalicylovou (100 mg denne) a následne pokračoval v monoterapii klopidogrelom ďalších 8 mesiacov. Päť mesiacov od ukončenia protidoštičkovej monoterapie (t.j. 19 mesiacov od uzáveru PFO) bol rehospitalizovaný s klinickým a ultrasonografickým obrazom akútnej končatinovej ischémie ľavej dolnej končatiny. Transtorakálna a transezofagová echokardiografia verifikovali rozsiahlu masu v ľavej predsieni, fixovanú na ľavopredsieňový disk oklúzora. Reziduálny skrat nebol prítomný. Pacient absolvoval katétrovú embolektómiu z ľavej femorálnej artérie. Nález na počítačovej tomografii po dvoch mesiacoch antikoagulácie warfarínom bol identický ako na echokardiografii. Zistila sa rezistencia na aktivovaný proteín C. Realizovali sme chirurgickú extirpáciu masy a uzáver defektu predsieňového septa perikardiálnou záplatou. Histopatologický nález extirpovanej masy svedčil pre trombus.
**Záver:** Tromboembolizmus po uzávere PFO pomocou Occlutech Figulla Flex II PFO oklúzora je výnimočná komplikácia, ktorá môže vzniknúť neskoro po výkone napriek antitrombotickej profylaxii.



*Keywords:*
Acute limb ischemia
Occlutech Figulla Flex II PFO occluder
Patent foramen ovale
Percutaneous closure
Thrombus

ABSTRACT

**Background***:* Thrombus formation is an exceedingly rare complication after transcatheter patent foramen ovale (PFO) occlusion. To the best of the authors' knowledge, a case of late symptomatic thrombosis of Occlutech Figulla Flex II PFO occluder has not yet been published.
**Case presentation:** A 45-year-old man with a history of peripheral artery embolism, and subsequent PFO closure with Occlutech Figulla Flex II PFO occluder. The patient completed dual antiplatelet therapy with clopidogrel (75 mg/day) and aspirin (100 mg/day) after 6 months and subsequently continued single antiplatelet therapy (SAPT) with clopidogrel for other eight months. Five months after the discontinuation of SAPT (i.e. 19 months after PFO closure), he was readmitted with a clinical and ultrasound presentation of acute limb ischemia of the left lower extremity. Transtoracic and transesophageal echocardiography revealed a huge left atrial mass, attached to the left atrial disc of the occluder. The residual shunt was not present. A catheter embolectomy from the left femoral artery was performed. Computed tomography after two months of warfarin anticoagulation showed identical findings to echocardiography. Activated protein C resistance was found. The mass was surgically extirpated and the atrial septal defect was corrected with a pericardial patch. Pathology confirmed the mass to be a thrombus.
**Conclusion:** Thromboembolism after PFO closure with an Occlutech Figulla Flex II PFO occluder is an exceptional complication that can occur late after the procedure despite antithrombotic prophylaxis.

**Address:** MUDr. Juraj Dúbrava, PhD., Department of Cardiology, University Hospital Bratislava, Antolská 11, 85107 Bratislava, Slovakia,
e-mail: dubrava.kv@gmail.com
**DOI:** 10.33678/cor.2025.078

**Please cite this article as:** Dubrava J, Hajzoková M, Drangová E, Gašparovič I. Late-onset acute limb ischemia after transcatheter patent foramen ovale closure with Occlutech Figulla Flex II PFO Occluder. Cor Vasa 2025;67:89–92.

## Introduction

Percutaneous occlusion of patent foramen ovale (PFO) is indicated in precisely selected patients with cryptogenic central or peripheral thromboembolism and a high probability of a causal relationship with PFO after excluding other identifiable causes.[1]

Numerous devices have been used for the PFO closure. Figulla Flex II occluders are among the most commonly used devices. The observed incidence of adverse effects after implantation of this device during long-term follow-up is low. Based on the published studies, thrombus formation on the Figulla Flex II occluder was not observed during the mid-term follow-up of 6 months to 1.1 years.[2–4]

We present a case of symptomatic late thrombus formation 19 months after percutaneous closure of PFO with an Occlutech Figulla Flex II PFO occluder.

## Case presentation

A 45-year-old man with a history of right femoral and popliteal artery embolism treated with thrombolysis. The patient was subsequently diagnosed with a PFO with a massive right-to-left shunt. The channel length and diameter were 9 and 4 mm, respectively. Other causes of peripheral thromboembolism were excluded. Paradoxical embolism through a PFO was believed to be a cause of acute limb ischemia. So, he underwent a PFO closure with Occlutech Figulla Flex II PFO Occluder 23/25 mm, resulting in no residual shunt. Dual antiplatelet therapy (DAPT) with long-term clopidogrel (75 mg/day) and aspirin (100 mg/day) during the first six months following the procedure was recommended. The patient completed DAPT as recommended after 6 months and subsequently continued single antiplatelet therapy (SAPT) with clopidogrel.

At transthoracic echocardiography (TTE) study 12 months after PFO occlusion, the occluder was free of leak and thrombus. The patient discontinued clopidogrel monotherapy 14 months after PFO closure.

Five months after the discontinuation of SAPT (i.e. 19 months after PFO closure), he was admitted repeatedly with a clinical and ultrasound presentation of acute limb ischemia of the left lower extremity. On presentation, his vital signs were normal: blood pressure 130/84 mmHg, heart rate 84 beats per minute, temperature 36.5°C, and respiratory rate 18 breaths per minute. The left calf was cool, pale, without palpable pulsations on the popliteal artery and, more distally, with a movement disorder of the fingers. The rest of the physical examination was unremarkable. Initial basic routine laboratory tests (blood count, biochemistry, INR, aPTT, fibrinogen) did not reveal significant abnormalities. The electrocardiogram recording and the chest radiograph were normal.

TTE found a large homogeneous hypoechogenic 34 × 15 × 12 mm mass in the left atrium below the anterior mitral leaflet. The rest of the TTE examination was unremarkable.

Two- and three-dimensional transesophageal echocardiography (TEE) confirmed a huge left atrial ovoid 30 × 24 xx 12 mm mass, which was attached by a 7 mm wide stalk to the left atrial disc of the Figulla Flex occluder (**Fig. 1**). This partially mobile mass was not prolapsing into the left ventricle. There was no mitral valve obstruction or regurgitation. Both discs of the occluder were in the correct position. The residual shunt was not present. The mass displayed on echocardiography was considered as likely to be an extensive thrombus. Myxoma was unlikely.

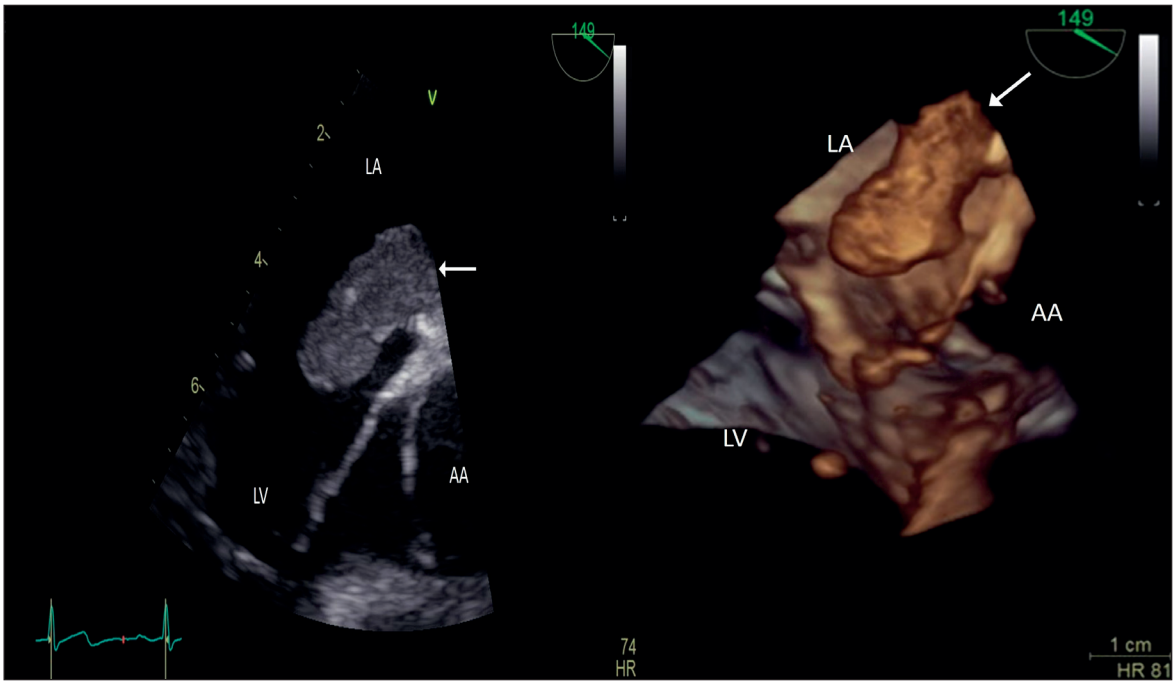


**Fig. 1 – Two-dimensional (left) and three-dimensional (right) transesophageal echocardiography. Large hypoechogenic left atrial mass (←) attached to a PFO occluder.** AA – ascending aorta; LA – left atrium; LV – left ventricle.

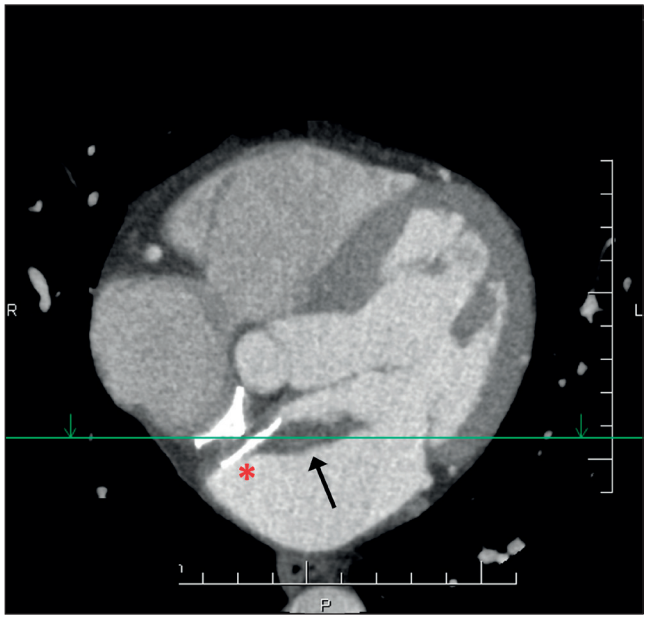


**Fig. 2 – CT scan showing a mass (→) on the left atrial disk (*) of the PFO occluder.**

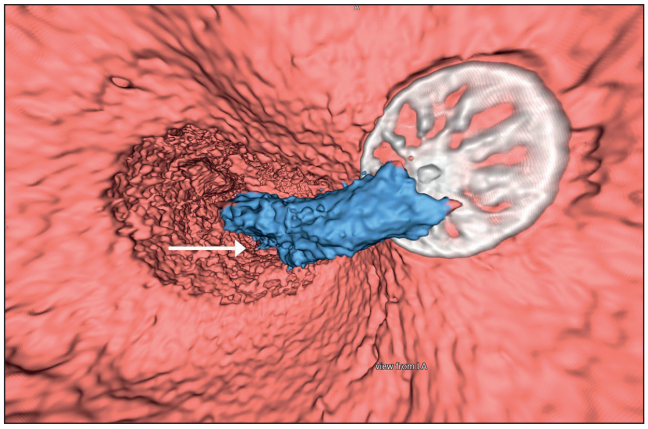

**Fig. 3 – Three-dimensional CT scan reconstruction (view from the left atrium) demonstrating a mass (→) on the left atrial disk of the PFO occluder.**

Successful arterial embolectomy from the left common, superficial, and deep femoral artery was performed using the Fogarty embolectomy catheter. A warfarin therapy was started.

Computed tomography (CT) after two months of oral anticoagulation showed an analogous finding as in the previous TEE – a hypodense 34 × 11 × 10 mm mass with a stalk attached to the left atrial disk of the PFO occluder (**Figs 2 and 3**). The mass was thought to be a thrombus rather than a myxoma. CT coronary angiography demonstrated the coronary artery disease without significant stenoses. Surgical management was advised and unfractionated heparin drip was started. The mass and the occluder were extirpated (**Fig. 4**). The atrial septal defect was corrected with a pericardial patch. The histopathological examination of the removed mass was consistent with a thrombus. Coagulation assays were performed to

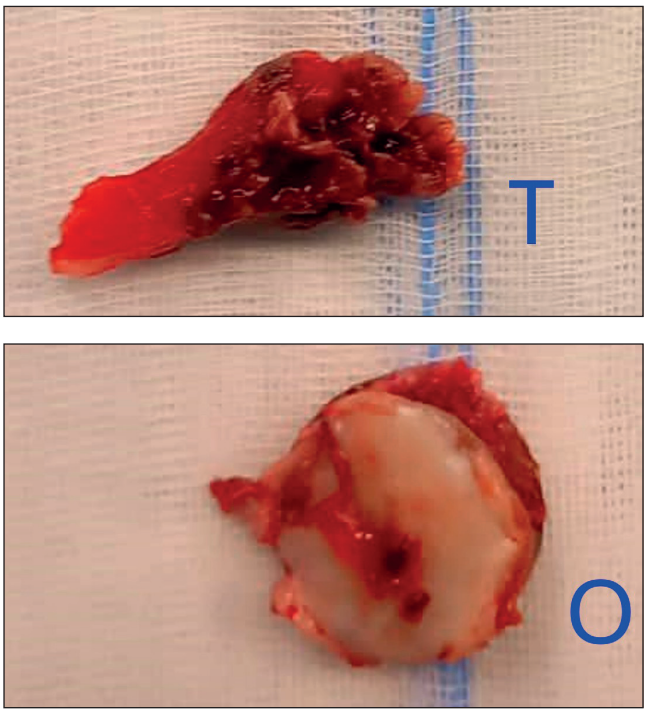


**Fig. 4 – Explanted Figulla-Flex II Occluder (O) and thrombus (T).**

detect hereditary or acquired thrombophilic disorders. Activated protein C resistance was found. Other thrombophilic conditions were not found. Rivaroxaban was recommended for three months to prevent recurrent thromboembolism. The postoperative status was complicated by hemodynamic instability and sepsis caused by erysipelas bullosum of the right calf. After appropriate treatment, the patient was stabilized and later discharged on the tenth postoperative day.

## Discussion

Thromboembolism is an exceedingly rare complication after transcatheter PFO closure. However, its consequences can be serious and even life-threatening.[5] In our case, we reported acute limb ischemia caused by thrombosis on the Occlutech Figulla Flex II PFO Occluder 19 months after the procedure. Thromboembolism occurred despite antithrombotic prophylaxis. To the best of the authors' knowledge, a case of late symptomatic thrombosis of this type of PFO occluder has not yet been published.

Our case report raises the question of how long antiplatelet prophylaxis should last after PFO occlusion. According to the European position paper, it is reasonable to propose DAPT for 1 to 6 months after PFO closure. Single antiplatelet therapy should be continued for at least 5 years. However, the strength of both statements is only conditional.[1] The extension of the single antiplatelet therapy beyond 5 years should be based on the balance between the patient's overall risk of stroke for other causes and hemorrhagic risk. However, real-world practice is heterogeneous and the duration of thromboprophylaxis is often shorter than 5 years.

The thromboembolic complication in our patient is in contrast to the results of published studies. Trabattoni et al. reported 406 consecutive patients after PFO occlusion with either the Occlutech Figulla (n = 227) occluder or the Amplatzer PFO occluder (n = 179) after cerebral ischemic attack ascribed to the PFO. Aspirin (100 mg/day) was administered at least 24 hours before the procedure and continued for six months after the closure. Clopidogrel was started immediately after the closure and continued for three months. No thrombi were detected on TTE within 24 hours after the procedure. The occurrence of thrombi on the occluders in further follow-up is not reported.[6]

In a study by Toggweiler et al., 193 consecutive patients who underwent PFO closure with the Amplatzer occluder or the Occlutech Figulla-Flex-II occluder were included. DAPT with aspirin (100 mg/day) and clopidogrel (75 mg/day) was recommended during the first 3 months after the procedure, followed by 3 months of aspirin monotherapy. No thrombus on the PFO device was found during the follow-up of 6-month.[4]

In both studies, DAPT with aspirin (100 mg/day) and clopidogrel (75 mg/day) was recommended during the first 3 months after the procedure, followed by 3 months of aspirin monotherapy.[4,6] No thrombus on the PFO occluders was noted during echocardiographic follow-up in these studies. Our patient had more intensive antiplatelet therapy than in both studies (DAPT for 6 months, followed by 8 months of clopidogrel monotherapy). Despite this, he developed a thrombus on the PFO occluder 19 months after PFO closure.

Neuser et al. occluded PFO with Figulla Flex II Occluder in 57 patients with cryptogenic thromboembolism. DAPT with aspirin (100 mg/day) and clopidogrel (75 mg/day) was recommended during at least the first 6 months following the procedure. Before discontinuation of DAPT thrombus formation on the occluder was ruled out by TEE. Examinations did not reveal any thrombus formation.[2]

The largest published retrospective multi-center registry evaluating the safety and efficacy of PFO closure with Figulla Flex II PFO and UNI occluders was the RISE study. Pioch et al. included 527 patients. The median follow-up was 1.1 years. Thrombus formation on both devices was 0%.[3] Postprocedural thromboprophylaxis was not specified.

Belgrave et al. reported several risk factors for thrombus formation on occluders – coagulopathies, female gender, age, the relative safety of the individual device, use of anticoagulant therapy, arrhythmias, atherosclerosis of the aorta, and the time since implantation. Most studies found events within the first year after the procedure.[5] Our patient developed a thromboembolism 19 months after PFO closure, and five months after the discontinuation of antiplatelet therapy. Of the known risk factors, he presented only with thrombophilia (activated protein C resistance).

The risk of thrombus formation and thromboembolic events raises the question at what intervals should repeat echocardiography be performed after device implantation. The Amplatzer device manufacturer recommends intervals of one week, six months, and one year after the closure.[5] Thrombus can rarely occur up to 5 years after Amplatzer device implantation.[7]

Myxoma should also be considered for masses on the occluders. Gupta et al. presented a TEE finding of a large hypermobile mass arising from the left atrial disc two years after PFO closure with an Amplatzer occluder. Histopathological analysis confirmed myxoma.[8]

## Conclusion

Thromboembolism after the closure of PFO with an Occlutech Figulla Flex II occluder is an exceptional but potentially serious complication that can occur late after the procedure despite antithrombotic prophylaxis.

**Conflict of interest**
Nothing to declare.

**Funding**
Nothing to declare.

**Ethical statement**
This case report was conducted in accordance with the principles of the Declaration of Helsinki.

**Informed consent**
The authors confirm that written consent for the publication of this case report has been obtained from the patient.

**References**

1. Pristipino C, Sievert H, D'Ascenzo F, et al. European position paper on the management of patients with patent foramen ovale. General approach and left circulation thromboembolism. Eur Heart J 2019;40:3182–3195.
2. Neuser J, Akin M, Bavendiek U, et al. Mid-term results of interventional closure of patent foramen ovale with the Occlutech Figulla® Flex II Occluder. BMC Cardiovasc Disord 2016;16:217.
3. Pioch N, Trabattoni D, Bouvaist H, et al. The RISE Study: Retrospective Registry for the International Safety and Efficacy Results of Patent Foramen Ovale Closure with Figulla Flex II PFO and UNI Occluders. J Clin Med 2024;13:1681.
4. Toggweiler S, Moccetti F, Conrad N, et al. Amplatzer or Figulla Flex II Occluder: a comparative study of outcomes after transcatheter patent foramen ovale closure. J Invasive Cardiol 2024;36.
5. Belgrave K, Cardozo S. Thrombus formation on amplatzer septal occluder device: pinning down the cause. Case Rep Cardiol 2014:2014:457850.
6. Trabattoni D, Gaspardone A, Sgueglia GA, et al. AMPLATZER versus Figulla occluder for transcatheter patent foramen ovale closure. EuroIntervention 2017;12:2092–2099.
7. Kounis NG, Lianas D, Kounis GN, et al. Late huge thrombus formation after percutaneous closure of an atrial septal defect with an Amplatzer septal occluder: Implications of Kounis syndrome. Anatol J Cardiol 2016;16:300–301.
8. Gupta N, Abdelsalam M, Maini B, et al. Intra-atrial mass-thrombus versus myxoma, post-amplatzer atrial septal defect closure device deployment. J Am Coll Cardiol 2012;60:639.