



## Case Report

## Cardiac tamponade following aortic root erosion by an Amplatzer PFO-Occluder in a 41-year-old woman: Only a matter of sizing?



Holger H. Sigusch (MD)<sup>a,\*</sup>, Berit Zimmermann (MD)<sup>a</sup>, Thomas Kuntze (MD)<sup>b</sup>, Jens Gerth (MD)<sup>c</sup>

<sup>a</sup>Heinrich-Braun-Klinikum, Department of Internal Medicine, Division of Cardiology, Zwickau, Germany

<sup>b</sup>Zentralklinik Bad Berka, Division of Cardiac Surgery, Bad Berka, Germany

<sup>c</sup>Heinrich-Braun-Klinikum, Department of Internal Medicine, Division of Nephrology, Zwickau, Germany

## ARTICLE INFO

## Article history:

Received 1 April 2020

Received in revised form 7 August 2020

Accepted 2 October 2020

## Keywords:

Persistent patent foramen ovale

Patent foramen ovale closure

Aortic root erosion

Device sizing

## ABSTRACT

A 41-year-old woman who had suffered an acute stroke underwent closure of a persistent patent foramen ovale (PFO) two months later. Eleven months after PFO closure the patient was hospitalized with signs of cardiogenic shock due to cardiac tamponade. Imaging studies showed a correct position of the left occluder disc, whereas the right atrial disc was in direct contact with the aortic root. At day 6, the patient underwent surgery via a minimally invasive route under cardiopulmonary bypass. The left atrial disc of the occluder was in a correct position. A too big right atrial disc together with a sharp angle misalignment toward the right atrial wall led to an erosion of the right atrial wall and of the wall of the aortic root. The occluder was explanted and the PFO closed by direct suture.

Given the increasing number of procedures performed, serious and potentially life-threatening complications – even if rare – deserve special attention. Even though device oversizing was the most likely factor causing the erosion, other factors may play a role, as the patient used whole-body vibration starting three months before the incident. This could explain why the event happened as late as 11 months after the initial PFO closure.

**<Learning objective:** Recent trials have shown that patent foramen ovale (PFO) closure reduces the risk of recurrent stroke after an initial event of cryptogenic stroke in patients younger than 60 years. If PFO closure is performed more frequently, even rare complications have to be considered. Device-induced erosion of adjacent cardiac structures remains a possible short- or long-term complication after PFO closure. This is an unlikely (0.018%) but potentially life-threatening event. An oversized and misaligned device is the central mechanism.>

© 2020 Japanese College of Cardiology. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## Introduction

Recent trials have shown that patent foramen ovale (PFO) closure reduces the risk of recurrent stroke after an initial event of cryptogenic stroke in patients younger than 60 years who have a PFO with moderate to large right to left shunting, atrial septum aneurysm or both [1–3].

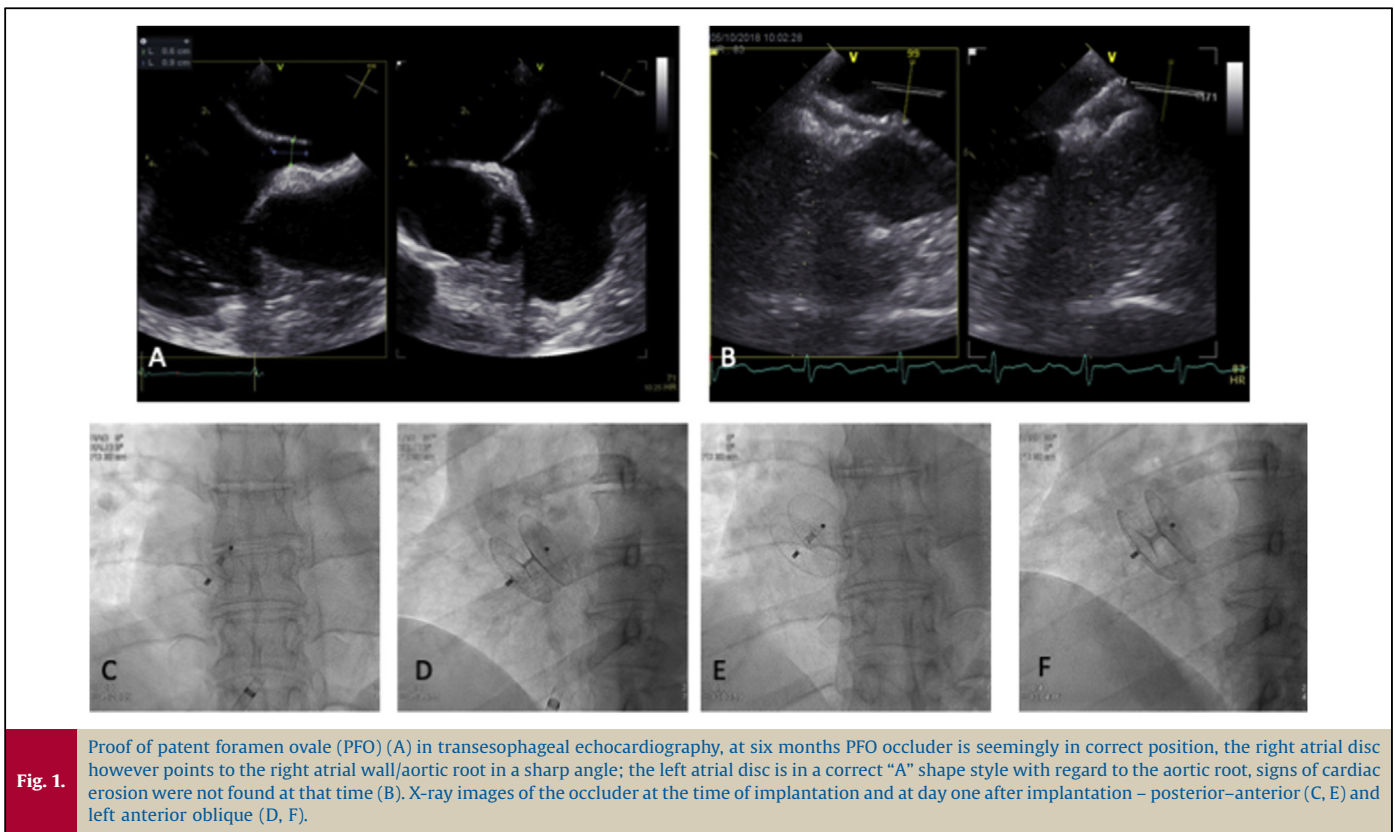
Assuming that these data will lead to a more frequent use of interventional PFO closure procedures, device-related complications – even if rare – have to be addressed. Based on reports to the

manufacturer, a rate of erosion after PFO closure using the Amplatzer PFO device (Abbott Laboratories, Chicago IL, USA) is as low as 0.018%. Until 2008, after implantation of about 11,000 occluders only 2 erosions had been reported [4]. Both cases of erosions after PFO closure occurred in the early phase after market-release of the device in the year 2000. In contrast, in atrial septal defect closure using the Amplatzer septal occluder cardiac erosion occurred in 0.043–0.3% and is therefore 2- to 16-fold more common than in PFO closure.

## Case report

In February 2018, a 41-year-old woman suffered an acute stroke caused by an occlusion of the mid cerebral artery. She was treated by intravenous recombinant tissue plasminogen activator throm-

\* Corresponding author at: Heinrich-Braun-Klinikum-Zwickau, Dept. Internal Medicine, Div. Cardiology, Karl-Keil-Strasse 35, 08060 Zwickau, Germany.  
E-mail address: [Holger.Sigusch@hbz-zwickau.de](mailto:Holger.Sigusch@hbz-zwickau.de) (H.H. Sigusch).



bolysis followed by mechanical thrombectomy. After the neurologic symptoms had improved a diagnostic work-up revealed the absence of arteriosclerotic changes or stenosis of the supra aortic arteries. Cranial magnetic resonance imaging scan showed repeated strokes in the territories supplied by mid cerebral and posterior cerebral arteries. Transesophageal echocardiography (TEE) demonstrated a persistent PFO with massive right to left shunt of contrast under Valsalva maneuver (Fig. 1A). The incomplete adhesion between the flap valve and the fossa rim formed a large crevice at the entire anterosuperior quadrant of the rim. The PFO was judged to be the cause of stroke and PFO closure was advised based on the data of controlled randomized trials [1–3]. PFO closure was performed in April 2018. Based on the finding of a large right to left shunt under Valsalva maneuver and the additional TEE finding of a crevice at the entire anterosuperior quadrant of the Fossa ovalis a 30 mm Amplatzer PFO occluder was implanted via the right femoral vein under fluoroscopic guidance (Fig. 1C & D). The postinterventional course was uneventful and the patient was discharged next day after demonstration of a correct occluder position by cine X-ray (Fig. 1E & F) and transthoracic echocardiography. At discharge the patient received long-term aspirin 100 mg once daily and clopidogrel 75 mg once daily for 3 months. A 6-month follow-up TEE was performed in October 2018 demonstrating a seemingly correct occluder position without a residual shunt through or next to the occluder (Fig. 1B). The left atrial disc was in a correct position in relation to the aortic root ("A" style configuration). The right atrial disc of the device however, was in a sharp angle misaligned to the right atrial wall.

On March 2, 2019 – about 11 months after PFO closure – the patient experienced syncope after vomiting, diarrhea, and abdominal pain. An abdominal computed tomography showed a large pericardial effusion which triggered the transfer to our institution. Bedside echocardiography confirmed a relevant pericardial effusion of 20 mm thickness and showed a correct occluder position. After transfer to the catheterization laboratory a

supraaortic valve angiography demonstrated the absence of an active leak toward the pericardium or cardiac chambers (Fig. 2A). Signs of cardiac tamponade (tachycardia, hypotension, pulsus paradoxus) lead to pericardiocentesis. After drainage of 100 ml of blood, the systolic blood pressure and the heart rate normalized. During the further hospital stay the patient remained hemodynamically stable without further intervention and without progression of pericardial effusion. At day 2 after the initial event, TEE and cardiac computed tomography were performed. Both methods showed the left atrial disc of the occluder in a correct position, whereas the right atrial disc was in a sharp angle misaligned and in direct contact with the right atrial wall and the aortic root (Fig. 2B & C). Color Doppler study could however not detect any abnormal flow.

The case was discussed in the heart team and based on a high suspicion of right atrial wall and aortic root erosion, the decision to surgically explant the occluder was made. At day 6, the patient underwent surgery via a minimally invasive route through a right anterolateral mini-thoracotomy under cardiopulmonary bypass. The left atrial disc of the occluder was in a correct position. The right atrial disc however, seemed too big in relation to the anatomic dimensions of the atrial septum pointing toward and eroding the right atrial wall and the aortic wall (Fig. 2D). The occluder was explanted (Fig. 2E) and the PFO closed by direct suture. The postoperative course of the patient was uneventful and she was discharged at day 10 after surgery.

## Discussion

The case presented might have relevant impact on three aspects. First, considering the increasing number of procedures that are performed, serious and potentially life-threatening complications – even if rare – deserve special attention. Second, the question of device sizing in PFO closure is not definitely solved and probably has to be addressed in the future. Third, the unusual

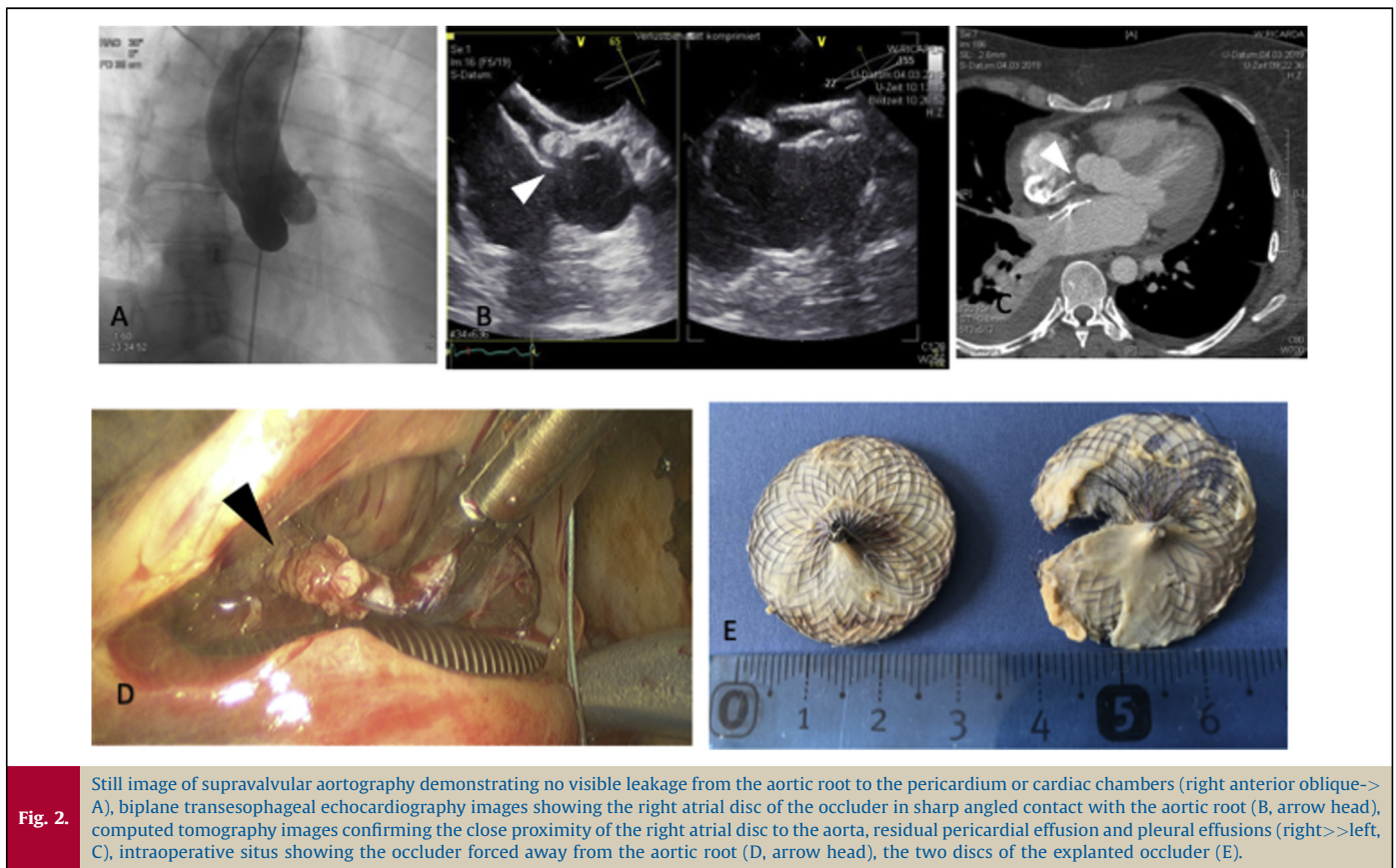


Fig. 2.

Still image of supra-valvular aortography demonstrating no visible leakage from the aortic root to the pericardium or cardiac chambers (right anterior oblique-> A), biplane transesophageal echocardiography images showing the right atrial disc of the occluder in sharp angled contact with the aortic root (B, arrow head), computed tomography images confirming the close proximity of the right atrial disc to the aorta, residual pericardial effusion and pleural effusions (right->>left, C), intraoperative situs showing the occluder forced away from the aortic root (D, arrow head), the two discs of the explanted occluder (E).

delay of erosion after occluder implantation deserves special attention, particularly because the patient used whole-body vibration induced by a vibration plate in order to lose weight before the incident.

In atrial septal defect, as well as in PFO closure, cardiac erosions have been linked to oversizing of the device and rim deficiency [4,5]. The manufacturer recommends a device sizing based on the lengths of the aortic and superior vena cava rims. A device whose radius is equal to or smaller than the shortest measured rim should be selected. This rule however is controversial. Other patient-based factors such as age, sex, body mass index, as well as anatomical factors such as presence of interatrial septal aneurysm, length of tunnel, and size of shunt play a role in the selection of the device. Therefore, this decision has to be made ultimately by the operator [4,6–8]. There is general agreement that balloon sizing is not recommended for device selection [4]. In our patient the aortic rim and superior vena cava rims were 13 mm and 12 mm, respectively. Based on these recommendations the 30-mm device was oversized regarding the occluder radius by at least 3 mm. This oversized device misaligned in the right atrium contacting the right atrial wall and ultimately the aortic root in a sharp angle.

The two cases of cardiac erosion in PFO closure using the Amplatzer device reported in the literature occurred at 1 day and 1 month after closure, respectively [4]. In contrast, in our patient the erosion happened 11 months after the procedure. The TEE follow-up after 6 months showed a correct occluder position and the patient was free of symptoms at this time. There are only two reports of late cardiac erosion in the literature. One – using the Cardiastar device (cardia, Inc., Eagan MN, USA) – about 1 year after implantation and a second (type of device not reported) as late as 5 years after implantation [8,9].

The patient started using whole-body vibration with the intention to lose weight about 3 months before the incident.

There are no reports on an influence of body vibration on implanted cardiac devices in the literature. Biological effects on the vasculature however occur, as one study on its influence on arterial wall stiffness has shown [10]. Whether whole-body vibration had an influence on the reported erosion in this particular case remains speculative.

In conclusion, erosion of adjacent cardiac structures remains a possible short- or long-term complication after PFO closure. This is an unlikely (0.018%) but potentially life-threatening event as illustrated by the presented case. An oversized and misaligned device is the central mechanism.

In our opinion there are not enough solid data for device sizing – balancing the risks of complications (e.g. cardiac erosion) versus leaving behind a remaining right to left shunt. The role of whole-body vibration in this patient remains unclear. Considering the substantial energy transfer to the body, an effect can however not completely be excluded.

### Conflict of interest

The authors declare that there is no conflict of interest.

### References

- [1] Søndergaard L, Kasner SE, Rhodes JF, Andersen G, Iversen HK, Nielsen-Kudsk JE, et al. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *N Engl J Med* 2017;377:1033–42.
- [2] Mas JL, Derumeaux G, Guillon B, Massardier E, Hosseini H, Mechtouff L, et al. Patent foramen ovale closure or anticoagulation vs. antiplatelets after stroke. *N Engl J Med* 2017;377:1011–21.
- [3] Mir H, Siemieniuk RAC, Ge LC, Foroutan F, Fralick M, Syed T, et al. Patent foramen ovale closure, antiplatelet therapy or anticoagulation in patients with patent foramen ovale and cryptogenic stroke: a systematic review and network meta-analysis incorporating complementary external evidence. *BMJ Open* 2018;8:e023761.

- [4] Amin Z, Hijazi ZM, Bass JL, Cheatam JP, Hellenbrand WE, Kleinman CS. PFO closure complications from the AGA registry. *Catheter Cardiovasc Interv* 2008;72:74–9.
- [5] McElhinney DB, Quartermain MD, Kenny D, Alboliras E, Amin Z. Relative risk factors for cardiac erosion following transcatheter closure of atrial septal defects. *Circulation* 2016;133:1738–46.
- [6] Venturini JM, Retzer EM, Estrada R, Mediratta A, Friant J, Nathan S, et al. A practical scoring system to select optimally sized devices for percutaneous patent foramen ovale closure. *J Struct Heart Dis* 2016;2:217–23.
- [7] Schwerzmann M, Dalehian O. Hazards of percutaneous PFO closure. *Eur J Echocardiogr* 2005;6:393–5.
- [8] Christen T, Mach F, Didier D, Kalangos A, Verin V, Trindade PT. Late cardiac tamponade after percutaneous closure of a patent foramen ovale. *Eur J Echocardiogr* 2005;6:465–9.
- [9] Nagpal SV, Lerakis S, Flueckiger PB, Halisa M, Willis P, Block PC, et al. Long-term outcomes after percutaneous patent foramen ovale closure. *Am J Med Sci* 2013;346:181–6.
- [10] Lai CL, Chen HY, Tseng SY, Liao WC, Liu BT, Lee MC, et al. Effect of whole-body vibration for 3 months on arterial stiffness in the middle-aged and elderly. *Clin Interv Aging* 2014;9:821–8.